Friday
September 14, 1984

Selected Subjects

Administrative Practice and Procedure
Federal Grain Inspection Service

Air Pollution Control
Environmental Protection Agency

Equal Employment Opportunity
Equal Employment Opportunity Commission

Exports
Animal and Plant Health Inspection Service
International Trade Administration

Freight Forwarders
Federal Maritime Commission

Government Procurement
General Services Administration
Health and Human Services Department
Public Health Service

Health Care
Defense Department

Hunting
Fish and Wildlife Service

Imports
Animal and Plant Health Inspection Service

Investment Companies
Securities and Exchange Commission

Maritime Carriers
Federal Maritime Commission

CONTINUED INSIDE
The President

ADMINISTRATIVE ORDERS

36065 Africa, financial assistance under the Migration and Refugee Assistance Act of 1962 (Presidential Determination No. 84-13 of September 8, 1984)

Executive Agencies

Agricultural Marketing Service

RULES

36072 Lemons grown in Arizona and California
36072 Ohio Valley

Agriculture Department

See Agricultural Marketing Service; Animal and Plant Health Inspection Service; Commodity Credit Corporation; Federal Grain Inspection Service; Forest Service.

Air Force Department

NOTICES

36136 Scientific Advisory Board (2 documents)

Animal and Plant Health Inspection Service

RULES

Animal and poultry import restrictions:
36078 France: African Swine Fever, disease status change
Animal exports:
36077 Minneapolis/St. Paul, Minn.; ports of embarkation; interim rule affirmed

Architectural and Transportation Barriers Compliance Board

NOTICES

36210 Chairs used primarily for enplaning and deplaning physically handicapped passengers; advisory standards; inquiry

Arts and Humanities, National Foundation

NOTICES

36179 Dance Advisory Panel
36179 Inter-Arts Advisory Panel
36190 Meetings; Sunshine Act

Blind and Other Severely Handicapped, Committee for Purchase from

NOTICES

36132 Procurement list, 1984; additions and deletions (2 documents)

Commerce Department

See International Trade Administration; National Bureau of Standards; Patent and Trademark Office.

Commodity Credit Corporation

NOTICES

36115 Wheat

Defense Department

See also Air Force Department.

RULES

Civilian health and medical program of uniformed services (CHAMPUS):
36087 Mental disorders, treatment

NOTICES

Meetings:
36135 Defense Systems Management College Board of Visitors
36135 Electron Devices Advisory Group (3 documents)
36133 Privacy Act; systems of records

Economic Regulatory Administration

NOTICES

Powerplant and industrial fuel use; prohibition orders, exemption requests, etc.:
36139 Brunswick Pulp & Paper Co.

Education Department

NOTICES

36136 Dependents' Education Advisory Council

Employment and Training Administration

PROPOSED RULES

36111 Alien permanent employment in U.S.; labor certification process; Canadian railway workers; withdrawn

NOTICES

Federal-State unemployment compensation programs:
36174 Unemployment insurance program letters

Employment Standards Administration

NOTICES

36226 Minimum wages for Federal and federally-assisted construction; general wage determination decisions, modifications, and supersedeas decisions (AR, CA, IL, MO, NV, NM, NY, PA, TN, TX, and WI)

Energy Department

See also Economic Regulatory Administration; Energy Information Administration; Energy Research Office; Federal Energy Regulatory Commission; Southwestern Power Administration.

NOTICES

International atomic energy agreements; civil uses; subsequent arrangements:
36136, 36137, 36137, 36137, 36137, 36137
European Atomic Energy Community [3 documents]
European Atomic Energy Community and Brazil
European Atomic Energy Community et al.
Switzerland
Meetings:
36138 National Petroleum Council

Energy Information Administration

NOTICES

36138 Agency information collection activities under OMB review
<table>
<thead>
<tr>
<th>Energy Research Office</th>
<th>Federal Emergency Management Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOTICES</strong></td>
<td><strong>NOTICES</strong></td>
</tr>
<tr>
<td>Meetings:</td>
<td>Disaster and emergency areas:</td>
</tr>
<tr>
<td>36139</td>
<td>Nevada</td>
</tr>
<tr>
<td>Energy Research Advisory Board</td>
<td>New Mexico</td>
</tr>
<tr>
<td><strong>Environmental Protection Agency</strong></td>
<td>Meetings:</td>
</tr>
<tr>
<td><strong>RULES</strong></td>
<td>National Fire Academy Board of Visitors</td>
</tr>
<tr>
<td>Air quality implementation plans; approval and promulgation; various States:</td>
<td><strong>NOTICES</strong></td>
</tr>
<tr>
<td>36096</td>
<td><strong>Hearings, etc.:</strong></td>
</tr>
<tr>
<td>North Carolina</td>
<td>Arizona Public Service Co.</td>
</tr>
<tr>
<td><strong>NOTICES</strong></td>
<td>Carolina Power &amp; Light Co.</td>
</tr>
<tr>
<td><strong>Pesticide programs:</strong></td>
<td><strong>36140</strong></td>
</tr>
<tr>
<td>Agency statements; weekly receipts</td>
<td>Columbia Gas Transmission Corp.</td>
</tr>
<tr>
<td>36153</td>
<td><strong>36141</strong></td>
</tr>
<tr>
<td>Confidential information and data transfer to contractors (2 documents)</td>
<td>Commonwealth Edison Co.</td>
</tr>
<tr>
<td>Toxic and hazardous substances control:</td>
<td><strong>36141</strong></td>
</tr>
<tr>
<td>36151</td>
<td>Consolidated Edison Co. of New York, Inc.</td>
</tr>
<tr>
<td>Premanufacture notices receipts</td>
<td><strong>36142</strong></td>
</tr>
<tr>
<td>Water pollution; discharge of pollutants (NPDES):</td>
<td>Florida Exploration Co. et al.</td>
</tr>
<tr>
<td>36154</td>
<td><strong>36143</strong></td>
</tr>
<tr>
<td>Nebraska</td>
<td>Florida Power Corp.</td>
</tr>
<tr>
<td><strong>Equal Employment Opportunity Commission</strong></td>
<td><strong>36143</strong></td>
</tr>
<tr>
<td><strong>RULES</strong></td>
<td>Gulf States Utilities Co.</td>
</tr>
<tr>
<td>Employment discrimination; charges; designation of State and local fair employment practice agencies (706 agencies):</td>
<td>Natural Gas Pipeline Co. of America</td>
</tr>
<tr>
<td>36086</td>
<td>Niagara Mohawk Power Corp.</td>
</tr>
<tr>
<td>Missouri</td>
<td>Otter Tail Power Co.</td>
</tr>
<tr>
<td><strong>Federal Aviation Administration</strong></td>
<td><strong>36144</strong></td>
</tr>
<tr>
<td><strong>NOTICES</strong></td>
<td>Panhandle Eastern Pipe Line Co.</td>
</tr>
<tr>
<td>Grants; availability, etc.:</td>
<td><strong>36145</strong></td>
</tr>
<tr>
<td>36186</td>
<td>Puget Sound Power &amp; Light Co.</td>
</tr>
<tr>
<td>Airport improvement program; grant assurance and agreement; correction</td>
<td>Southwestern Electric Power Co.</td>
</tr>
<tr>
<td><strong>Federal Communications Commission</strong></td>
<td><strong>36145</strong></td>
</tr>
<tr>
<td><strong>RULES</strong></td>
<td>Transcontinental Gas Pipe Line Corp.</td>
</tr>
<tr>
<td>Radio services, special:</td>
<td><strong>36146</strong></td>
</tr>
<tr>
<td>36107</td>
<td>Williston Basin Interstate Pipeline Co. et al.</td>
</tr>
<tr>
<td>Amateur service; transmitting power, definition and measurement</td>
<td><strong>Federal Grain Inspection Service</strong></td>
</tr>
<tr>
<td>36104</td>
<td><strong>RULES</strong></td>
</tr>
<tr>
<td>Maritime services; radar stations on ships between 500 and 1,600 gross tons</td>
<td>Administration:</td>
</tr>
<tr>
<td>36105</td>
<td><strong>Definitions</strong></td>
</tr>
<tr>
<td>Maritime services; reporting and recordkeeping requirements, and technical specification for survival craft radios; clarification</td>
<td><strong>Federal Maritime Commission</strong></td>
</tr>
<tr>
<td>36105</td>
<td><strong>RULES</strong></td>
</tr>
<tr>
<td>Private land mobile services; Los Angeles Urbanized Area; effective radiated power</td>
<td>Agreements by ocean common carriers, etc.; interim:</td>
</tr>
<tr>
<td><strong>PROPOSED RULES</strong></td>
<td>36103</td>
</tr>
<tr>
<td>Radio services, special:</td>
<td>Reporting and recordkeeping requirements; suspension</td>
</tr>
<tr>
<td>36112</td>
<td>36296</td>
</tr>
<tr>
<td>Aural baseband of television transmitters; subcarrier frequencies use (stereophonic sound etc.); extension of time</td>
<td>Freight forwarders, independent ocean; licensing Shipping Act of 1984; implementation:</td>
</tr>
<tr>
<td><strong>NOTICES</strong></td>
<td>36303</td>
</tr>
<tr>
<td>Common carrier services:</td>
<td>Marine terminal operations and passenger vessels</td>
</tr>
<tr>
<td>36113</td>
<td>36163, 36164</td>
</tr>
<tr>
<td>Amateur service; antennas; request for Federal preemption of local zoning</td>
<td><strong>NOTICES</strong></td>
</tr>
<tr>
<td>36113</td>
<td>Agreements filed, etc. (2 documents)</td>
</tr>
<tr>
<td>Private land mobile services; narrowband technologies for base and mobile communications; extension of time</td>
<td><strong>36190</strong></td>
</tr>
<tr>
<td><strong>Television broadcasting:</strong></td>
<td><strong>Meetings; Sunshine Act</strong></td>
</tr>
<tr>
<td>36112</td>
<td><strong>36164</strong></td>
</tr>
<tr>
<td>Aural baseband of television transmitters; subcarrier frequencies use (stereophonic sound etc.); extension of time</td>
<td><strong>36164</strong></td>
</tr>
<tr>
<td><strong>NOTICES</strong></td>
<td>Norstar Bancorp Inc.</td>
</tr>
<tr>
<td>Common carrier services:</td>
<td><strong>Fish and Wildlife Service</strong></td>
</tr>
<tr>
<td>36155</td>
<td><strong>RULES</strong></td>
</tr>
<tr>
<td>Radiodetermination satellite service applications; Geostar Corp.</td>
<td>Migratory bird hunting:</td>
</tr>
<tr>
<td><strong>Food and Drug Administration</strong></td>
<td><strong>PROPOSED RULES</strong></td>
</tr>
<tr>
<td><strong>RULES</strong></td>
<td>Seasons, limits, and shooting hours; establishment etc.</td>
</tr>
<tr>
<td>Food additives:</td>
<td><strong>PROPOSED RULES</strong></td>
</tr>
<tr>
<td>Polymers; ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer formulations; correction</td>
<td>Migratory bird hunting:</td>
</tr>
<tr>
<td>36086</td>
<td>Lead poisoning in bald eagles; alternate conservation measures</td>
</tr>
</tbody>
</table>
Federal Register | Vol. 49, No. 180 / Friday, September 14, / Contents

**Medical devices:**
- Reporting and recordkeeping requirements

**PROPOSED RULES**
- Food for human consumption:
  - Fruit or vegetable juice beverages, diluted; labeling; extension of time

**NOTICES**
- Human drugs:
  - Anticholinergic/sedative combination products; hearing denied, etc.
- Cough, cold, or allergy prescription drugs; actifed-C expectorant; approval withdrawn

**Forest Service**
- **PROPOSED RULES**
  - Land disposal; sale of lands for agricultural use; CFR part removal
- **NOTICES**
  - Daniel Boone National Forest, Kentucky: jurisdiction change with Army Department

**General Services Administration**
- **PROPOSED RULES**
  - Acquisition regulations (CSAR):
    - Contract Appeals Board procedure rules; ADP procurement protests
- **RULES**
  - Acquisition regulations

**NOTICES**
- Agency information collection activities under OMB review

**Health and Human Services Department**
- See also Food and Drug Administration; Health Care Financing Administration; Public Health Service.

**RULES**
- Acquisition regulations

**Health Care Financing Administration**
- Medicare:
  - Overpayments and underpayments to providers and suppliers; interest charges

**Historic Preservation, Advisory Council**
- **NOTICES**
  - Programmatic memorandums of agreement: Tennesse; coal exploration and surface coal mining and reclamation operations

**Housing and Urban Development Department**
- **RULES**
  - Manufactured home construction and safety standards:
    - Formaldehyde emissions from plywood and particleboard, and fire safety standards; correction

**Interior Department**
- See Fish and Wildlife Service; Land Management Bureau.

**International Trade Administration**
- **RULES**
  - Export licensing:
    - Iran and Iraq; validated export license requirements for chemical exports; interim

**NOTICES**
- Antidumping:
  - Steel wire rope from Japan
- Countervailing duties:
  - Potassium chloride from Israel
- Meetings:
  - Computer Systems Technical Advisory Committee: date change, etc.
  - Steel trigger price levels:
  - Stainless steel round wire; fourth quarter Trade adjustment assistance determination petitions:
  - Manson & Barish, Inc., et al.

**Interstate Commerce Commission**
- **NOTICES**
  - Motor carriers:
    - Agricultural cooperative transportation; filing notices
  - Compensated intercorporate hauling operations; intent to engage in Rail carriers:
  - Coal rate guidelines, nationwide; postponement of oral argument
  - Staggers Rail Act of 1980: effects on rail industry; inquiry
  - Railroad operation, acquisition, construction, etc.: Missouri Pacific Railroad Co., Norfolk Southern Corp.
  - Railroad services abandonment:
    - Burlington Northern Railroad Co.

**Labor Department**
- See Employment and Training Administration; Employment Standards Administration; Mine Safety and Health Administration; Pension and Welfare Benefit Programs Office.

**Land Management Bureau**
- **NOTICES**
  - Environmental statements; availability, etc.:
    - Livestock grazing; preparation schedule
  - Public lands for State indemnity selection applications:
    - Utah

**Management and Budget Office**
- **NOTICES**
  - Budget rescissions and deferrals; cumulative reports

**Mine Safety and Health Administration**
- **NOTICES**
  - Petitions for mandatory safety standard modifications:
    - Phelps Dodge Corp.

**National Bureau of Standards**
- **NOTICES**
  - National Fire Codes:
    - Fire safety standards revision; inquiry
  - Technical Committee reports; inquiry

**National Science Foundation**
- **NOTICES**
  - Antarctic Conservation Act of 1978; permit applications, etc.
Meetings:
36179 Atmospheric Sciences Advisory Committee
36180 Systematic Biology Advisory Panel

Nuclear Regulatory Commission
NOTICES
Environmental statements; availability, etc.: 36180 Michigan State University

Export and import license applications for nuclear facilities or materials (Mitsui & Co. (USA), Inc.)

Export and import license applications for nuclear facilities or materials (Mitsubishi International Corp. et al.); correction

Reports, availability, etc.: 36181 Nuclear power plants, safety analysis reports review

Patent and Trademark Office
RULES
Patent cases: 36096 Patent maintenance fees; correction

Pension and Welfare Benefit Programs Office
NOTICES
Employee benefit plans; prohibited transaction exemptions:

Atalanta/Sosnoff Segmentation Fund, L.P., et al.

Postal Rate Commission
NOTICES
Post office closings; petitions for appeal:

Dodgeville, MI

Public Health Service
RULES
Acquisition regulations; final rule and request for comments

NOTICES
Meetings; advisory committees:

October and November

Securities and Exchange Commission
RULES
Investment companies:

NOTICES
Hearings, etc.:

Bank of New York

Chase Manhattan Bank, N.A.

Self-regulatory organizations; proposed rule changes:

Boston Stock Exchange, Inc.

National Association of Securities Dealers, Inc.

(2 documents)

Pacific Securities Depository Trust Co.

Southwestern Power Administration
NOTICES
36146 Integrated system power rates; extension

Transportation Department
See Federal Aviation Administration.

United States Information Agency
NOTICES
Art objects, importation for exhibition:

Venice: The American View, 1860–1920

Veterans Administration
NOTICES
36187 Agency information collection activities under OMB review
36188 Privacy Act; systems of records

Separate Parts in This Issue

Part II
36210 Architectural and Transportation Barriers Compliance Board

Part III
36226 Department of Labor, Employment Standards Administration, Wage and Hour Division

Part IV
36236 Department of Health and Human Services, Public Health Service

Part V
36272 Department of the Interior, Fish and Wildlife Service

Part VI
36296 Federal Maritime Commission

Part VII
36326 Department of Health and Human Services, Food and Drug Administration

Part VIII
36354 Office of Management and Budget

Reader Aids
Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.
CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

<table>
<thead>
<tr>
<th>3 CFR</th>
<th>Administrative Orders:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Presidential Determinations:</td>
</tr>
<tr>
<td></td>
<td>No. 84-13 of September 8, 1984</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>800</td>
<td>36067</td>
</tr>
<tr>
<td>910</td>
<td>36072</td>
</tr>
<tr>
<td>1033</td>
<td>36072</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>91</td>
<td>36077</td>
</tr>
<tr>
<td>94</td>
<td>36078</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>15 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>36079</td>
</tr>
<tr>
<td>399</td>
<td>36079</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>270</td>
<td>36080</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>20 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>656</td>
<td>36111</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>21 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>177</td>
<td>36086</td>
</tr>
<tr>
<td>600</td>
<td>36326</td>
</tr>
<tr>
<td>603</td>
<td>36326</td>
</tr>
<tr>
<td>1102</td>
<td>36326</td>
</tr>
<tr>
<td>1003</td>
<td>36326</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>22 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>102</td>
<td>36111</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>24 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3880</td>
<td>36086</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>25 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1981</td>
<td>36096</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>32 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>199</td>
<td>36097</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>36 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>281</td>
<td>36112</td>
</tr>
<tr>
<td>37 CFR</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>36096</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>40 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>52</td>
<td>36096</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>42 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>403</td>
<td>36097</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>46 CFR</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>510</td>
<td>36296</td>
</tr>
<tr>
<td>515</td>
<td>36303</td>
</tr>
<tr>
<td>520</td>
<td>36303</td>
</tr>
<tr>
<td>525</td>
<td>36303</td>
</tr>
<tr>
<td>530</td>
<td>36303</td>
</tr>
<tr>
<td>540</td>
<td>36303</td>
</tr>
<tr>
<td>572</td>
<td>36103</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>47 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>63</td>
<td>36104, 36105</td>
</tr>
<tr>
<td>90</td>
<td>36105</td>
</tr>
<tr>
<td>97</td>
<td>36107</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>48 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>73</td>
<td>36112</td>
</tr>
<tr>
<td>90</td>
<td>36113</td>
</tr>
<tr>
<td>97</td>
<td>36113</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>49 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ch. 3</td>
<td>36109</td>
</tr>
<tr>
<td>Ch. 3, Appendix A</td>
<td>36236</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>50 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>36272</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>51 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>36290</td>
</tr>
</tbody>
</table>
Title 3—

The President

Presidential Determination No. 84–13 of September 8, 1984

Determination Pursuant to Section 2(c)(1) of the Migration and Refugee Assistance Act of 1962, as amended, authorizing the use of up to $5 million of funds from the United States Emergency Refugee and Migration Assistance Fund

Memorandum for the Secretary of State

In order to meet unexpected urgent refugee and migration needs in Africa and to respond to appeals of the International Committee of the Red Cross and the United Nations High Commissioner for Refugees, I hereby determine, pursuant to Section 2(c)(1) of the Migration and Refugee Assistance Act of 1962, as amended (the Act), that it is important to the national interests that up to $5 million shall be made available from the United States Emergency Refugee and Migration Assistance Fund for contributions to the International Committee of the Red Cross and to the activities of the United Nations High Commissioner for Refugees for assistance to persons in Africa.

The Secretary of State is requested to inform the appropriate committees of the Congress of this Determination and the obligation of funds under this authority.

This Determination shall be published in the Federal Register.

THE WHITE HOUSE,

[Signature]

FR Doc. 84–24533
Filed 9–12–84; 3:03 pm]
Billing code 3195–01–M
This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are key to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510. The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE
Federal Grain Inspection Service
7 CFR Part 800

Definitions
AGENCY: Federal Grain Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Federal Grain Inspection Service (FGIS or Service) is finalizing, with minor adjustment, its proposed rule on definitions published in the Federal Register on April 16, 1984 (49 FR 14958). This action amends the regulation on "Meaning of terms" by revising the section to clarify definitions, remove obsolete definitions, add definitions for Compliance and Standardization, and to add the definitions from the other sections of the regulations, all of which will facilitate the use of the regulations. This action further deletes definitions from the other sections of the regulations and makes other changes necessary because of the shift of definitions from other sections to the Meaning of terms section.


FOR FURTHER INFORMATION CONTACT: Lewis Lebakken, Jr., Information Resources Management Branch, USDA, FGIS, Room 0667 South Building, 14th Street and Independence Avenue, SW., Washington, D.C. 20250, telephone (202) 725-1738.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This final rule has been issued in conformance with Executive Order 12291 and Departmental Regulation 1512-1. The action has been classified as nonmajor, because it does not meet the criteria for a major regulation established in the Order.

Regulatory Flexibility Act Certification

Kenneth A. Gilles, Administrator, FGIS, has determined that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because most users of the inspection and weighing services and those entities that perform these services do not meet the requirements for small entities, and this action poses no new or additional duties or obligations to business entities involved in the loading, weighing, handling, or sampling of grain.

Review of Regulations

The review of the regulations' definitions found in §§ 800.0, 800.16, 800.25, 800.56, 800.73, 800.84, and 800.171 (7 CFR 800.0, 800.16, 800.25, 800.56, 800.73, 800.84, and 800.171) included a determination of the continued need for and consequences of each definition. An objective was to assure that the language of the definitions is clear and that the definitions are consistent with FGIS policy. FGIS determined that these definitions, in general, are serving their intended purpose; are consistent with FGIS policy; and should remain in effect. However, in the April 15, 1984, Federal Register (49 FR 14958), FGIS proposed certain revisions to the sections. Based upon the comments received and all other information available, this final rule makes the following revisions:

1. Amend § 800.0(b), Definitions, by revising the section to: (i) Clarify definitions for (3) Agency; (7) Approved weigher; (10) Assigned area of responsibility; (17) Circuit; (19) Container; (23) Deceptive loading, handling, weighing, or sampling; (25) Department of Agriculture; (29) Export elevator; (31) Export port location; (40) Official certificate; (52) Official form; (54) Official inspection; (56) Official inspection personnel; (59) Official mark; (60) Official sample; (65) Official U.S. Standards for Grain; (67) Official weighing; (68) Class X or Class Y weighing equipment testing; (70) Respondent; (89) Supervision; (90) Supervision of weighing; and (94) Warehouse sampler; (ii) remove obsolete definitions; (89) Official stowage examiner, because FGIS does not use the term; (75) Region, because FGIS no longer has regions; and (76) Regional office, because FGIS no longer has regional offices; and (iii) redesignate definitions. Also in section 800.0(b) FGIS will (i) add the definitions for Compliance and Standardization to clarify the parameters of the FGIS Compliance and Standardization programs under the Act; (ii) consolidate the definitions in one location by adding the definitions for: Elevator areas and facilities; Merchandiser; Quantity; Regular workday; Nonregular workday; Holiday; Service representative; Contract service; Door-probe sample; Shallow-probe sample; Definition of the definitions currently found in § 800.16(a), (b), and (c), respectively; (iv) revise the definition for Export elevator in § 800.0(b)(29) by integrating the definition at § 800.16(a); and (v) revise the definition for Export port location in § 800.0(b)(31) by integrating the definition at § 800.16(b).

FGIS is reserving § 800.0(b)(50) because a new definition will be proposed in a separate regulation review.

Because of the above changes, the definitions in section 800.0(b) are redesignated so as to present them in alphabetical order:

2. Remove § 800.16, Determinations; export elevator and export port location, because the definition for Export elevator at § 800.16(a) is to be combined with the one at current § 800.0(b)(29), and the definition for Export port location at § 800.16(b) is to be combined with the one at current § 800.0(b)(31).

3. Amend § 800.25, Elevator and merchandising records required to be kept, by removing paragraph (a) which is to be added to § 800.0(b) and redesignating paragraphs (b) as (a), (c) as (b), (d) as (c), (e) as (d), (f) as (e), and (g) as (f).

4. Remove § 800.56 including the note, Official certificates, official forms, and official marks, because the definitions comprising this section are moved to § 800.0(b).

5. Amend § 800.73, Computation and payment of service fees; general fee information, by removing paragraph (c) which is to be added to § 800.0(b) and redesignating paragraphs (d) as (c), (e) as (d), (f) as (e), and (g) as (f).
6. Amend § 800.84. Inspection of grain in land carriers, containers, and barges in single lots, by removing paragraph (f)(4) which is to be added to § 800.0(b); by changing the words "(f)(1) through (5)" in paragraph (f)(6) to "(f)(1) through (4)"; and by redesignating paragraph (f)(5) as (f)(4).

7. Amend § 800.171. Who may be licensed or authorized, by removing paragraph (e) which is to be added to § 800.0(b).

FGIS received two comments to the proposed rule which allowed 60 days for public comment. One commentor supported the adoption of the revisions as proposed. The other commentor was of the opinion that the definition for Elevator areas and facilities goes past the intent of the Grain Standards Act. The commentor believes that FGIS inspection and weighing activities should not include access to storage areas, bins, interstices, the basement, belts, other conveyors and the automatic data processing facilities related to inspection and weighing. The commentor recommended that the definition be amended to include only those areas necessary to verify the accuracy of weights and inspections. The Service received similar comments prior to promulgating the definition at § 800.23a(1) in its regulations published in the March 11, 1980, Federal Register. At that time, FGIS finalized the section as originally proposed, with minor nonsubstantive adjustments. The basis for its decision appearing on page 15804 was:

(1) The Act gives the Service access to elevators and other grain handling facilities in order to provide service and monitor the services; and

(2) The Service has been very careful not to abuse this access in the past and has inserted wording (§ 800.26(b)) to reflect the fact that it will notify the elevator manager or his/her representative before entering an elevator.

The basis and rationale for the promulgation of the definition of Elevator areas and facilities made in 1980 remains applicable today. The Service needs access to the listed areas so as to properly establish and maintain a national grain inspection system and to regulate the weighing of grain. In doing so, the Service will, as authorized by the Act, be able to adequately supervise and monitor its programs, maintain program integrity and perform enforcement duties as necessary. Over the past few years, FGIS has not encountered any difficulties in applying the definition of Elevator areas and facilities in its programs. This definition is limited to only those areas which would be necessary to verify the accuracy of weights and inspections and as such comports with the commentor’s recommendation that the definition be so limited. Accordingly, the definition of Elevator areas and facilities will remain as proposed.

FGIS has reviewed further its proposal to remove the definition for Approved scale testing organization. The scale testing organization program is presently under review. A decision has not been made as to whether the program should be fully implemented or not retained at all. At this time, pending a final determination of this matter, it has been decided that the definition should be retained. Accordingly, FGIS is retaining the definition without change at § 800.0(b)(6). Because of this action, the definitions in proposed § 800.0(b)(6) through (b)(104) are redesignated in this final rule as § 800.0(b)(7) through (b)(105). As its part of its reorganization to add definitions to § 800.0 from other sections of the regulations, FGIS proposed that the definitions relating to fees which appear in section 800.73 be included in the proposed § 600.0 definitions. As such, the definitions of Regular workday, Nonregular workday, Service representative and Contract service were proposed to be added to § 800.0. The intent of this action was to move all of the definitions which appear in § 800.73 to § 800.0. Inadvertently, the definition of Holiday was not included in the proposed § 800.0 nor was the proposed deletion of the definitions relating to fees in § 800.73 provided for so as to eliminate duplication as was the case in transfers of definitions from other sections of the regulations. Further, by final rule dated June 28, 1984, at 49 FR 26560, FGIS revised the definitions of Regular and Nonregular workday and redesignated the definition section as § 800.73(d) from § 800.73(c).

For the above reasons, this final rule will include these revisions. Accordingly, the definitions of Regular and Nonregular workday will be changed from the proposal to reflect the revisions made at 49 FR 26560, the definition of Holiday will be added as § 800.0(b)(43) and § 800.73, Computation and payment of service fees; general fee information, will be amended by removing paragraph (d), Definitions relating to fees, and redesignating paragraphs (e), (f) and (g) as (d), (e) and (f), respectively. The final rule at 49 FR 26560 also revised the definition of Business day which appears in § 800.0. This final rule will incorporate this change and correctly reference the section of the regulations for Business day as § 800.0(b)(13) and not (b)(12).

Additionally, the footnote which appeared in the proposal for the definition of official personnel will be correctly cited as the footnote numbered 2 and not 1.

List of Subjects in 7 CFR Part 800

Administrative practice and procedure, Export, and Grain.

PART 800—GENERAL REGULATIONS

Definitions

Accordingly, the regulations are amended as follows:

1. Section 800.0. Meaning of terms, is amended by removing paragraph (b) to read as follows:

§ 800.0 Meanings of terms.

(b) Definitions. For the purpose of these regulations, unless the context requires otherwise, the following terms shall have the meanings given for them below. The terms defined in the Act have been incorporated herein for easy reference.


(2) Administrator. The Administrator of the Federal Grain Inspection Service or his delegates.

(3) Agency. A delegated State or an official agency designated by the Administrator, as appropriate.

(4) Appeal inspection service. An official review by a field office of the results of an original inspection service or a reinspection service.

(5) Applicant. An interested person who requests an official inspection or a Class X of Class Y weighing service.

(6) Approved scale testing organization. A State or local governmental agency, or person, approved by the Service to perform official equipment testing services with respect to weighing equipment.

(7) Approved weigher. A person employed by or at an approved weighing facility and approved by the Service to physically perform Class X of Class Y weighing services, and certify the results of Class Y weighing.

(8) Approved weighing equipment. Any weighing device or related equipment approved by the Service for the performance of Class X or Class Y weighing services.

(9) Approved weighing facility. An elevator that is approved by the Service to receive Class X or Class Y weighing services.

1 A definition taken from the U.S. Grain Standards Act, as amended, with certain modifications which do not change the meanings.
(10) Assigned area of responsibility. A geographical area assigned to an agency or to a field office for the performance of official inspection or Class X or Class Y weighing services.
(11) Board appeal inspection service. An official review by the Board of Appeals and Review of the results on an appeal inspection service.
(12) Board of Appeals and Review. The Board of Appeals and Review of the Services.
(13) Business day. The established field office working hours, any Monday through Friday that is not a holiday, or the working hours and days established by an agency.
(14) Cargo shipment. Bulk or sacked grain that is loaded directly aboard waterborne carrier for shipment. Grain loaded aboard a land carrier for shipment aboard a waterborne carrier shall not be considered to be a cargo shipment.
(15) Carrier. A truck, trailer, truck/trailer(s) combination, railroad car, barge, ship, or other container used to transport bulk or sacked grain.
(17) Circuit. A geographical area, assigned to a field office.
(18) Class X or Class Y weighing equipment testing. Any operation or procedure performed by official personnel to determine the accuracy of the equipment used, or to be used, in the performance of Class X or Class Y weighing services.
(19) Combined lot. Grain loaded aboard, or being loaded aboard, or discharged from two or more carriers as one lot.
(20) Compliance. Conformance with all requirements and procedures established by statute, regulation, instruction, or directive so that managerial, administrative, and technical functions are accomplished effectively. Compliance functions include: evaluating alleged violations, initiating preliminary investigations; initiating implementation of all necessary corrective actions; conducting management and technical reviews; administering the designation of agencies and the delegation of State agencies to perform official functions; identifying and, where appropriate, waiving and monitoring conflicts of interest; licensing agency personnel; responding to audits of FGIS programs; and reviewing and, when appropriate, approving agency fee schedules.
(21) Container. A carrier, or a bin, other storage space, bag, box, or other receptacle for grain.
(22) Contract grade. The official grade, official factors, or official criteria specified in the contract for sale or confirmation of sale; or in the absence of a contract the official grade, official factors, or official criteria specified by the applicant for official service.
(23) Contract service. An inspection or weighing service performed under a contract between an applicant and the Service.
(24) Contractor. A person who enters into a contract with the Service for the performance of specified official inspection or official monitoring services.
(25) Date of official inspection service or Class X or Class Y weighing services. The day on which an official inspection, or a Class X or Class Y weighing service is completed. For certification purposes, a day shall be considered to end at midnight, local time.
(26) Deceptive loading, handling, weighing, or sampling. Any manner of loading, handling, weighing, or sampling that knowingly deceives or attempts to deceive official personnel.
(27) Delegated State. A State agency delegated authority under the Act to provide official inspection service, or Class X or Class Y weighing services, or both, at one or more export port locations in the State.
(28) Department of Agriculture and Department. The United States Department of Agriculture (USDA).
(29) Designated agency. A State or local governmental agency, or person, designated under the Act to provide either official inspection service, or Class X or Class Y weighing services, or both, at locations other than export port locations.
(30) Door-probe sample. A sample taken with a probe from a lot of bulk grain that is loaded so close to the top of the carrier that it is possible to insert the probe in the grain only in the vicinity of the tailgate of the truck or trailer, the door of the railroad boxcar, or in a similarly restricted opening or area in the carrier in which the grain is located or is loaded in hopper cars or barges in such a manner that a representative sample cannot be obtained.
(31) Elevator. Any warehouse, storage, or handling facility used primarily for receiving, storing, or shipping grain. In a facility that is used primarily for receiving, storing, and shipping grain, all parts of the main facility, as well as annexes, shall be considered to be part of the elevator. A warehouse, storage, and handling facility that is located adjacent to and is operated primarily as an adjunct of a grain processing facility shall not be considered to be an elevator.
(32) Elevator areas and facilities. All operational areas, including the automated data processing facilities that are an integral part of the inspection or weighing operations of an elevator, the loading and unloading docks; the headhouse and control rooms; all storage areas, including the bins, the interstices, the bin floor, and the basement; and all handling facilities, including the belts, other conveyors, distributor scales, spouting, mechanical samplers, and electronic controls.
(33) Employed. An individual is employed if the individual is actually employed or the employment is being withheld pending issuance of a license under the Act.
(34) Exporter. Any person who ships or causes to be shipped any bulk or sacked grain in a final carrier or container in which the grain is transported from the United States to any place outside the United States.
(35) Export elevator. Any grain elevator, warehouse, or other storage or handling facility in the United States (1) from which bulk or sacked export grain is loaded (A) aboard a carrier in which the grain is shipped from the United States to any place outside thereof, or (B) into a container for shipment to an export port location where the grain and the container will be loaded aboard a carrier in which it will be shipped from the United States to any place outside thereof; and (ii) which has been approved by the Service as a facility where Class X or Class Y weighing of grain may be obtained.
(36) Export grain. Grain for shipment from the United States to any place outside thereof.
(37) Export port location. A commonly recognized port of export in the United States or Canada, as determined by the Administrator, from which grain produced in the United States is shipped to any place outside the United States. Such locations include any coastal or border location or site in the United States which contains one or more export elevators, and is identified by the Service as an export port location.
(38) False, incorrect, and misleading. Respectively false, incorrect, and misleading in any particular.
(40) Field Office. An office of the Service designated to perform or supervise official inspection services and Class X and Class Y weighing services.
(41) Grain. Corn, wheat, rye, oats, barley, flaxseed, sorghum, soybeans,
triticale, mixed grain, and any other food grains, feed grains, and oilseeds for which standards are established under Section 4 of the Act.1

(42) **Handling.** Loading, unloading, elevating, storing, binning, mixing, blending, drying, aerating, screening, cleaning, washing, treating, or fumigating grain.

(43) **Holiday.** The legal public holidays specified in paragraph (a) of Section 6103, Title 5, of the United States Code (5 U.S.C. 6103(a)) and any other day declared to be a holiday by Federal statute or Executive Order. Under Section 610 and Executive Order No. 10557, as amended, if the specified legal public holiday falls on a Saturday, the preceding Friday shall be considered to be the holiday, or if the specified legal public holiday falls on a Sunday, the following Monday shall be considered to be the holiday.

(44) **“IN” movement.** A movement of grain into an elevator, or into or through a city, town, port, or other location without a loss of identity.

(45) **Instructions.** The Notices, Instructions, Handbooks, and other directives issued by the Service.

(46) **Interested person.** Any person having a contract or other financial interest in grain as the owner, seller, purchaser, warehouseman, or carrier, or otherwise.1

(47) **Interstate or foreign commerce.** Commerce from any State to or through any other State, or to or through any foreign country.1

(48) **Licensee.** Any person licensed by the Service.

(49) **Loading.** Placing grain in or aboard any carrier or container.

(50) **“LOCAL” movement.** A bin run or other inhouse movement, or grain in bins, tanks, or similar containers which are not in transit or designed to transport grain.

(51) [Reserved.]

(52) **Lot.** A specific quantity of grain identified as such.3

(53) **Material error.** An error in the results of an official inspection service that exceeds the official tolerance, or any error in the results of a Class X or Class Y weighing service.

(54) **Material portion.** A portion of a lot which, in accordance with the inspection plans prescribed in the instructions, is considered inferior to the contract or declared grade.

(55) **Merchandiser.** Any person, other than a producer, who buys and sells grain and takes title to the grain. A person who operates as a broker or commission agent and does not take title to the grain shall not be considered to be a merchandiser.

(56) **Monitoring.** Observing or reviewing activities performed under or subject to the Act for adherence to the Act, the regulations, standards, and instructions and preparing reports thereon.

(57) **Nonregular working day.** Any Sunday or holiday.

(58) **Official agency.** Any State or local government agency, or any person, designated by the Administrator pursuant to subsection (f) of Section 7 of the Act for the conduct of official inspection (other than appeal inspection), or subsection (c) of Section 7A of the Act for the conduct of Class X or Class Y weighing (other than review of weighing).2

(59) **Official certificate.** Those certificates which show the results of official services performed under the Act as provided in the instructions, and any other official certificates which may be approved by the Service in accordance with the instructions.

(60) **Official criteria.** A quantified physical or chemical property of grain that is approved by the Service to determine the quality or condition of grain or other facts relating to grain.

(61) **Official factor.** A quantified physical or chemical property of grain as identified in the Official U.S. Standards for Grain.

(62) **Official forms.** License, authorizations, and approvals; official certificates; official pan tickets; official inspection or weighing logs; weight sheets; shipping bin weight loading logs; official equipment testing reports; official certificates of registration; and any other forms which may be issued or approved by the Service that show the name of the Service or an agency and a form number.

(63) **Official grade designation.** A numerical or sample grade designation, specified in the standards relating to kind, class, quality, and condition of grain provided for in the Act.1

(64) **Official inspection.** The determination (by original inspection, and when requested, reinspection and appeal inspection) and the certification, by official personnel, of the kind, class, quality, or condition of grain, under standards provided for in the Act; or the condition of vessels and other carriers or receptacles for the transportation of grain so far as it may affect the quality of such grain; or other facts relating to grain under other criteria approved by the Administrator (the term “officially inspected” shall be construed accordingly).1

(65) **Official inspection equipment testing.** Any operation or procedure by official personnel to determine the accuracy of equipment used, or to be used, in the performance of official inspection services.

(66) **Official inspection technician.** Any official personnel who perform or supervise the performance of specified official inspection services and certify the results thereof, other than certifying the grade of the grain.

(67) **Official inspector.** Any official personnel who perform or supervise the performance of official inspection services and certify the results thereof including the grade of the grain.

(68) **Official marks.** The symbols or terms “official certificate,” “official grade,” “officially sampled,” “officially inspected,” “official inspection,” “U.S. inspected,” “loaded under continuous official inspection,” “officially weighed,” “officially supervised weighing,” “official supervision of weighing,” “officially supervised weight,” “loaded under continuous official weighing,” “loaded under continuous official inspection and weighing,” “officially weighed,” “official Class X weighing,” “official Class Y weighing,” “Class X weighing,” “official Class Y weighing,” and “Class Y weight.”

(69) **Official personnel.** Persons licensed or otherwise authorized by the Administrator pursuant to Section 8 of the Act to perform all or specified functions involved in official inspection, Class X or Class Y weighing, or in the supervision of official inspection, or Class X or Class Y weighing.

(70) **Official sample.** A sample obtained from a lot of grain by, and submitted for official inspection by, official personnel (the term “official sampling” shall be construed accordingly).1

(71) **Official sampler.** Any official personnel who perform or supervise the performance of official sampling services and certify the results thereof.

(72) **Official storage examination.** Any examining operation or procedure performed by official personnel to determine the suitability of a carrier or container to receive or store grain.

(73) **Official tolerance.** A statistical allowance prescribed by the Service, on the basis of expected variation, for use in performing or supervising the performance of official inspection services, official equipment testing services, and, when determined under an established loading plan, reinspection services and appeal inspection services.

1This definition is the same as the definition for "Official inspection personnel" found at Section 5 of the Act. Warehousemen are not considered official personnel but they are licensed under authority of Section 11 of the Act.
(74) **Official U.S. Standards for Grain.** The Official U.S. Standards for Grain established under the Act describe the physical and biological condition of grain at the time of inspection.

(75) **Official weigher.** Any official personnel who perform or supervise the performance of Class X or Class Y weighing services and certify the results thereof, including the weight of the grain.

(76) **Official weighing.** (Referred to as Class X weighing.) The determination and certification by official personnel of the quantity of a lot of grain under standards provided for in the Act, based on the actual performance of weighing or the physical supervision thereof, including the physical inspection and testing for accuracy of the weights and scales and the physical inspection of the premises at which weighing is performed and the monitoring of the discharge of grain into the elevator or conveyance. (The terms “officially weigh” and “officially weighed” shall be construed accordingly.)

(77) **Official weighing technician.** Any personnel who perform or supervise specified weighing services and certify the results thereof other than certifying the weight of grain.

(78) **Official weight sample.** Sacks of grain obtained at random by, or under the complete supervision of, official personnel from a lot of sacked grain for the purpose of computing the weight of the grain in the lot.

(79) **Original inspection.** An initial official inspection of grain.

(80) **“Out” movement.** A movement of grain out of an elevator or out of a city, town, or other location.

(81) **Person.** Any individual, partnership, corporation, association, or other business entity.

(82) **Quantity.** Pounds or kilograms, tons or metric tons, or bushels.

(83) **Reasonably continuous operation.** A loading or unloading operation in one specific location which does not include inactive intervals in excess of 889 consecutive hours.

(84) **Regular workday.** Any Monday, Tuesday, Wednesday, Thursday, Friday, or Saturday that is not a holiday.

(85) **Regulations.** The regulations in Parts 300, 301, and 802 of this chapter.

(86) **Reinspection service.** An official review of the results of an original inspection service by the agency or field office that performed the original inspection service.

(87) **Respondent.** The party proceeded against.

(88) **Review of weighing service.** An official review of the results of a Class X or Class Y weighing service.
§ 800.73 [Amended]

5. Section 800.73, Computation and payment of service fees; general fee information, is amended by removing paragraph (d) and redesignating paragraphs (a) as (d), (e) as (a), and (f) as (f).

6. Section 800.84, Inspection of grain in land carriers, containers, and barges in single lots, is amended by removing paragraph (f)(4); by changing the words "(f)(1) through (5)" in paragraph (f)(5) to "(f)(1) through (4)"; and by redesignating paragraph (f)(5) as (f)(4) to read as follows:

§ 800.84 Inspection of grain in land carriers, containers, and barges in single lots

(f) * * *

(4) Restriction. No "partial inspection—heavily loaded" inspection certificate shall be issued for such grain or for any inspection other than the inspection described in paragraphs (f)(1) through (4) of this section and § 800.65(h)(2).

§ 800.171 [Amended]

7. Section 800.171, Who may be licensed or authorized, is amended by removing paragraph (e).

(Secs. 8, 9, 10, 14, 18, Pub. L. 94-582, 90 Stat. 2672, 2673, 2677, 2682, 2684; (7 U.S.C. 79, 79a, 79b, 84, 87a, 87e) and Sec. 155, Pub. L. 97-35, 92 Stat. 371; (7 U.S.C. 79, 79a))


Kenneth A. Gilles,
Administrator.

[FR Doc. 84-24225 Filed 9-13-84; 8:45 am]
BILLING CODE 3410-E-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Reg. 481]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market at 235,200 cartons during the period September 16-22, 1984. Such action is needed to provide for orderly marketing of fresh lemons for the period due to the marketing situation confronting the lemon industry.


FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Secretary's Memorandum 1512-1 and Executive Order 12291, and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

This final rule is issued under Marketing Order No. 910, as amended (7 CFR Part 910) regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 611-674). The action is based upon recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is found that this action will tend to effectuate the declared policy of the Act.

This action is consistent with the marketing policy currently in effect. The committee met publicly on September 11, 1984, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports that lemon demand is steady. It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the Federal Register (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the Act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the Act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910


PART 910—[AMENDED]

Section 910.781 is added as follows:

§ 910.781 Lemon regulation 481.

The quantity of lemons grown in California and Arizona which may be handled during the period September 16, 1984, through September 22, 1984, is established at 235,200 cartons.

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


Thomas R. Clark,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 84-24555 Filed 9-13-84; 8:45 am]
BILLING CODE 4410-D-M

7 CFR Part 1033

[Docket No. AO-166-A52]

Milk in the Ohio Valley Marketing Area; Order Amending Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action amends the Ohio Valley milk marketing order. The amendments: (1) Eliminate minus location adjustments at plants located outside the marketing area and generally to the south and east of such area; (2) impose a charge on handler payments that are overdue; (3) reduce the qualification requirements for pool plants; (4) adopt less-restrictive diversion provisions; (5) revise the method of payment for bulk fluid milk products received from a pool plant operated by a cooperative association; and (6) revise certain handler reporting requirements.

The order changes are based on evidence presented at a public hearing held at Columbus, Ohio, on October 12-13, 1983. They are needed to reflect current marketing conditions and to promote marketing efficiencies. Cooperative associations representing more than two-thirds of the dairy farmers supplying milk for the market during June 1984 have approved issuance of the order, as amended.

EFFECTIVE DATE: September 14, 1984.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:
Suspension Order: Issued December 6, 1983; published December 12, 1983 (48 FR 55275).

23 CFR Part 910

EFFECTIVE DATE: September 14, 1984.

FOR FURTHER INFORMATION CONTACT:

Suspension Order: Issued January 12, 1984; published January 17, 1984 (49 FR 1890).

Termination Order: Issued February 24, 1984; published February 29, 1984 (49 FR 7383).

Suspension Order: Issued March 16, 1984; published March 22, 1984 (49 FR 10856).

Partial Recommended Decision: Issued July 11, 1984; published July 16, 1984 (49 FR 28272).

Partial Final Decision: Issued August 30, 1984; published September 6, 1984 (49 FR 35101).

Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the Ohio Valley order was first issued and when it was amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) Findings upon the basis of the hearing record. Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order regulating the handling of milk in the Ohio Valley marketing area. Upon the basis of the evidence introduced at such hearing and the record made therefrom, it is found that:

(1) The said order as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the said marketing area, and the minimum prices specified in the order as hereby amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

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

(b) Additional findings. It is necessary in the public interest to make this order amending the order effective upon publication of this document in the Federal Register. Any delay beyond that date would tend to disrupt the orderly marketing of milk in the marketing area.

The provisions of this order are known to handlers. The partial recommended decision of the Deputy Administrator, Marketing Program Operations, was issued July 11, 1984 (49 FR 28272), and the partial final decision of the Assistant Secretary containing all amendment provisions of this order was issued August 30, 1984 (49 FR 35101).

The changes effected by this order will not require extensive preparation or substantial alteration in method of operation for handlers. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order effective upon publication of this document in the Federal Register, and that it would be contrary to the public interest to delay the effective date of this order for 30 days after its publication in the Federal Register. (Sec. 553(d), Administrative Procedure Act, 5 U.S.C. 551-559.)

(c) Determinations. It is hereby determined that:

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

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

(3) The issuance of the order amending the order is approved or favored by more than two-thirds of the producers who during the determined representative period were engaged in the production of milk for sale in the marketing area.

List of Subjects in 7 CFR Part 1033

Milk marketing order, Milk, Dairy products.

Order Relative to Handling

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

PART 1033—MILK IN THE OHIO VALLEY MARKETING AREA

§ 1033.11 [Amended]

1. In § 1033.11, the word "transferred" is changed to "delivered".

2. Section 1033.12 is revised to read as follows:

§ 1033.12 Pool plant.

"Pool plant" means a plant described in paragraph (a), (b), or (c) of this section that is not a producer-handler plant or a plant that is subject to another Federal order as set forth in § 1033.56.

(a) A distributing plant with:

(1) Route disposition in the marketing area during each month of not less than 15 percent of its total route disposition; and

(2) Route disposition of not less than 40 percent during each of the months of September through February, and 35 percent during each of the months of March through August, of its total receipts of fluid milk products (including milk diverted from such plant but excluding bulk fluid milk products received by transfer or diversion from other plants as Class II or Class III milk) that are approved by a duly constituted health authority for fluid consumption, subject to the following conditions:

(i) In making the percentage computations in paragraphs (a) (1) and (2) of this section, a plant's route disposition and receipts shall be exclusive of filled milk and of packaged fluid milk products priced as Class I milk under this or any other Federal order;

(ii) A distributing plant [except a plant that met the route disposition percentage on a unit basis under paragraph (a)(2)(iii) of this section] that does not meet the minimum route disposition percentage specified in paragraph (a)(2) of this section to qualify for pool status in the current month shall be deemed to have met such qualifying percentage in such month, if the plant met the applicable percentage in each of the three immediately preceding months; and

(iii) Two or more plants operated by the same handler may be considered as a unit for the purpose of meeting the total route disposition percentage specified in paragraph (a)(2) of this section if such handler requests that the plants be so considered and each plant in the unit meets the in-area route disposition percentage specified in paragraph (a)(1) of this section.

(b) A supply plant from which during the month 35 percent or more of the receipts at such plant from producers
(including producer milk diverted from the plant but excluding milk diverted to such plant) and from handlers described in §1033.16(c) is delivered by transfer or diversion as fluid milk products, except filled milk, to pool distributing plants qualified pursuant to paragraph (a) of this section, subject to the following conditions:

1. The operator of a supply plant may include milk diverted from such plant to pool distributing plants as qualifying deliveries in meeting up to one-half of the required deliveries;

2. A supply plant that does not meet the minimum delivery requirement specified in paragraph (b) of this section to qualify for pool status in the current month because a distributing plant to which the supply plant delivered its fluid milk product during such month failed to qualify as a pool plant pursuant to paragraph (a) of this section shall continue to be a pool plant for the current month if such supply plant qualified as a pool plant in the three immediately preceding months; and

3. A supply plant that qualified as a pool plant in each of the immediately preceding months of September through February, the operator of a pool plant in each of the immediately preceding months; and

4. Any milk diverted in excess of the limit set forth in paragraph (e) (2) or (3) of this section shall not be producer milk. The diverting handler shall designate the dairy farmer deliveries that shall not be producer milk. If the handler fails to designate the dairy farmer deliveries which are ineligible, producer milk status shall be forfeited with respect to all milk diverted to nonpool plants by such handler;

(f) Milk diverted pursuant to paragraph (d) or (e) of this section shall be priced at the location of the plant where it is received.

5. In §1033.16, paragraphs (b) and (c) are revised to read as follows:

§1033.16 Handler.

(b) A cooperative association with respect to the producer milk which is diverted to nonpool plants for the account of such association pursuant to §1033.15, excluding producer milk diverted by the association as the operator of a pool plant pursuant to paragraph (a) of this section;

(c) A cooperative association with respect to producer milk which is delivered for its account from the farm to a pool plant in a tank truck owned and operated by, or under contract to, such cooperative association. Milk delivered pursuant to this paragraph shall not include producer milk diverted to another pool plant by the association as the operator of a pool plant pursuant to paragraph (a) of this section. The operator of such plant may divert a total quantity of milk not exceeding 50 percent of the producer milk physically received at or diverted from such pool plant during the month;

(3) In any month of September through February, a cooperative association may divert an aggregate quantity of milk not exceeding 50 percent of the producer milk that the cooperative association caused to be physically received at or diverted from pool plants during the month and

§1033.14 Producer.

(a) Except as provided in paragraph (b) of this section, "Producer" means any person who produces milk approved by a duly constituted health authority for fluid consumption, whose milk is:

1. Received at a pool plant directly from such person;

2. Received at a pool plant from a handler described in §1033.16(c); or

3. Diverted from a pool plant in accordance with §1033.15.

(b) "Producer" shall not include:

1. Any person defined as a producer-handler under a Federal milk order (including this part) issued pursuant to the Act;

2. Any person with respect to milk produced by such dairy farmer which is diverted to a pool plant from another order plant if the other order designates such person as a producer under that order and such milk is allocated to Class II or Class III utilization pursuant to §1033.46(a)(8)(ii) and the corresponding step of §1033.46(b); or

3. Any person with respect to milk produced by such dairy farmer which is reported as diverted to another order plant if any portion of such person's milk so moved is assigned to Class I under the provisions of such other order.

4. Section 1033.15 is revised to read as follows:

§1033.15 Producer milk.

"Producer milk" means the skim milk and butterfat contained in milk from producers which is:

1. Received at a pool plant directly from a producer, excluding any such milk received by diversion from another pool plant;

2. Received at a pool plant from a handler described in §1033.16(c) under the conditions set forth therein;

3. Received by a handler described in §1033.16(c) from producers in excess of the quantity delivered to pool plants;

4. Diverted from a pool plant for the account of the handler operating such plant to another pool plant; or

5. Diverted from a pool plant to a nonpool plant (other than a producer-handler plant) for the account of the handler described in §1033.16(b), subject to the following conditions:

1. During each of the months of September through November not less than one day's production of the producer milk received by the handler, excluding any such producer milk delivered to another pool plant by the association as the operator of a pool plant pursuant to paragraph (a) of this section, subject to the following conditions:

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

3. In any month of September through February, a cooperative association may divert an aggregate quantity of milk not exceeding 50 percent of the producer milk that the cooperative association caused to be physically received at or diverted from pool plants during the month.

§1033.30 [Amended]

6. In §1033.30(b)(2), the reference "§1033.15(a)(2)" is changed to "§1033.15(b)".

7. In §1033.31, paragraphs (c), (d), and (e) are revised and two new paragraphs (f) and (g) are added to read as follows:

§1033.31 Producer association.

(c) A cooperative association with respect to producer milk which is diverted to nonpool plants for the account of such association pursuant to §1033.15, excluding producer milk diverted by the association as the operator of a pool plant pursuant to paragraph (a) of this section;

(c) A cooperative association with respect to producer milk which is delivered for its account from the farm to a pool plant in a tank truck owned and operated by, or under contract to, such cooperative association. Milk delivered pursuant to this paragraph shall not include producer milk diverted to another pool plant by the association as the operator of a pool plant pursuant to paragraph (a) of this section. The operator of such plant may divert a total quantity of milk not exceeding 50 percent of the producer milk physically received at or diverted from such pool plant during the month; and

(3) In any month of September through February, a cooperative association may divert an aggregate quantity of milk not exceeding 50 percent of the producer milk that the cooperative association caused to be physically received at or diverted from pool plants during the month.
Federal Register / Vol. 49, No. 180 / Friday, September 14, 1984 / Rules and Regulations 36075

§ 1033.31 Other reports.

(c) On or before the 26th day of the month, each handler who receives milk from any producer and does not make payment to such producer shall report the following information to the market administrator with respect to the receipts of milk by such handler during the first 15 days of the month:

(1) The identity of each such producer from whom milk was received;
(2) The total pounds of producer milk received from such producer;
(3) The amount and nature of any deductions, as authorized by the producer, to be made from the partial payment for such milk;
(4) The total pounds of milk received from a handler described in § 1033.16(c); and
(5) The total pounds of skim milk and butterfat in bulk fluid milk products received from a pool plant operated by a cooperative association.

§ 1033.32 Payroll reports.

(a) On or before the 20th day after the end of the month, each handler who elects to pay producers pursuant to § 1033.37(d) shall report to the market administrator, the following information with respect to the handler’s partial and final payments for producer milk received during such month:

(1) The identity of the handler and the producer and the month to which the payment applies;
(2) The total pounds and, with respect to final payments, the average butterfat content of the milk for which payment is being made;
(3) The minimum rate of payment required by the order and the rate of payment used if such rate is other than the applicable minimum rate;
(4) The amount and nature of any deductions from the amount otherwise due the producer;
(5) The net amount of payment to the producer; and
(6) The dates such payments were made.

(b) On or before the 20th day after the end of the month, each handler operating a partially regulated distributing plant who elects to make payments pursuant to § 1033.37(a) shall report to the market administrator, in the detail and on forms prescribed by the market administrator, his payroll for such month for dairy farmers from whom he received bottling grade milk. Such payroll shall show for each dairy farmer the total pounds of milk received from him, the average butterfat content thereof, and the rate and net amount of the payment made to such dairy farmer, together with the amount and nature of any deductions involved.

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

9. In § 1033.45, a new paragraph (d) is added to read as follows:

§ 1033.45 Computation of skim milk and butterfat in each class.

(d) Bulk fluid milk products transferred or diverted from a pool plant operated by a cooperative association to another pool plant shall be classified in accordance with the rules set forth in § 1033.43(a) and the value thereof at class prices (applicable at the location of the transferee-plant) shall be used to compute the receiving handler’s pool obligation for such milk pursuant to § 1033.60.

10. In § 1033.53, the section title is changed, paragraph (a) is revised, and a new paragraph (c) is added to read as follows:

§ 1033.53 Plant location adjustments for handlers.

(a) For milk received at a plant from producers that is classified as Class I milk without movement in bulk form to a pool distributing plant at which a higher Class I price applies, the price specified in § 1033.51(a) shall be adjusted on the basis of where the plant receiving the milk is located, as follows:

(1) At a plant located in one of the zones set forth in § 1033.6, the adjustment shall be as follows:

<table>
<thead>
<tr>
<th>Zone</th>
<th>Adjustment per hundredweight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northwestern zone</td>
<td>Minus 5 cents.</td>
</tr>
<tr>
<td>Central zone</td>
<td>No adjustment.</td>
</tr>
<tr>
<td>Southeastern zone</td>
<td>Plus 5 cents.</td>
</tr>
</tbody>
</table>

(2) At a plant located outside the marketing area and more than 60 miles from the city hall of the nearest city listed herein, the adjustment shall be the adjustment applicable to Cincinnati, Coshocton, Dayton, Lima, Marietta or Toledo, Ohio; Ashland or Maysville, Kentucky; or Beckley or Charleston, West Virginia; whichever city is nearest;

(3) At a plant located outside the marketing area and more than 60 miles from the city hall of the nearest city listed in paragraph (a)(2) of this section,
the adjustment shall be the adjustment applicable at the nearest city, less 11 cents and less an additional 1.5 cents for each 10 miles or fraction thereof in excess of 70 miles that such plant is located from the city hall of the nearest city listed above. However, no minus location adjustment shall apply at any plant located in the Louisville-Lexington-Evanstville marketing area under Part 1046 of this chapter or east of the Mississippi River and south of the northern boundary of Kentucky, West Virginia or Virginia; and

(a) For the purpose of computing location adjustments pursuant to this section, distances shall be measured by the shortest hard-surfaced highway distance as determined by the market administrator.

(c) The Class I price applicable to other source milk shall be adjusted at the rates set forth in paragraph (a) of this section.

§ 1033.57 [Amended]

11. In the introductory text and in paragraph (a)(1)(ii) of § 1033.57, the references to "1033.31(d)" should read "1033.32(b)" in both places.

12. In § 1033.60, paragraph (a) is revised to read as follows:

§ 1033.60 Computation of the net pool obligation of each handler.

(a) Multiply the pounds of producer milk in each class as determined pursuant to § 1033.48(c) and the pounds of bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.45(d) in each class as determined pursuant to § 1033.49(a) by the applicable Class I price and add the resulting amounts;

13. Section 1033.71 is revised to read as follows:

§ 1033.71 Payments to the market administrator.

(a) Subject to paragraph (c) of this section, each handler shall pay to the market administrator on or before the 26th day of each month an amount determined by multiplying the hundredweight of producer milk and bulk fluid milk products received from a pool plant operated by a cooperative association received by such handler during the first 15 days of the month by the basic formula price for the preceding month less proper deductions and charges authorized in writing by such producers.

(b) Subject to paragraph (c) of this section, each handler shall pay to the market administrator on or before the 15th day after the end of each month the value of such handler's milk pursuant to § 1033.60(a) adjusted by the butterfat differential specified in § 1033.73 plus the amounts computed pursuant to § 1033.60(b) through (g), less:

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

(2) Partial payments made pursuant to paragraph (a) of this section for such month; and

(3) Proper deductions and charges authorized in writing by producers from whom the handler received milk, except that the total deductions and charges made under this section for the month for each producer shall not be greater than the total value of the milk received from such producer during the month.

(c) The following conditions shall apply with respect to the payments prescribed in paragraphs (a) and (b) of this section:

(1) Payments to the market administrator shall be deemed not to have been made until such payments have been received by the market administrator;

(2) If the date by which payments must be received by the market administrator falls on a Saturday or Sunday or any day that is a national holiday, payments shall be considered to have been received by the due date if they are received not later than the next day on which the market administrator's office is open for public business; and

(3) Payments due the market administrator from a cooperative association as a handler may be offset by payments determined by the market administrator to be due the cooperative association pursuant to § 1033.72.

14. In § 1033.72, the section title is changed and the section is revised to read as follows:

§ 1033.72 Payment to producers and to cooperative associations.

(a) On or before the 28th day of the month, the market administrator shall make payment, subject to paragraphs (c) and (d) of this section, to each producer for milk received from such individual producer and to each cooperative association for bulk fluid milk products delivered from its pool plant to another pool plant during the month by handlers from whom the appropriate payments have been received pursuant to § 1033.71(a) at a rate per hundredweight equal to the basic formula price for the preceding month, less the deductions authorized in writing by producers and charges made by handlers with respect to such milk.

(b) On or before the 17th day after the end of the month, the market administrator shall make payment, subject to paragraphs (c) and (d) of this section, to each producer for milk received from such individual producer and to each cooperative association for bulk fluid milk products delivered from its pool plant to another pool plant during the month by handlers from whom the appropriate payments have been received pursuant to § 1033.71(b) at the uniform price per hundredweight as adjusted pursuant to §§ 1033.73 and 1033.74 less:

(1) Partial payments made pursuant to paragraphs (a) and (b) of this section with respect to such milk;

(2) Deductions for marketing services pursuant to § 1033.75; and

(3) Other deductions authorized in writing by producers and made by handlers with respect to such milk.

(c) In lieu of making payments to individual producers pursuant to paragraphs (a) and (b) of this section, the market administrator shall pay, on or before the day prior to the dates specified in such paragraphs, to each cooperative association that so requests, the proceeds due to such association.

(d) In lieu of making payments to individual producers pursuant to paragraphs (a) and (b) of this section, the market administrator shall pay, on or before the day prior to the dates specified in such paragraphs, to each handler who so requests, the proceeds due to such handler from producers for whom a cooperative association is not collecting payments pursuant to paragraphs (a) and (b) of this section.

§ 1033.74 [Amended]

13. In § 1033.74, the section is revised to read as follows:

§ 1033.74 Less:

(a) The 1033.32(b) in both places.

14. In § 1033.74, the section is revised to read as follows:

§ 1033.73 Less:

(a) The 1033.32(b) in both places.
making payments pursuant to this paragraph, the handler shall furnish the following information to each producer:

1. The identity of the handler and the producer and the month to which the payment applies;
2. The total pounds and, with respect to final payments, the average butterfat content of the milk for which payment is being made;
3. The minimum rate of payment required by the order and the rate of payment used if it is other than the applicable minimum rate;
4. The amount and nature of any deductions subtracted from the amount otherwise due the producer; and
5. The net amount of payment to the producer.

The following conditions shall apply with respect to the payments by the market administrator prescribed in paragraphs (a) through (d) of this section:

1. If the date by which such payments are to be made falls on a Saturday or Sunday or on any day that is a national holiday, such payments need not be made until the next day on which the market administrator's office is open for public business and
2. If the application of § 1033.71(c)(2) of paragraph (e)(1) of this section results in a delay in the partial or final payments by handlers to the market administrator or by the market administrator to producers or cooperative associations, the corresponding partial or final payments prescribed in paragraphs (a) through (d) of this section may be delayed by the same number of days.

If the market administrator does not receive the full payment required of a handler pursuant to § 1033.71, he shall reduce uniformly per hundredweight the payments to producers and shall complete such payments on or before the next date for making payments pursuant to this section following the date on which the funds become available.

15. Section 1033.76 is revised to read as follows:

§ 1033.76 Expense of administration.

As a pro rata share of the expense of administration of the order, each handler shall pay to the market administrator on or before the 15th day after the end of the month 4 cents per hundredweight, or such lesser amount as the Secretary may prescribe, with respect to:

(a) Receipts of producer milk (including such handler's own farm production and milk received from a handler described in § 1033.16(c) but excluding bulk fluid milk products delivered from a pool plant operated by a cooperative association to another pool plant pursuant to § 1033.45(d));
(b) Receipts of bulk fluid milk products from a pool plant operated by a cooperative association pursuant to § 1033.45(d);
(c) Receipts of other source milk allocated to Class I pursuant to § 1033.46(a)(8), (7), and (11) and the corresponding steps of § 1033.46(b), except such other source milk on which no handler obligation applies pursuant to § 1033.60(g); and
(d) Route disposition in the marketing area from a partially regulated distributing plant that exceeds the Class I milk:
1. Received during the month at such plant from pool plants and other order plants that is not used as an offset under a similar provision of another order issued pursuant to the Act; and
2. Specified in § 1033.57(b)(2)(i).

16. A new section 1033.78 is added to read as follows:

§ 1033.78 Charges on overdue accounts.

Any unpaid obligation of a handler pursuant to §§ 1033.57, 1033.71, 1033.72(d), 1033.76, 1033.77, or 1033.78 shall be increased one (1) percent beginning on the first day after the due date, and on the same day of each succeeding month until such obligation is paid, subject to the following conditions:

(a) Charges on overdue accounts collected pursuant to this section shall be deposited into the administrative assessment fund maintained by the market administrator;
(b) Amounts payable pursuant to this section shall be computed by the market administrator monthly on the unpaid balance (including any unpaid charges previously assessed pursuant to this section) remaining on each overdue obligation on such date; and
(c) Any obligation that was determined at a date later than that prescribed by the order because of a handler's failure to submit a report to the market administrator when due, shall be considered to have been payable by the date it would have been due if the report had been filed when due.

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

Effective date: September 14, 1984.


C.W. McMillan,
Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 84-2432 Filed 9-13-84; 8:45 am]
BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR Part 91

[Docket No. 84-076]

Ports Designated for Exportation of Animals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule.

SUMMARY: This document affirms the interim rule which amended the "Inspection and Handling of Livestock for Exportation" regulations by adding Minneapolis/St. Paul, Minnesota (airport only), to the list of ports designated as ports of embarkation and by adding the American Livestock Export Company as the export inspection facility for that port. This action is necessary because it has been determined that the export facility of the American Livestock Export Company for the port at Minneapolis/St. Paul meets the requirements of the regulations for inclusion in the list of export inspection facilities.

EFFECTIVE DATE: September 14, 1984.

FOR FURTHER INFORMATION CONTACT: Dr. George Winegar, Import/Export Animals and Products Staff, VS, APHIS, USDA, Room 845, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8383.

SUPPLEMENTARY INFORMATION:

Background

The "Inspection and Handling of Livestock for Exportation" regulations in 9 CFR Part 91 regulate the exportation of animals from the United States. On June 11, 1984, a document was published in the Federal Register (49 FR 24013-24014)
which amended § 61.14(a) of the regulations by adding Minneapolis-St. Paul (airport only) to the list of ports designated as ports of embarkation and by adding the "American Livestock Export Company, 25769 Northfield Blvd., Hampton, MN 55031, (612) 831-3873" as the export inspection facility for that port.

The interim rule was made effective on June 11, 1984. Comments were solicited for 60 days following publication. No comments were received. The factual situation which was set forth in the document of June 11, 1984, still provides a basis for the amendment.

Executive Order 12291 and Regulatory Flexibility Act

This action has been reviewed in conformance with Executive Order 12291 and has been determined to be not a major rule. The Department has determined that this action will not have an annual effect on the economy of $100 million or more; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not have any adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

It is anticipated that, compared with the total number of animals exported annually from the United States, less than one percent of the total number of animals will be exported annually through the port at Minneapolis/St. Paul, Minnesota.

Under these circumstances, Mr. Bert W. Hawkins, Administrator, Animal and Plant Health Inspection Service, has determined that this action will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 9 CFR Part 91

Animal diseases, Animal welfare, Exports, Humans animal handling, Livestock and livestock products, Transportation.

Accordingly, the interim rule which was published at 49 FR 24013-24014 on June 11, 1984, is adopted as a final rule.


Done at Washington, D.C., this 10th day of September 1984.

K.R. Hook,
Acting Deputy Administrator, Veterinary Services.

BILLING CODE 4450-34-M

9 CFR Part 94
[Docket No. 84-078]
Change in Disease Status of France Because of African Swine Fever

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends the regulations concerning the importation into the United States of pork and pork products by removing France from the list of countries regulated because of African swine fever (ASF). It has been determined that ASF no longer exists in France. This rule will remove certain restrictions on the importation of pork and pork products from France because of ASF. However, France is not included in the lists of countries declared to be free of rinderpest and foot-and-mouth disease, hog cholera, and swine vesicular disease. Therefore, the importation of pork and pork products into the United States from France will remain subject to restrictions imposed because of these diseases.


FOR FURTHER INFORMATION CONTACT: Dr. M. R. Crane, Import-Export Animals and Products Staff, VS,APHIS, USDA, Room 646, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8170.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR Part 94 (referred to below as the regulations) regulate the importation into the United States of specified animals and animal products in order to prevent the introduction into the United States of various diseases, including African swine fever (ASF).

A document published in the Federal Register on June 19, 1984 (49 FR 25006-25008) proposed to amend § 94.8 of the regulations by removing France from the list of countries in which ASF exists or is reasonably believed to exist. Comments were solicited for 60 days after publication. Only one comment was received. The commenter supported the proposed change. The rationale set forth in the proposal still provides a basis for the amendment. Therefore, the regulations are amended as proposed.

The effect of this action is to remove certain restrictions on the importation of pork and pork products from France because of ASF. However, pork and pork products from France will remain subject to the provisions in Part 94 because of rinderpest and foot-and-mouth disease, hog cholera, and swine vesicular disease. These provisions, among other things, require that pork and pork products from France be heat treated or cured as a condition for importation.

Executive Order 12291 and Regulatory Flexibility Act

This action has been reviewed in conformance with Executive Order 12291 and has been determined to be not a "major rule." The Department has determined that this rule will not have an annual effect on the economy of $100 million or more; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will have no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

It is anticipated that insignificant quantities of pork and pork products will be imported into the United States from France as a result of this action.

For this rulemaking action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

Under the circumstances explained above, Mr. Bert W. Hawkins, Administrator of the Animal and Plant Health Inspection Service, has determined that this action will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 9 CFR Part 94

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLague), NEWCASTLE DISEASE, AVIAN PNEUMONEcephALITIS, AFRICAN SWINE FEVER, AND HOG CHOLERA: PROHIBITED AND RESTRICTED IMPORTATIONS

§ 94.8 [Amended]

Acting Deputy Administrator, Veterinary Administration, International Trade and Iraq; Validated Export License Services.

AGENCY: Required

ACTION: Ill, 134a, 134b, 134c, 134f; 7 CFR 2.17, 2.51, BILUNG CODE 3410-34-M

September 1984.

secs. 2, 3, 4, 11; 76 Stat. 129, 130, 132; 21 U.S.C. (AVIAN PNEUMONEcephALITIS), amended by removing “France” from the

§ 94.8 [Amended]


Done at Washington, D.C., this 10th day of September 1984.

K.R. Hook,
Acting Deputy Administrator, Veterinary Services.

[FR Doc. 84-24353 Filed 9-13-84; 8:45 am]
BILLING CODE 3410-34-M

DEPARTMENT OF COMMERCE
International Trade Administration

15 CFR Parts 385 and 399

[Docket No. 40815-4115]

Exports of Certain Chemicals to Iran and Iraq; Validated Export License Required

AGENCY: Office of Export Administration, International Trade Administration, Commerce.

ACTION: Interim rule with request for comments.

SUMMARY: This rule expands foreign policy controls on the export from the United States to Iran and Iraq of certain chemicals used in producing chemical weapons. The additional chemicals are:

dimethylamine

dimethylamine hydrochloride

ethylen chlorohydrin (chloroethanol)

The Department of Commerce, after consultation with the Department of State, has determined that the controls are necessary to further significantly the foreign policy of the United States and that, notwithstanding any availability of these commodities from foreign sources, adequate evidence is available that absence of controls would prove detrimental to such interests. This rule further the U.S. policy of opposing prohibited use of chemical weapons and maintaining neutrality in the Iran/Iraq war, and promoting a mediated end of that war. A validated license now is required for all exports from the United States of the chemicals listed above to Iran and Iraq.

This rule expands the foreign policy controls on the export of certain chemicals to Iran and Iraq effective March 30, 1984 (49 FR 13135-13136, April 3, 1984). As of September 14, 1984, 1200 noon EDT, a validated license is required for all exports from the United States of the chemicals listed above to Iran and Iraq.

DATES: This rule is effective September 14, 1984. Comments must be received by November 13, 1984.

ADDRESS: Written comments (six copies) should be sent to: Betty Ferrell, Exporter Services Division, Office of Export Administration, U.S. Department of Commerce, P.O. Box 273, Washington, D.C. 20044.

FOR FURTHER INFORMATION CONTACT: Vincent Greenwald, Exporter Services Division, (202) 377-3856.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements and Invitation to Comment

In connection with various rulemaking requirements of the Office of Export Administration has determined that:

1. Since this regulation involves a foreign affairs function, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring a notice of proposed rulemaking, an opportunity for public participation and a delay in effective date are inapplicable.

However, because of the importance of the issues raised by these regulations, this rule is issued in interim form and comments will be considered in developing final regulations. These regulations may be revised before the end of the comment period. Accordingly, interested persons who desire to comment are encouraged to do so at the earliest possible time to permit the fullest consideration of their views.

2. Applicants for the validated export license required by this rule will use Form ITA-622P. This form has been approved by the Office of Management and Budget under control number 0625-0001.

3. This rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq.

4. Because this rule is being issued with respect to a foreign affairs function, it is not subject to Executive Order 12291 (46 FR 13193, February 19, 1981), “Federal Regulation.”

The period for submission of comments will close November 13, 1984. All comments received before the close of the comment period will be considered by the Department in the development of final regulations. While comments received after the end of the comment period will be considered if possible, their consideration cannot be assured. The Department will not accept public comments that are accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. Such comments and materials will be returned to the person submitting the comments and will not be considered in the development of final regulations.

All public comments on these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, comments in written form are preferred. If oral comments are received, they must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will be made available for public inspection.

The public record concerning these regulations will be maintained in the International Trade Administration Freedom of Information Records Inspection Facility, Room 4001, U.S. Department of Commerce, 14th Street and Pennsylvania Avenue, NW., Washington, D.C. 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in Part 4 of Title 15 of the Code of Federal Regulations. Information about the inspection and copying of records at the facility may be obtained from Patricia L. Mann, International Trade Administration Freedom of Information Officer, at the above address or by calling (202) 377-3031.

List of Subjects in 15 CFR Parts 385 and 399

Communist countries, Exports.

Accordingly, the Export Administration Regulations (15 CFR Parts 368–399) are amended as follows:

§ 385.4 [Amended]

1. Paragraph (e) of § 385.4 is amended by revising the first sentence to read as follows:

[e] * * * In support of U.S. foreign policy, and particularly U.S. policies of opposing prohibited use of chemical weapons and maintaining neutrality in the Iran/Iraq war and of promoting a
mediated end to that war, an individual valid license is required to export from the United States postassium fluoride, dimethyl methylphosphonate, methyl phosphonyl difluoride, thiodiglycol, phosphorus oxychloride, dimethylamine, dimethylamine hydrochloride, and ethylene chlorohydrin (chloroethanol) to Iran and Iraq.

§ 399.11 [Amended]
2. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 7, Chemicals, Metalloids, Petroleum Products and Related Materials is amended by revising the last sentence of the Validated License Required paragraph of entry 5799D to read “A validated license also is required for export of dimethyl methylphosphonate, methyl phosphonyl difluoride, and dimethylamine hydrochloride to Iran and Iraq.”; and by revising the Reason for Control paragraph to read “National security: foreign policy. Foreign policy controls apply only to exports of dimethyl methylphosphonate, methyl phosphonyl difluoride, and dimethylamine hydrochloride to Iran and Iraq.”

§ 399.11 [Amended]
3. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 7, Chemicals, Metalloids, Petroleum Products and Related Materials is amended by revising the last sentence of the Validated License Required paragraph of entry 6799C to read “A validated license also is required for exports of potassium fluoride, phosphorus oxychloride, thiodiglycol, ethylene chlorohydrin (chloroethanol) and dimethylamine to Iran and Iraq.”

§ 399.2 [Amended]
4. Interpretation 24, Chemicals, of Supplement No. 1 to § 399.2 is amended by revising the entry “Dimethyl amine” (Organic Chemicals) to read “Dimethylamine” with a footnote reading: “A validated license is required for export of dimethylamine to Iran and Iraq.”


John K. Boldock,
Director, Office of Export Administration,
International Trade Administration.
certain conditions. After rule 17f-5 was initially proposed, the Division of Investment Management took the position that it would not recommend enforcement action to the Commission if investment companies were to establish foreign custody arrangements that conformed to the conditions contained in the Chase or BONY orders. In the rule proposal, provided of course that those arrangements were modified if necessary to conform to the conditions of the final rule when adopted.

The Commission today is issuing two notices advising Chase and BONY that it intends to modify certain conditions of their exemptive orders to conform to the conditions of the final rule. Any investment companies that may have made foreign custody arrangements in reliance on the Chase or BONY orders or the staff's no-action position will be given until March 1, 1985 to modify those arrangements to the orders as modified or to the final rule adopted today. While investment companies relying on the Chase or BONY orders or on the staff's no-action position will have until March 1, 1985 to modify existing foreign custody arrangements where necessary, any new foreign custody arrangements made by those companies after the effective date of the rule must comply with the conditions of the rule that the Commission intends to modify them.

I. Discussion

In response to the revised rule proposal, the Commission received fifteen comment letters. With respect to the scope of the rule, the commentators addressed the type of foreign custody arrangements which would be appropriate for Canadian investment companies, the type of securities that investment companies may keep with foreign custodians and the type of foreign custodians that should be considered eligible custodians. The commentators also addressed whether investment company directors should be permitted to delegate their responsibility for making foreign custody arrangements to intermediaries and if so, the type of entity which should be considered qualified to act as intermediary.

As discussed in more detail below, the final rule, as in the revised proposal, allows Canadian investment companies to maintain their assets in overseas branches of qualified U.S. banks and defines foreign securities to include securities issued and sold primarily outside the United States by a foreign or U.S. issuer. The final rule differs, however, from the revised proposal by reducing the minimum shareholders' equity required of foreign banking institutions and trust companies from $400 to $200 million. The final rule also reduces the minimum shareholders' equity required of foreign subsidiaries of U.S. banks and bank-holding companies from $290 to $100 million, applying that standard to the subsidiary rather than its parent.

Like the revised proposal, the final rule does not permit investment company directors to delegate the responsibility of authorizing the company's foreign custody arrangements to U.S. intermediaries. The text of the rule, however, has been redrafted to make clear that the Commissioners does not intend to discourage an investment company from using an expert third party, such as its U.S. custodian, to assist it in selecting the country where the assets will be located or the foreign custodian which will have custody of the assets. Nor does the Commission intend to deter an investment company from relying on an intermediary to negotiate a contract with an eligible foreign custodian or to oversee the performance of that custodian. However, the rule makes clear that the directors must have an opportunity to approve the country, the foreign custodian and the contract negotiated with the custodian before a foreign custody arrangement is implemented. Further, the rule makes clear that it is the directors' responsibility to independently evaluate the company's existing foreign custody arrangements even though the company may use an intermediary to assist in that process.

As discussed below, the instruction in the revised proposal relating to cash and cash equivalents and certain instructions relating to the custody agreement are moved directly to the text of the final rule to become express conditions. The instruction relating to physical segregation of assets has been deleted. The remaining instructions have been redesignated as "notes" to the final rule and an additional paragraph has been added concerning the selection of foreign custodians. In view of the trend towards evidentiary proof of ownership of foreign securities by book-entry, the paragraph relating to physical segregation of assets has been deleted.

A. Scope of the Rule

1. Canadian companies

The final rule allows Canadian investment companies that are registered under the Act pursuant to the conditions of rule 7d-1 to maintain foreign securities, cash and cash equivalents with overseas branches of qualified U.S. banks. A qualified U.S. bank is defined to be a banking institution or trust company that meets:

- Cf. Chase and BONY orders that condition exemptive relief, Inter-alia, upon the foreign custody agreement being subject to the investment company's approval. These orders do not explicitly state that such approval be obtained before the foreign custody agreement is implemented. As of this date, the Commission is issuing notices of its intent to amend the Chase and BONY orders to, Inter-alia, make clear that any investment company relying upon those orders must have a majority of its directors approve any foreign custody arrangement made by Chase or BONY before that arrangement is implemented.

- Cf. Chase and BONY applications that state only that under rule 17f-4 (17 CFR 270.17f-4), a majority of directors of the investment company are required to review the custody agreement with Chase and with any foreign securities depository at least annually. As of this date, the Commission is issuing notices of its intent to amend the Chase and BONY orders to require the directors to establish a system to monitor all of their company's existing foreign custody arrangements and to review those arrangements at least annually to determine whether their continuance is in the best interest of the company and its shareholders.

- Cf. Chase and BONY orders which do not address the amount of cash and cash equivalents that an investment company may maintain in a foreign bank or foreign securities depository. As of this date, the Commission is issuing notices of its intent to amend those orders to require that an investment company may maintain cash and cash equivalents with an eligible foreign custodian only in amounts reasonably necessary to affect the company's foreign securities transactions.
the definition of bank contained in section 2(a)(5) of the Act and that has an aggregate capital, surplus and undivided profits of at least $500,000.

Three commentators believed that the final rule should not differentiate between Canadian and U.S. investment companies. In their view, if the rule limited Canadian companies to maintaining their foreign securities in overseas branches of qualified U.S. banks, those companies would be subjected to unnecessary financial and operational burdens. These commentators argued that once a foreign fund has been permitted to register pursuant to section 7(d) of the Act, the Commission’s jurisdictional concerns should be resolved, because a statutory condition to registration under the section is a Commission finding that “it is both legally and practically feasible effectively to enforce the provisions of [the Act] against such company . . . .” Two of those commentators suggested that instead of requiring Canadian investment companies to maintain 100% of their assets in the custody of U.S. bank branches, Canadian companies could be required to maintain at least 25% of their assets in such branches. Two other commentators recommended that the term “an overseas branch” of a qualified U.S. bank branches be changed to “a foreign branch” because otherwise the rule could be read to prohibit a Canadian investment company from maintaining custody of its assets with Canadian branches of qualified U.S. banks.

The Commission believes that registered Canadian investment companies should maintain their securities within the United States as contemplated by rule 7d-1* unless the primary trading market for a security is overseas, i.e., outside the United States and Canada. To the extent that a Canadian investment company’s foreign custodial arrangements involve foreign entities other than overseas branches of U.S. banks, the Commission further believes that the staff should continue to evaluate such arrangements in the context of individual applications in order to address adequately the potential difficulties which a U.S. shareholder or the Commission may encounter in obtaining jurisdiction over, or enforcing a judgment against, such Canadian companies and their officers and directors.

2. Definition of foreign securities

The final rule, as in the revised proposal, defines the term “foreign securities” to include securities issued and sold primarily outside the United States by a foreign or U.S. issuer.10 One commentator recommended that the definition be amended to include securities which although issued and sold in the United States have a significant trading market outside the United States. Another wanted foreign securities redefined as “securities issued, sold or having a trading market outside the United States,” arguing that this revised definition would eliminate the uncertainty that the word “primarily” produces and would introduce the concept of a foreign trading market “as an appropriate nexus justifying the choice of a foreign depository.” The Commission has decided, however, that the proposed definition should not be modified in this regard. The rule is intended essentially to give investment companies the flexibility to maintain their assets in or near their primary trading markets when those markets are outside the United States—not to give investment companies the opportunity to keep abroad assets customarily purchased or sold in the United States.

3. Eligible foreign custodians

a. Definition of eligible foreign banking institutions and trust companies. The final rule reduces the proposed minimum shareholders’ equity requirement for foreign banking institutions and trust companies from $400 to $200 million (U.S. $ or the equivalent of U.S. $) and replaces the proposed requirement that a U.S. bank or bank-holding company have at least $200 million shareholders’ equity in order for its majority-owned foreign subsidiaries to qualify as eligible foreign custodians with a requirement that a majority-owned foreign subsidiary must have shareholders’ equity in excess of $100 million. Any foreign banking institution or trust company and any foreign subsidiary of a U.S. bank or bank-holding company that maintains custody of the company’s assets must meet these minimum equity requirements throughout the time that it serves as the company’s custodian or subcustodian.

Seven commentators believed that minimum equity should not determine whether a foreign bank or trust company is competent to serve as an eligible foreign custodian. Four of those commentators argued that the proposed equity requirement was arbitrary and excessive and would preclude otherwise qualified foreign banks from serving as eligible foreign custodians. Two commentators observed that there are countries where there are no banks that would meet the minimum requirement and that certain foreign banks, particularly those that are owned by a foreign government, might not have shareholders’ equity.

The commentators suggested several alternative definitions of eligible foreign banking institutions and trust companies. One commentator recommended that the requirement provide that an eligible foreign custodian have total assets in excess of $500 million. Another commentator suggested that the definition include foreign banking institutions or trust companies that are regulated by a foreign government or agency thereof or that have shareholders’ equity in excess of $400 million. A third commentator suggested that the minimum equity requirement should be no higher than that which the alternative formulation of the revised proposal would impose on U.S. intermediaries (i.e., at least $200 million); and in a foreign country where no foreign bank meets that equity requirement, the five largest banks of that country should be considered eligible foreign custodians. That commentator believed, however, that if a qualified U.S. intermediary selects the foreign custodian, the foreign custodian should not have to satisfy any size criterion. Another commentator observed that if the equity requirement is denominated in U.S. dollars, some eligible foreign custodians could become suddenly ineligible due to foreign currency fluctuations. That commentator suggested that the rule state that if a foreign bank is an eligible foreign custodian at the time a custody agreement is entered into, it will not become ineligible if it falls to continue to satisfy the size standard because of foreign currency fluctuations or other developments. Two commentators suggested that instead of prescribing size criteria, the rule should require that investment company directors consider more relevant factors which stress an institution’s competence as a custodian.

The Commission believes that the revised definition will permit investment companies to find a sufficient number of qualifying foreign banks and trust
companies and foreign subsidiaries of U.S. banks and bank-holding companies while reducing to the extent practicable the risks inherent in foreign custody arrangements. While the revised definition may preclude a smaller foreign bank with custodial expertise from serving as an eligible foreign custodian under the rule, that bank can always be the subject of an application for exemptive relief and, if appropriate, the rule can be amended in the future, based on that application experience.

b. Definition of eligible foreign securities depositories and clearing agencies. The definition of eligible foreign securities depositories and clearing agencies has not been changed in the final rule. In order to be an eligible foreign custodian, a securities depository or clearing agency must be incorporated under the laws of a country other than the United States and must either operate the central system for handling of securities or equivalent book-entries in a particular country or operate a transnational system for the central handling of securities or equivalent book entries. The definition of eligible foreign securities depositories may not operate the only central system for handling of securities issued in a particular country. These depositories and clearing agencies which operate a central system for the handling of securities or equivalent book-entries. Another commentator objected to the proposed definition. Two objects because certain foreign securities depositories may not operate the only central system for handling of securities or equivalent book-entries. Another commentator objected to the proposed definition because transnational clearing systems may be operated by a foreign branch of a U.S. bank.

The Commission believes that foreign custody arrangements with foreign securities depositories or clearing agencies that do not operate the central system for handling securities or equivalent book-entries in a given country should be evaluated on a case-by-case basis. Transnational securities depositories and clearing agencies which are operated by overseas branches of U.S. banks would be considered eligible foreign custodians under the definition as proposed. While certain trust national depositories and clearing systems may be operated by an overseas branch of a U.S. bank, it is the Commission's understanding that the depository or clearing agency is still incorporated or organized outside the United States.

B. Involvement of a Third Party

The final rule has been redrafted to make clear that the directors may use an expert third party to: (i) Select the country where the company's assets will be located; (ii) select the foreign custodian(s) that will have custody of those assets; (iii) negotiate custody agreements with those custodians; and (iv) oversee those foreign custody arrangements. The third party selection of country and/or foreign custodian and any contract with the third party with that foreign custodian must be approved by the directors before the foreign custody arrangement can be implemented. Further, the performance of the foreign custodian is subject to the directors' review and approval at least once a year.

Eleven commentators urged that the proposed rule be revised to permit the directors to delegate to a qualified third party the responsibility of selecting foreign custodians, negotiating contracts with those custodians and overseeing their performance. One commentator believed that the rule should also permit the directors to delegate the selection of the foreign country where the company's assets will be located.

Several commentators pointed out that most investment companies employ U.S. intermediaries because the companies do not have the bargaining power or the resources to deal with foreign custodians directly. According to these commentators, because intermediaries have established relationships with various foreign custodians, they are more experienced than investment company directors in negotiating custody agreements that provide cost savings and adequate safeguards for the company's assets. In contrast, two commentators believed that investment company directors should retain ultimate responsibility for approving each of the company's foreign custody arrangements.

The Commission does not intend in the final rule (nor did it intend in the revised proposal) to prevent investment companies from using an intermediary to establish and supervise foreign custody arrangements because there may be instances where the intermediary has greater expertise than the directors in dealing with a particular foreign banking institution, trust company, securities depository or clearing agency. Where an intermediary has established a relationship with a foreign custodian, the intermediary may be in a better position to evaluate the risks associated with foreign custody arrangements with that custodian. In addition, as noted by the commentators, investment companies that use an intermediary may experience cost savings from operating efficiencies that the intermediary is able to effect. However, the Commission believes that the company's assets should be moved to a new location only after the directors have had an opportunity to approve that foreign custody arrangement. Further, the Commission believes that the directors should retain primary responsibility for periodically evaluating those arrangements.

C. Conditions to the Exemption

The final rule includes in its text certain conditions to the exemption which appeared as instructions in the revised proposal. In particular, the rule requires the custody agreement to provide that: (i) the company will be adequately indemnified and its assets adequately insured in the event of loss; (ii) the company's assets will not be subject to any right, charge, security interest, lien or claim of any kind in favor of the foreign custodian or its creditors except a claim for payment for their safe custody or administration; (iii) beneficial ownership for the company's assets will be freely transferable without the payment of money or value other than for safe custody or administration; (iv)
adequate records will be maintained identifying the assets as belonging to the company;[18] the company's independent public accountants will either be given access to those records or confirmation of the contents of those records;[17] and (vi) the company will receive periodic reports with respect to the safekeeping of its assets, including but not necessarily limited to, notification of any transfer to or from the company's account.[18] In addition, the final rule contains as a condition, instead of an instruction, a requirement that the company's cash and cash equivalents be maintained with eligible foreign custodians only in amounts reasonably necessary to effect the company's foreign securities transactions.[19] The Commission believes that these conditions are so critical to the adequate safekeeping of investment company securities that they belong in the text of the rule as formal conditions to exemption. With the exception of the condition relating to cash and cash equivalents, all of these conditions are conditions to the exemptive relief granted Chase and BONY customers on November 4, 1983.[20] In addition, the capability to provide efficiently physical segregation of assets, because of the increased risks involved, mandate a high degree of scrutiny.

List of Subjects in 17 CFR Part 270
Accountants, Accounting, Fraud, Investment companies, Securities, Surety bonds.

II. Text of Final Rule and Rule Amendments

PART 270—AMENDED

Section 270.17f-4

§ 270.17f-4 Deposits of securities in securities depositories.

(a) A registered management investment company (investment company) or any qualified custodian may deposit all or any part of the securities owned by the investment company in a foreign securities depository or clearing agency in accordance with rule 17f-5 (17 CFR 270.17f-5) or in a (1) clearing agency registered with the Commission under section 17A of the Securities Exchange Act of 1934 (clearing agency), which acts as a securities depository, or (2) the book-entry system as provided in Subpart O of Treasury Circular No. 300, 31 CFR 236, Subpart B of 31 CFR Part 350, and the book-entry regulations of federal agencies substantially in the same form as Subpart O, in accordance with the following paragraphs of this rule.

(b) A registered management investment company (investment company) or any qualified custodian may deposit all or any part of the securities owned by the investment company in a foreign securities depository or clearing agency in accordance with rule 17f-5 (17 CFR 270.17f-5) or in a (1) clearing agency registered with the Commission under section 17A of the Securities Exchange Act of 1934 (clearing agency), which acts as a securities depository, or (2) the book-entry system as provided in Subpart O of Treasury Circular No. 300, 31 CFR 236, Subpart B of 31 CFR Part 350, and the book-entry regulations of federal agencies substantially in the same form as Subpart O, in accordance with the following paragraphs of this rule.

3. By adding § 270.17f-5 to read as follows:

§ 270.17f-5 Custody of investment company assets outside the United States. (a) Any management investment company registered under the Act, and incorporated or organized under the laws of the United States or of a state, may place and maintain in the care of an eligible foreign custodian the company's foreign securities, cash and cash equivalents in amounts reasonably necessary to effect the company's foreign securities transactions, Provided That:

(i) A majority of the board of directors of the company shall have:

(ii) Determined that maintaining the company's assets in a particular country or countries is consistent with the best interests of the company and its shareholders;

(iii) Approved, as consistent with the best interests of the company and its shareholders, a written contract which will govern the manner in which such custodian will maintain the company's assets and which provides that:

(A) The company will be adequately indemnified and its assets adequately insured in the event of loss;

15 See Chase application, as amended, at p. 3.

16 See supra note 13-19.

17 See Chase application, as amended, at p. 13.
The company's assets will not be subjected to any right, charge, security interest, lien or claim of any kind in favor of the foreign custodian or its creditors except a claim of payment for their safe custody or administration; and any benefit conferred on the company's assets will be freely transferable without the payment of money or value other than for safe custody or administration;

(2) The company should establish a system to monitor such foreign custody arrangements to ensure compliance with the conditions of this rule;

(3) A majority of the board of directors, at least annually, reviews and approves the continuance of such arrangements as consistent with the best interests of the company and its shareholders.

(b) Any management investment company, incorporated or organized under the laws of Canada and registered under the Act pursuant to the conditions of rule 7d-1, may place and maintain the company's foreign securities, cash and cash equivalents in the care of an overseas branch of a qualified U.S. bank. Provided That:

(1) Prior to the placing of any such assets with such overseas branch, a majority of the board of directors of the company shall have determined that maintaining such assets in a particular country or countries is consistent with the best interests of the company and its shareholders;

(2) The board of directors establishes a system to monitor such foreign custody arrangements and to ensure that the amount of cash and cash equivalents maintained in the care of such overseas branch is limited to an amount reasonably necessary to effect the company's foreign securities transactions; and

(3) A majority of the board of directors, at least annually, reviews and approves the continuation of such arrangements as consistent with the best interests of the company and its shareholders.

(c) As used herein, "Foreign Securities" include: securities issued and sold primarily outside the United States by a foreign government, a national of any foreign country or a corporation or other organization incorporated or organized under the laws of any foreign country and securities issued or guaranteed by the Government of the United States or by any state or any political subdivision thereof or by any agency thereof or by any entity organized under the laws of the United States or of any state thereof which have been issued and sold primarily outside the United States.

(2) "Eligible Foreign Custodian" means:

(i) A banking institution or trust company, incorporated or organized under the laws of a country other than the United States, that is regulated as such by that country's government or an agency thereof and that has shareholders' equity in excess of $200,000,000 (U.S. $) or the equivalent of U.S. $);

(ii) A majority-owned direct or indirect subsidiary of a qualified U.S. bank or bank-holding company that is incorporated or organized under the laws of a country other than the United States and that has shareholders' equity in excess of $100,000,000; or

(iii) A securities depository or clearing agency, incorporated or organized under the laws of a country other than the United States, which operates the central system for handling of securities or equivalent book-entries in that country;

(iv) A securities depository or clearing agency, incorporated or organized under the laws of a country other than the United States which operates a transnational system for the central handling of securities or equivalent book-entries.

(3) "Qualified U.S. Bank" means (i) a banking institution organized under the laws of the United States, (ii) a member bank of the Federal Reserve System, (iii) any other banking institution or trust company organized under the laws of any state or of the United States, whether incorporated or not, doing business under the laws of any state or of the United States, a substantial portion of the business of which consists of receiving deposits or exercising fiduciary powers similar to those permitted to national banks under the authority of the Comptroller of the Currency and which is supervised and examined by State or Federal authority having supervision over banks, and which is not operated for the purpose of evading the provisions of this rule, or (iv) a receiver, conservator, or other liquidating agent of any institution or firm included in clauses (i), (ii), or (iii) of this paragraph. Any entity described in clause (i), (ii), (iii) or (iv) must have an aggregate capital, surplus, and undivided profits of a specified minimum amount, which shall not be less than $500,000.

Notes.—The provisions of rule 17f-5 set forth determinations which the directors of the registered investment management company must make in connection with approving foreign custody arrangements. Those determinations should be made only after consideration of all matters which the directors, in carrying out their fiduciary duties, find relevant, including but not necessarily limited to, consideration of the following:

1. With respect to the selection of the country where the company's assets will be maintained, the directors of U.S. and Canadian investment companies should consider:

   a. Whether applicable foreign law would restrict the access afforded the company's independent public accountants to books and records kept by an eligible foreign custodian located in that country;

   b. Whether applicable foreign law would restrict the company's ability to recover its assets in the event of the bankruptcy of an eligible foreign custodian located in that country;

   c. Whether applicable foreign law would restrict the company's ability to recover assets that are lost while under the control of an eligible foreign custodian located in the country;

   d. The likelihood of expropriation, nationalization, freezes, or confiscation of the company's assets; and

   e. Whether difficulties in converting the company's cash and cash equivalents to U.S. dollars are reasonably foreseeable;

2. With respect to the selection of a foreign custodian, the directors of a U.S. investment company should consider:

   a. The financial strength of the foreign custodian, its general reputation and standing in the country in which it is located, its ability to provide efficiently the custodial services required and the relative cost for those services;

   b. Whether the foreign custodian would provide a level of safeguards for maintaining the company's assets not materially different from that provided by the company's U.S. custodian in maintaining the company's securities in the United States;

   c. Whether the foreign custodian has branch offices in the United States in order to facilitate the assertion of jurisdiction over and enforcement of judgments against such custodian; and

   d. In the case of a foreign securities depository, the number of participants in, and operating history of, the depository.

3. The extent of a U.S. or Canadian company's exposure to loss and the potential effect thereof upon shareholders should be
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 177
[Docket No. 83F-0068]

Indirect Food Additives; Polymers; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the document that provided for the safe use of certain ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer formulations in contact with foods and beverages containing up to 50 percent alcohol (49 FR 29576; July 23, 1984). That document failed to reflect an amendment published in the Federal Register of June 22, 1984 (49 FR 25628). This document corrects that error.


SUPPLEMENTARY INFORMATION: In FR Doc. 84-21078 appearing on page 31996 of the August 9, 1984, issue of the Federal Register as set forth below:

On page 32008, in the right column, amendment number "1," is corrected to read as follows:

1. Section 220.106 is amended by revising paragraph (c) and by adding a new paragraph (d) as set forth below:

§ 220.106 Exit facilities; egress windows. *

(c) Locks, latches, operating handles, tabs, and any other window screen or storm window devices which need to be operated in order to permit exiting, shall not be located in excess of 54 inches from the finished floor.

(d) Integral rolled-in screens shall not be permitted in an egress window unless the window is of the hinged-type.


DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
Office of the Assistant Secretary for Housing—Federal Housing Commissioner
24 CFR Part 3260

MANUFACTURED HOME CONSTRUCTION AND SAFETY STANDARDS; CORRECTION

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

ACTION: Correction to a final rule.

SUMMARY: On August 9, 1984, the Department published a final rule revising its Manufactured Home Construction and Safety Standards. The final rule is scheduled to be effective on February 11, 1985 (See Notice announcing corrected effective date published on August 17, 1984, 49 FR 32647.) The first amendment in the August 9, 1984 rule contained an error, which today's document corrects.

FOR FURTHER INFORMATION CONTACT: Richard A. Mendlen, Manufactured Home Construction and Safety Standards Division, Office of Manufactured Housing and Regulatory Functions, Room 9154, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410. Telephone (202) 755-5798. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Accordingly, this document corrects FR Doc Doc. 84-21078 appearing on page 31996 of the August 9, 1984, issue of the Federal Register as set forth below:

On page 32008, in the right column, amendment number "1," is corrected to read as follows:

1. Section 3200.106 is amended by revising paragraph (c) and by adding a new paragraph (d) as set forth below:

§ 3200.106 Exit facilities; egress windows. *

(c) Locks, latches, operating handles, tabs, and any other window screen or storm window devices which need to be operated in order to permit exiting, shall not be located in excess of 54 inches from the finished floor.

(d) Integral rolled-in screens shall not be permitted in an egress window unless the window is of the hinged-type.

DEPARTMENT OF DEFENSE
Office of the Secretary
32 CFR Part 199
[DoD 6010.8-R, Amdt. No. 28]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Treatment of Mental Disorders

AGENCY: Office of the Secretary, DoD.

ACTION: Amendment of final rule.

SUMMARY: This amends portions of the CHAMPUS DoD 6010.8-R that describe the benefits available under the Civilian Health and Medical Program of the Uniformed Services for the treatment of mental disorders. This amendment is necessary to implement certain policy decisions of the Secretary of Defense intended to bring the CHAMPUS benefits into line with the current practices of professionals who treat mental disorders and to strengthen our ability to monitor and control the cost and quality of services in this significant benefit area.

DATE: The provisions of this amendment are effective November 13, 1984. Any Residential Treatment Center or Alcoholism Treatment Facility which has not entered into a participation agreement with the Director, OCHAMPUS, as set forth in this amendment, by June 1, 1985, will no longer be considered a CHAMPUS-authorized provider and no benefits will be paid for any service rendered by such facility.

ADDRESS: Office of the Civilian Health and Medical Program of the Uniformed Services, (OCHAMPUS), Policy Branch, Aurora, CO 80045.

FOR FURTHER INFORMATION CONTACT: Rose M. Sabo, Policy Branch, OCHAMPUS, telephone (303) 361-4014.


The treatment of mental disorders is a significant benefit under the CHAMPUS because the Uniformed Services medical treatment facilities have limited capacity to provide such services. Military dependents and retirees who might have access to the Uniformed Service medical treatment facilities for much of their medical care must often rely on civilian providers when in need of treatment for psychological and emotional disorders. Therefore, while CHAMPUS pays for only a portion of the total medical services received by our 6.5 million beneficiaries, it pays for most of the mental health services our beneficiaries receive. This heavy reliance on CHAMPUS coverage means that about 16% of the total CHAMPUS benefit payments are for mental health services.

The CHAMPUS benefit for treatment of mental disorders is also unique in that there are few limitations. Most third party benefit programs and health insurance programs establish absolute limits on the number of inpatient days or outpatient visits they will cover for the treatment of mental disorders or set a maximum dollar limit on coverage of the treatment of mental disorders. In general, CHAMPUS will cover services for the treatment of mental disorders so long as the care is medically or psychologically necessary. Even a recent funding limitation which limits coverage of inpatient mental health services to 60 days in a calendar year for a beneficiary permits coverage of services in excess of 60 days in extraordinary circumstances are present. This issue will be addressed in a separate amendment.

This lack of limitations on CHAMPUS coverage of the treatment of mental disorders means that we must be unusually concerned with assuring that the services we cover are medically or psychologically necessary and are of high quality.

Since the publication of the CHAMPUS Regulation in 1977, we have identified a number of issues related to the program's benefits for the treatment of mental disorders that should be clarified or amended. These modifications are necessary for a number of reasons: changes in professional practices, identification of areas of the benefit that require closer monitoring, and areas in which current requirements are unnecessarily burdensome.

Accordingly, on September 15, 1982, in FR Doc. 82-23252 (42 FR 48064), we published a notice of proposed rulemaking for public comment. Comments were received from 44 individuals and organizations.

The notice proposed to amend the Regulation in the following general areas: the basic benefits for inpatient and outpatient treatment of mental disorders by both professional and institutional providers, benefits and provider authorization standards for residential treatment centers, benefits and provider authorization standards for the treatment of alcoholism, standards for CHAMPUS authorization of professional providers, and miscellaneous technical and clarifying amendments.

Following is a discussion of the comments we received and the action we are taking in response.

Basic Benefits for Treatment of Mental Disorders

1. Definition of Mental Disorder. Many of the comments objected to the proposed definition of mental disorder. Those commenting stated that the definition was unduly restrictive, would prevent coverage of needed services, and was a distortion of the definition of mental disorder generally in use by the profession.

The Regulation currently defines a (Nervous and) Mental Disorder as a condition listed in the Diagnostic and Statistical Manual of Mental Disorders, 2nd edition (DSM-II). We proposed to amend this definition, first, because the third edition of the manual, DSM-III, is now in wide use, and, second, because this limited definition does not adequately describe the condition that CHAMPUS provides coverage for.

Consequently, we proposed to change this definition to read as follows: "Mental Disorder means a nervous or mental condition which involves a clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and is associated with a painful symptom [distress] and an impairment in functioning in one or more age-appropriate life activities."

We stated in the notice that this definition was similar to the definition of mental disorder in DSM-III. The significant difference is that our proposed definition requires distress and functional impairment whereas the DSM-III definition discusses distress or impairment.

It is long-standing program policy that, in order for benefits to be paid for the treatment of mental disorders, the patient's condition must be serious enough to interfere with his or her ability to carry out usual activities. This definition does not add that...
requirement, but simply incorporates it into the Regulation. CHAMPUS cannot cover any services designed simply to improve the patient’s general level of health or well-being. We cover only those services which are medically or psychologically necessary to diagnose or treat an illness or injury. It is the program’s position that, while a person may exhibit signs or symptoms which meet the diagnostic criteria of DSM-III, treatment becomes medically or psychologically necessary, for purposes of CHAMPUS coverage, when the mental disorder is of a degree which interferes with the patient’s ability to carry out usual activities, such as work or school.

We believe that early intervention is as important in the treatment of mental disorders as it is in the treatment of other conditions. We would point out that the definition does not require that a patient be unable to carry out usual activities. It requires rather that the patient’s ability to function be impaired.

Because of the concern of the commenters, however, we are clarifying that the definition of mental disorder only defines a level of disorder which qualifies for benefit payment.

2. Treatment of Mental Disorders by Other Than Physicians. Several comments wanted the Regulation to state that all services must be performed by physicians or under a physician’s supervision. Other comments objected to the requirement that the services of clinical social workers and marriage and family counselors be performed under physician supervision.

Still others requested that we recognize as authorized providers types of providers not now listed in the regulation, such as certified psychoanalysts and certified mental health counselors.

CHAMPUS rules regarding who may be considered an independent professional provider, with no requirement for physician supervision, derive from language contained in the annual Defense Appropriation Act. To the extent that the Appropriation Act restrictions permit us to consider a provider to be independent of physician supervision, we are taking the general position in the notice that we will provide payment for services provided to eligible beneficiaries if: 1. The service is a benefit of CHAMPUS and meets all requirements for coverage. 2. the provider of the care is a CHAMPUS-authorized provider in accordance with § 199.12 of Part 199, and 3. the provider’s state license permits the rendering of the specific service.

All instructions we issue to claims processors and professional reviewers to implement this amendment will emphasize that medical services must be rendered by or under a physician’s supervision and that lack of physician involvement, when such is demanded by the circumstances of the case, is a basis for denial of payment on quality grounds.

In some cases, however, where we do specify a particular provider, we do so because we feel that important issues of quality care require it. It should also be noted, while CHAMPUS might not require that a provider be supervised by or work in collaboration with a physician, the provider’s state license may. In that case, we would cover only those services rendered in accordance with the provisions of that state licensure.

In the proposed rule, clinical social workers were listed as providers for whom physician supervision was required. At the time the notice was published, CHAMPUS was conducting a test of coverage of the services of clinical social workers independent of physician supervision, at the direction of Congress. Since that time and in accordance with congressional direction, we have concluded the test and authorized CHAMPUS coverage of clinical social workers as independent providers. All issues relating to standards for CHAMPUS authorization of clinical social workers were removed from this amendment and addressed in a separate rulemaking document. These comments we received in response to the notice on the subject proposal that specifically addressed clinical social workers were considered in the social workers’ amendment.

In response to a comment, we have changed a provider designation from “Certified Psychiatric Nurse Practitioner” to “Certified Psychiatric Nurse Specialist.”

We do not plan to add any categories of authorized professional providers of mental health services at this time. We believe that CHAMPUS beneficiaries have a reasonably broad choice of providers from among the generally recognized professions that treat mental disorders.

3. Limits and review requirements—Psychotherapy. In the proposed rule, § 199.10(c)(3)(ix) sets forth certain limits and review requirements for payment of inpatient and outpatient psychotherapy. Several comments requested that we liberalize the limitations. We have not accepted this suggestion; the proposal generally represents more liberal limits than are currently in effect. One comment, however, did recommend that we provide a special exception to the maximum therapy-per-day limit in special circumstances. We think this suggestion has merit and can be accommodated within the proposed language. The proposed language deleted the reference in the Regulation that limited psychotherapy to one session in a 24-hour period. Instructions to claims processors and professional reviewers will specifically authorize more than one psychotherapy session on the same day under special circumstances, where medical or psychological necessity exists. We continue to believe that, in general, more than one psychotherapy session on the same day is not the standard of care, but we also understand that certain circumstances might make more than one session appropriate.

We will continue to review carefully any case where more than one psychotherapy sessions are provided on the same day and will expect that the attending provider will document fully the medical or psychological necessity for them.

One comment asked that we change the reference to professional review of claims to peer review. We have not accepted this recommendation. The CHAMPUS system for conducting reviews of the quality and appropriateness of care is a combination of review by peers and review by other professionals. We feel the term “professional review” more clearly describes this combined system. Further, as mentioned previously, the CHAMPUS focus is on the service rendered, not necessarily on the discipline of the provider rendering that service. We are in the process of developing standards and criteria for review of claims for treatment of mental disorders by various mental health specialties recognized as authorized CHAMPUS providers.

4. Coverage of specific mental health services. A group of comments requested that the Regulation list the specific approaches to treatment of mental disorders which CHAMPUS covers and set out the specific requirements for coverage of electroshock therapy. We have not accepted this suggestion; this level of detail is covered in the implementing instructions issued to claims processors and professional reviewers.

Treatment of Alcoholism

1. Aversion Therapy. The current regulation is silent on coverage of aversion therapy, defined as the programmed use of physical measures, such as electric shock, alcohol, or other drugs, as negative reinforcement to prevent a conditioned aversion to beverage alcohol. Because professional opinion we have received on the issue of
Aversion therapy has been mixed, we concluded that aversion therapy was not widely accepted by the general medical community as effective for the treatment of substance abuse. Because the CHAMPUS Regulation specifically prohibits coverage of services which are investigational or not generally accepted by the medical community as effective, we proposed to exclude aversion therapy as a covered service in the treatment of alcoholism. We received several comments in opposition to this exclusion. It is clear that support for the efficacy of aversion therapy has grown; however, our very real concern over the safety of aversion therapy has led us to retain the exclusion of this service in the final amendment.

Nevertheless, we do believe that this is an appropriate area for further development. We will be asking interested professionals in the field to meet with us to determine whether it is possible to establish standards and criteria for the review of claims for aversion therapy. We will be particularly interested in determining whether we can develop standards for providers of aversion therapy to assure responsible patient selection and medical screening and to assure that adequate safeguards, including informed consent, exist for the patient undergoing aversion therapy. If such standards can be developed and a mechanism can be created for assuring that providers meet the standards, an amendment of the Regulation to authorize coverage for aversion therapy would be considered.

2. Treatment of other substance abuse

A comment suggested that we amend the alcohol benefits to apply also to the treatment of other substance abuse. While we agree that specific information concerning benefits for treatment of other substance abuse is required in the Regulation, we do not necessarily agree that the benefits and provider standards prescribed for treatment of alcoholism are appropriate for other substance abuse. We are in the process of developing guidelines for this area; they will be issued separately.

3. Three-episode lifetime limit

Several comments objected to the lifetime limit on benefits for the treatment of alcoholism. They point out that alcoholism is a chronic disease, characterized by relapses, and that by limiting the number of treatment episodes, patients may be denied treatment that would be effective in overcoming the disease. We do not plan to change this provision. We believe that offering coverage for multiple episodes does recognize the nature of the disease.

4. Alcohol Rehabilitation—21-day limit

As with the lifetime limit on coverage, several comments objected to the 21-day limit on alcohol rehabilitation services. Their objections centered on the argument that many alcohol programs are designed as 21- to 30-day programs. Our limit means that patients must often bear a portion of the cost of the program themselves. We do not plan to change this limit at this time. The 21-day limit on residential alcohol rehabilitation has been a CHAMPUS policy since 1977. We have seen no research that indicates that longer programs result in improved outcomes, although we understand that such research is being conducted. If the research should show a relationship between length of program and outcome, we would consider reopening the issue.

5. Coverage of other providers

One comment requested that we consider expanding the list of facilities we authorize to include recovery homes and halfway houses. While we recognize the importance of these facilities to the recovering alcoholic, their primary focus is domiciliary care rather than treatment. Statutorily, CHAMPUS is prohibited from covering domiciliary services.

6. Coverage of Antabuse (disulfiram)

Several comments asked that we clarify whether the exclusion of aversion therapy meant that administration of Antabuse (disulfiram) is also excluded. It does not. We do not consider the administration of disulfiram to be aversion therapy since the intent is not to establish a conditioned reflex. Disulfiram is covered under CHAMPUS as a prescription drug.

7. Detoxification services

We have added language to the amendment to clarify what is included in the comments. Detoxification services are covered, whether provided in a hospital or in an alcohol rehabilitation facility qualified to provide it. If the patient's medical condition is serious and requires the staff and facilities of an acute, general hospital, detoxification is payable (for up to seven days) on the same basis as any other covered hospital admission. If the patient is able to be detoxified in an authorized alcohol rehabilitation facility, under medical supervision, coverage of the detoxification services is in addition to the coverage of rehabilitation services. The medical necessity for and the length of detoxification must be documented.

Authorized Providers

1. Requirement for accreditation by the Joint Commission on Accreditation of Hospitals. Several comments took issue with the requirement that facilities be accredited by the Joint Commission on Accreditation of Hospitals (JCAH) in order to be authorized providers under CHAMPUS. We have amended each occurrence of this requirement to provide that a facility must be accredited by JCAH or must be certified under Title XVIII of the Social Security Act (Medicare).

It has been long-standing policy that providers seeking authorization by CHAMPUS must meet standards established by their respective professional organizations and national accrediting bodies, where such exist. CHAMPUS is unable to conduct a program such as Medicare's to survey and certify each facility seeking authorization. It is our practice to review the standards set by the various professional organizations or national accrediting bodies and to require either eligibility for membership in the professional organization or accreditation by the body establishing acceptable standards. For a national program such as CHAMPUS, state licensure can only be one component of the provider certification effort, since each state's licensure requirements may differ.

We have modified the amendment to clarify that certification by Medicare is acceptable for CHAMPUS purposes, to the extent that Medicare certifies the same types of facilities that CHAMPUS recognizes. For other types of facilities, we specify the standards, if any, which we have reviewed and found to be acceptable.

2. Access to records

Several comments expressed concern that the standards for various facilities require the facilities to agree to make clinical records of CHAMPUS patients available to the Director, OCHAMPUS. While we certainly understand the concern over confidentiality of the patient's records, we would point out that patients authorize the release of records to OCHAMPUS as part of the procedure for claiming benefit payment. Further, by law, we may pay only for services which are medically or psychologically necessary to diagnose or treat illness or injury. Making such a determination often requires us to review clinical records.

Because we are cognizant of the sensitive nature of the records created in a case involving the treatment of a mental disorder, we make special efforts to ensure the security of any records we request.

Residential Treatment Centers

Therapeutic absences. One comment stated an objection to the proposed
revised to read as follows:

Visits,” “Hospitals: Psychiatric,”

SERVICES

CIVILIAN HEALTH AND MEDICAL
Care paragraph (i),” “Basic Program,”

“Medical,” and “Preauthorization” are

Clinical Psychologist,” “Collateral

Definitions of “Appropriate Medical

Program of the Uniformed

amended reading as follows:

insurance, and Military personnel.

covered service.

occupational therapy as a CHAMPUS

inadvertently omitted mention of

removal of a general exclusion

CHAMPUS authorized hospitals. The

Section 199.10, to specifically cover

simply contain a cross-reference to this

of basic benefits and other sections will

Technical Changes

We also received several editorial

suggestions, to improve clarity or

consistency. Those have been adopted.

Also, because this amendment

significantly revised certain

preauthorization requirements, we are

taking this opportunity to make
technical revisions in the location of

information regarding preauthorization

requirements in general. Section 199.10,

paragraph (a)(11) will contain the
general instructions on preauthorization

of basic benefits and other sections will

simply contain a cross-reference to this

paragraph.

We have also reorganized the notice

so that each change is sequential, rather

than grouped by subject, as was done in

the Notice of Proposed Rulemaking.

Finally, we have added a paragraph to

Section 199.10, to specifically cover

occupational therapy services when

provided to inpatients or outpatients of

CHAMPUS authorized hospitals. The

removal of a general exclusion

inadvertently omitted mention of

occupational therapy as a CHAMPUS

covered service.

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health

insurance, and Military personnel.

Accordingly, 32 CFR, Chapter I is

amended reading as follows:

PART 199—IMPLEMENTATION OF THE

CIVILIAN HEALTH AND MEDICAL

PROGRAM OF THE UNIFORMED

SERVICES

1. In § 199.8, paragraph (b) the

definitions of “Appropriate Medical

Care paragraph (f),” “Basic Program,”

“Clinical Psychologist,” “Collateral

Visits,” “Hospitals: Psychiatric,”

“Medical,” and “Preauthorization” are

revised to read as follows:

§ 199.8  Definitions.

(b)  * * *

Appropriate Medical Care.  * * *

(i) Services performed in connection

with the diagnosis or treatment of
disease or injury, pregnancy, mental
disorder, or well-baby care which are in
keeping with the generally accepted

norms for medical practice in the United

States.

Basic Program.  The primary medical

benefits authorized under Chapter 55 of
title 10, United States Code, and set
forth in § 199.10.

Clinical Psychologist.  A psychologist,
certified or licensed at the independent

practice level in his or her state, who

meets the criteria in § 199.12(c)(3)(iii)(c).

Collateral Visits.  Sessions with the

patient’s family or significant others for

purposes of information gathering or

implementing treatment goals.

Hospitals: Psychiatric.  An institution

that meets the criteria in § 199.12(b)(4)(ii).

Medical.  The generally used term

which pertains to the diagnosis and

treatment of illness, injury, pregnancy,

and mental disorders by trained and

licensed or certified health

professionals. For purposes of

CHAMPUS, the term “medical” should

be understood to include “medical,

psychological, surgical, and obstetrical”

unless it is specifically stated that a

more restrictive meaning is intended.

Preauthorization.  A decision issued in

writing by the Director, OCHAMPUS, or

a designee, that CHAMPUS benefits are

payable for certain services that a

beneficiary has not yet received.

2. In § 199.8, paragraph (b) by

removing the definitions of “DSM-III,”

“Medically Necessary,” “Nervous and

Mental Disorder,” “Psychiatric

Services,” “Residential Treatment

Centers for Emotionally Disturbed

Children (RTC’s),” and “RTC” by

adding, in alphabetical order, definitions

for “Certified Psychiatric Nurse

Specialists,” “Medically or

Psychologically Necessary,” “Mental

Disorder,” and “Residential Treatment

Center (RTC),” to read as follows:

Certified Psychiatric Nurse Specialist.

A licensed, registered nurse who meets
the criteria in § 199.12(c)(3)(iii)(g).

Medically or Psychologically

Necessary.  The frequency, extent, and
types of medical services or supplies

which represent appropriate medical
care and that are generally accepted by

qualified professionals to be reasonable

and adequate for the diagnosis and

treatment of illness, injury, pregnancy,

and mental disorders or that are

reasonable and adequate for well-baby

care.

Mental Disorder.  For purposes of the

payment of CHAMPUS benefits, a

mental disorder is a nervous or mental

condition that involves a clinically

significant behavioral or psychological

syndrome or pattern that is associated

with a painful symptom, such as
distress, and that impairs a patient’s

ability to function in one or more major

life activities. Additionally, the mental

disorder must be one of those conditions

listed in the DSM-III.

Residential Treatment Center (RTC)

A facility (or distinct part of a facility)

which meets the criteria in § 199.12(b)(4)(v).

3. In § 199.10, by redesignating

paragraph (a)(11) as (a)(12) and adding

new paragraph (a)(11), by removing

paragraphs (b)(1)(ii), (b)(1)(iii), (b)(1)(iv),

and (b)(1)(v), by redesignating

paragraph (b)(1)(vi) as (b)(1)(vii), by

removing paragraph (b)(1)(vii) as (b)(1)(vi), by

redesignating paragraph (b)(1)(vii) as

(b)(1)(vi), by redesignating paragraph (b)(1)(vii)

as (b)(1)(vi), by redesignating paragraph (b)(1)(viii)

as (b)(1)(vii); by revising paragraphs

(b)(4)(v), (b)(4)(vii), (c)(2)(v),

(c)(3)(vi), (c)(3)(ix), (c)(3)(x), (e)(4),

(e)(8)(iv), (e)(10)(iii), (g)(1), (g)(6), (g)(19),

(g)(22), (g)(41), and (g)(44); by removing the

language in paragraphs (g)(32),

(g)(48), and (g)(49) and reserving the

number designations to read as follows:

§ 199.10  Basic program benefits.

(a)  General.  * * *

(11)  Preauthorization.  Because

CHAMPUS benefits are limited for
certain types of care, the beneficiary is
required to obtain preauthorization from
the Director, OCHAMPUS, or a
designee, before the services are
provided. The types of care for which
preauthorization is required are
identified in other parts of this section.
Examples are adjunctive dental care
and plastic, cosmetic and reconstructive
surgery.

(i)  Purpose of preauthorization.

Preauthorization is required for those
types of services for which coverage is
limited or for which the conditions for
coverage are highly technical. In such
cases, the likelihood that CHAMPUS
benefits will not be available is high. To minimize the risk that beneficiaries will incur costs that CHAMPUS cannot cover, the beneficiary is expected to request preauthorization of the care before the services are received. If a beneficiary fails to obtain preauthorization before receiving the services, the Director, OCHAMPUS, or a designee, may extend CHAMPUS benefits if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization.

(ii) Admissions to authorized institutions requiring preauthorization. When the Director, OCHAMPUS, requires preauthorization to an inpatient facility, the request for preauthorization is processed by OCHAMPUS. If the beneficiary elects to proceed with an admission prior to receiving written preauthorization from OCHAMPUS, authorization may be requested subsequently. If the stay in the institution is determined to be appropriate under the provisions of this Regulation, the Director, OCHAMPUS, or a designee, shall authorize benefits retroactively to the date of admission to the institution. If the stay is determined not to qualify under the provisions of this Part, the Director, or a designee, shall deny benefits as of the date the care failed to meet the requirements for coverage.

10 Initial preauthorization: Limited to 90 days. The Director, OCHAMPUS, or a designee, shall limit the initial preauthorization to 90 days of inpatient care. At the end of this initial 90 days, the Director, OCHAMPUS, or a designee, shall review the care to determine whether it continues to be appropriate and to meet all requirements for coverage. The Director, OCHAMPUS, or designee, shall repeat this review every 30 days thereafter, or at such other time period as may be specified by the Director, OCHAMPUS, or a designee.

(b) Approved treatment plan. A request for preauthorization described in paragraph (a)(11) of this section, requires submission of a detailed treatment plan, in accordance with guidelines and procedures issued by the Director, OCHAMPUS.

(iii) Other preauthorization requirements: (a) The Director, OCHAMPUS, or a designee, shall respond to all requests for preauthorization in writing and shall send notification of approval or denial to the beneficiary.

(b) The Director, OCHAMPUS, or a designee, shall specify, in the approved preauthorization, the services and supplies the approval covers.

(c) An approved preauthorization is valid only for 90 days from the date of issuance. If the preauthorized services and supplies are not obtained or commenced within the 90-day period, a new preauthorization request is required.

(d) A preauthorization may set forth other special limits or requirements as indicated by the particular case or situation for which preauthorization is being issued.

(b) **(4)**

(v) Treatment of mental disorders. Services and supplies that are medically or psychologically necessary to diagnose and treat the mental disorder for which the patient was admitted to the RTC. Covered services and requirements for qualifications of providers are as listed in paragraph (c)(3)(ix) of this section.

(vi) Other necessary medical care. Emergency medical services or other authorized medical care may be rendered by the RTC provided it is professionally capable of rendering such services and meets standards required by the Director, OCHAMPUS. It is intended, however, that CHAMPUS payments to an RTC should primarily cover those services and supplies directly related to the treatment of mental disorders that require residential care.

(c) **(2)**

(v) **(4)**

(vi) **(3)**

(vi) Inpatient care: Concurrent. Concurrent inpatient care by more than one individual professional provider is covered if required because of the severity and complexity of the beneficiary’s condition or because the beneficiary has multiple conditions that require treatment by providers of different specialities. Any claim for concurrent care must be reviewed before extending benefits in order to ascertain the condition of the beneficiary at the time the concurrent care was rendered. In the absence of such determination, benefits are payable only for inpatient care rendered by the attending physician.

(ix) **(4)**

(vii) **(3)**

Treatment of mental disorders. CHAMPUS benefits for the treatment of mental disorders are payable for beneficiaries who are outpatients or inpatients of CHAMPUS-authorized general or psychiatric hospitals RTCs, or specialized treatment facilities, as authorized by the Director, OCHAMPUS, or a designee. All such services are subject to review for medical or psychological necessity and for quality of care.

(a) Covered diagnostic and therapeutic services. Subject to the requirements and limitations stated, CHAMPUS benefits are payable for the following professional services when rendered in the diagnosis or treatment of a covered mental disorder by a CHAMPUS-authorized, qualified mental health provider practicing within the scope of his or her license. Qualified mental health providers are: psychiatrists or other physicians; clinical psychologists, certified psychiatric nurse specialists, or clinical social workers; and marriage, family, and pastoral counselors, under a physician’s supervision. No payment will be made for any service listed in this paragraph (c)(3)(ix)(e) that is rendered by an individual who does not meet the criteria of § 195.12 for his or her respective profession, regardless of whether the provider is an independent professional provider or an employee of an authorized professional or institutional provider.

(1) Individual psychotherapy, adult or child. A covered individual psychotherapy session is no more than 60 minutes in length. An individual psychotherapy session of up to 120 minutes in length is payable for crisis intervention.

(2) Group psychotherapy. A covered group psychotherapy session is no more than 90 minutes in length.

(3) Family or conjoint psychotherapy. A covered family or conjoint psychotherapy session is no more than 90 minutes in length. A family or conjoint psychotherapy session of up to 180 minutes in length is payable for crisis intervention.

(4) Psychoanalysis. Psychoanalysis is covered subject to specific review for medical or psychological necessity and appropriateness by the Director, OCHAMPUS, or a designee.

(5) Psychological testing and assessment.

(6) Administration of psychotropic drugs. When prescribed by an authorized provider qualified by licensure to prescribe drugs.

(7) Electroconvulsive treatment. When provided in accordance with guidelines issued by the Director, OCHAMPUS.

(8) Collateral visits. Covered collateral visits are those that are medically or psychologically necessary for the treatment of the patient and, as such, are considered as a psychotherapy treatment.
medical condition. Longer stays provided for alcohol rehabilitation in a hospital-based rehabilitation facility are covered, subject to the provisions of paragraph (e)(4)(ii) of this section. Inpatient hospital services are also subject to the provisions of § 199.10(b)(5)(xi), regarding the limit on inpatient mental health services.

(ii) Authorized alcoholism treatment. Only those services provided in an organized alcoholism treatment program, by an authorized free-standing or hospital-based alcohol rehabilitation facility are covered. Covered services consist of any or all of the services listed below. A qualified mental health provider (physician, clinical psychologists, clinical social workers, psychiatric nurse specialists; see § 199.10(c)(3)(ix)) shall prescribe the particular level of treatment. Each eligible CHAMPUS beneficiary is entitled to three alcoholism treatment benefit periods in his or her lifetime. (A benefit period begins with the first date of covered alcoholism treatment and ends 365 days later, regardless of the total services actually used within the benefit period. Unused benefits cannot be carried over to subsequent benefit periods. Emergency and inpatient hospital services [as described in paragraph (e)(4)(i) of this section] do not constitute alcoholism treatment for purposes of establishing the beginning of a benefit period.)

(a) Rehabilitative care. Rehabilitative care in an authorized alcohol rehabilitation facility, whether free-standing or hospital-based, is covered on either a residential or partial care (day or night program) basis. Coverage is limited to no more than 21 days of rehabilitative care in a benefit period. If the patient is medically in need of alcohol detoxification, but does not require the personnel or facilities of a general hospital setting, up to seven days of detoxification services are covered in addition to the rehabilitative care. The medical necessity for the detoxification must be documented. Any detoxification services provided by the alcohol rehabilitation facility must be under general medical supervision.

(b) Outpatient care. Outpatient treatment provided by an approved alcohol rehabilitation facility, whether free-standing or hospital-based, is covered for up to 60 visits in a benefit period.

(c) Family therapy. Family therapy provided by an approved alcohol rehabilitation facility, whether free-standing or hospital-based, is covered for up to 15 visits in a benefit period.

(iii) Exclusions.
(a) Aversion therapy. The programmed use of physical measures, such as electric shock, alcohol, or other drugs as negative reinforcement (aversion therapy) is not covered, even if recommended by a physician.

(b) Domiciliary settings. Domiciliary facilities, generally referred to as halfway or quarterway houses, are not authorized providers and charges for services provided by these facilities are not covered.

(iv) Confidentiality. Release of any patient identifying information, including that required to adjudicate a claim, must comply with the provisions of section 523 of the Health Service Act (b)(1), as amended, (42 U.S.C. 254d–3), which governs the release of medical and other information from the records of patients undergoing treatment of alcoholism. If the patient refuses to authorize the release of medical records as specifically included in a treatment plan approved by the Director, OCHAMPUS, or a designee, necessary to determine benefits on a claim for treatment of alcoholism, the claim will be denied.

(iv) Preauthorization required. In order for CHAMPUS benefits to be extended for cosmetic, reconstructive and plastic surgical procedures which might qualify under paragraphs (a)(3)(i), and (a)(3)(v) of this section, preauthorization is required from the Director, OCHAMPUS, or a designee. Refer to § 199.10 paragraph (b)(11) for information on preauthorization. Preauthorization is not required for reconstructive breast surgery following mastectomy performed for the treatment of carcinoma, fibrocystic disease, nonmalignant tumors, or traumatic injuries.

(iii) Preauthorization required. In order to be covered, adjunctive dental care requires preauthorization from the Director, OCHAMPUS, or a designee, in accordance with paragraph (a)(11) of this section. When adjunctive dental care involves a medical (not dental) emergency (such as facial injuries resulting from an accident), the requirement for preauthorization is waived. Such waiver, however, is limited to the essential adjunctive dental care related to the medical condition requiring the immediate emergency treatment. A complete explanation, with supporting medical documentation, must be submitted with claims for emergency adjunctive dental care.

(1) Not Medically or psychologically necessary. Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness (including mental disorder) or injury, for the diagnosis and treatment of pregnancy, or for well-baby care.

(6) Therapeutic absences. Therapeutic absences from an inpatient facility, except when such absences are specifically included in a treatment plan approved by the Director, OCHAMPUS, or a designee.

(19) Preauthorization required. Services or supplies which require preauthorization if preauthorization was not obtained. Services and supplies which were not provided according to the terms of the preauthorization. The Director, OCHAMPUS, or a designee, may grant an exception to the requirement for preauthorization if the services otherwise would be payable except for the failure to obtain preauthorization.

(22) Services or supplies ordered by a court or other government agency. Services or supplies, including inpatient stays, directed or agreed to by a court or other governmental agency. However, those services and supplies (including inpatient stays) that otherwise are medically or psychologically necessary for the diagnosis or treatment of a covered condition and that otherwise meet all CHAMPUS requirements for coverage are not excluded.

(41) Counseling. Counseling services that are not medically necessary in the treatment of a diagnosed medical condition, for example, educational counseling, vocational counseling, and counseling for socio-economic purposes. Services provided by a marriage, family, or pastoral counselor in the treatment of a mental disorder are covered only as specifically provided in § 199.12, "Authorized Providers." Services provided by alcoholism rehabilitation counselors are covered only when rendered in a CHAMPUS-authorized alcohol rehabilitation facility and only when the cost of those services is included in the facility’s CHAMPUS-determined allowable cost rate.

(44) Education or training. Academic education or vocational training services and supplies, unless the provisions of § 199.10(b)(1)(v), relating to general or special education, apply. * * *

(48) [Reserved]
(49) [Reserved]

3. In § 199.11, by revising paragraphs (c)(4)(i), (c)(4)(ii), (c)(4)(iii) and (c)(4)(iv) to read as follows:

§ 199.11 Program for the Handicapped.

(c) * * *

(4) Application approval.
   (i) Authority for approval. The Director, OCHAMPUS, is vested with the final authority on all applications for coverage under the Program for the Handicapped. This includes the determination as to the severity of the handicap and the appropriateness of the supplies or services to the handicapping condition for which coverage is requested. The Director, OCHAMPUS, or a designee, shall request such information as is deemed necessary to make these determinations before issuing approvals or denials. Failure to supply such information will result in deferral or denial of the application for coverage.

   (ii) Deferral or denial of application. In those situations where a deferred or denied application for coverage under the Program for the Handicapped is subsequently approved, such subsequent approval may be applied retroactively to the date coverage would have been effective had adequate information been provided.

   (f) Procedures for obtaining benefits. Active duty members seeking benefits under the Program for the Handicapped for a dependent spouse or child must secure authorization from OCHAMPUS for such benefits in advance. Payment will not be made for any services or supplies under the Program for the Handicapped received or obtained prior to approval of the application by the Director, OCHAMPUS, or a designee. If a beneficiary fails to obtain preauthorization before receiving the services, the Director, OCHAMPUS, or a designee, may extend CHAMPUS benefits if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization.

   4. In § 199.12, by revising paragraphs (a)(6), (b)(1)(i), (b)(3)(i), (b)(4)(ii) introductory text, (b)(4)(ii)(d), (b)(4)(v), and (c)(3)(iii)(e); by redesignating paragraph (c)(3)(iii)(g) as (c)(3)(iii)(h); and by adding new paragraphs...
§ 199.12 Authorized providers.

(a) Provider required. In order to be considered for benefits, all services and supplies shall be rendered by, prescribed by, or furnished at the direction of, or on the order of a CHAMPUS-authorized provider or a designee.

(b) * * *

[Image 0x0 to 566x782]
recommend that the child be admitted to the residential treatment center.

(iv) A psychiatrist or a clinical psychologist shall direct the development of the child's treatment plan.

(v) All services shall be provided by or under the supervision of a qualified mental health provider (refer to §199.10(c)(3)(ix)).

(b) * * *

(viii) * * *

(3) Alcohol rehabilitation facilities. In order to be authorized under CHAMPUS as a provider of alcohol detoxification, rehabilitative services, outpatient treatment, and family therapy, alcohol rehabilitation facilities, both free-standing facilities and hospital-based facilities, shall operate primarily for the purpose of providing alcoholism treatment [on either inpatient [including partial care] or an outpatient basis] and shall meet the following criteria:

(i) The course of treatment shall be prescribed by and supervised by a qualified mental health provider (refer to §199.10(c)(3)(ix)) practicing within the scope of his or her license. When indicated by the patient's physical status, the patient shall be under the general supervision of a physician.

(ii) The type and level of care provided by the facility are otherwise authorized by this part.

(iii) The facility shall meet all licensing and other certification requirements of the jurisdiction in which the facility is located.

(iv) The facility shall be accredited by the JCAH or shall meet such other requirements as the Director, OCHAMPUS, finds necessary in the interest of the health and safety of the individuals who are furnished services in the facility.

(v) The facility shall have entered into a participation agreement with OCHAMPUS within which the facility agrees, in part, to:

(A) Accept payment for its services based on an allowable-cost rate acceptable to the Director, OCHAMPUS, or such other method as determined by the Director, OCHAMPUS;

(B) Furnish OCHAMPUS with cost data certified to by an independent accounting firm or other agency as authorized by the Director, OCHAMPUS;

(C) Accept the CHAMPUS-determined rate as payment in full and to collect from the CHAMPUS beneficiary those amounts that represent the beneficiary's liability, as defined in §199.10, and charges for services and supplies that are not a benefit of CHAMPUS;

(D) Make all reasonable efforts acceptable to the Director, OCHAMPUS, to collect those amounts which represent the beneficiary's liability, as defined in §199.10;

(E) Permit access by the Director, OCHAMPUS, to clinical records of CHAMPUS beneficiaries and to the financial and organizational records of the facility;

(F) Comply with the provisions of §199.14, and to submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS.

(vi) The alcoholism rehabilitation facility shall not be considered to be a CHAMPUS-authorized provider and CHAMPUS benefits shall not be paid for services provided by the alcoholism rehabilitation facility until the date the participation agreement is signed by the Director, OCHAMPUS, or a designee. 

Note.—Each alcoholism rehabilitation facility shall enter into a participation agreement as described in §199.12(b)(4)(vi)(b)(3), above, by June 1, 1985. An alcoholism rehabilitation facility that was a CHAMPUS-authorized provider as of September 14, 1984 and that otherwise meets the requirements of this §199.12(b)(4)(vi)(b)(3) (c) through (d) will continue to be authorized until the participation agreement is signed by June 1, 1985, whichever occurs first.

(c) * * *

(3) * * *

(iii) * * *

(a) Clinical psychologist. For purposes of CHAMPUS, a clinical psychologist is an individual who:

(i) Is licensed or certified by the state for the independent practice of psychology;

(ii) Possesses a doctoral degree in psychology from a regionally accredited university; and

(iii) Has had two years of supervised clinical experience in psychological health services of which at least one year is post-doctoral and one year (may be the post-doctoral year) is in an organized psychological health service training program; or

(iv) Is listed in the National Register of Health Service Providers in Psychology, published by the Council for the National Register of Health Service Providers in Psychology.

(g) Certified psychiatric nurse specialist. A certified psychiatric nurse specialist may provide covered care independent of physician referral and supervision. For purposes of CHAMPUS, a certified psychiatric nurse specialist is an individual who:

(i) Is a licensed, registered nurse; and

(ii) Has at least a master's degree in nursing with a specialization in psychiatric and mental health nursing;

and

(iii) Has had at least two years of post-master's degree practice in the field of psychiatric and mental health nursing, including an average of eight hours of direct patient contact per week; or

(iv) Is listed in a CHAMPUS-recognized, professionally sanctioned listing of clinical specialists in psychiatric and mental health nursing.

5. In §199.13, by removing paragraph (f)(2) and redesignating paragraph (e)(3) as (e)(2), and by revising paragraphs (f)(1) and (f)(1)(ii) to read as follows:

§199.13 Claims submission, review, and payment.

(f) * * *

(1) Preauthorization must be granted before benefits can be extended. In those situations requiring preauthorization, the request for such preauthorization shall be submitted and approved before benefits may be extended, except as provided in §199.10 paragraph (a)(11). If a claim for services or supplies is submitted without the required preauthorization, no benefits shall be paid, unless the Director, OCHAMPUS, or a designee, has granted an exception to the requirement for preauthorization.

(ii) Time limit on preauthorization. Approved preauthorizations are valid for specific periods of time, usually 90 days. If the preauthorized services or supplies are not obtained or commenced within the specified time limit, a new preauthorization is required before benefits may be extended.

(10 U.S.C. 1078, 1086; 5 U.S.C. 301)

Dated: September 6, 1984.

Patricia H. Means,

OSD Federal Register Liaison Officer,

Washington Headquarters Services,

Department of Defense.

[PR Doc. 04-2602, Filed 9-13-94, 8:45 am]
EPA had previously announced its intention to approve them upon their official submittal to the Agency. EPA today approves these two remaining portions of the SIP. This means that the 1982 SIP revision of the Charlotte CO nonattainment area is now approved in full.

**DATE:** This action will be effective November 13, 1984, unless notice is received within 30 days that someone wishes to submit adverse or critical comments.

**ADDRESSES:** Copies of this revision are available for inspection at:
- The Office of the Federal Register, 1100 L Street, NW., Room 84, Washington, DC 20468
- Public Information Reference Unit, EPA, 401 M Street, SW., Washington, DC 20460

Copies of the SIP revision and other materials relating to this rulemaking are available for inspection at:
- Environmental Protection Agency, Region IV, Air Management Branch, 345 Courtland Street, Atlanta, GA 30303
- Air Quality Section, Division of Environmental Management, North Carolina Department of Natural Resources and Community Development, Archdale Building, 512 N. Salisbury Street, Raleigh, NC 27611

**FOR FURTHER INFORMATION CONTACT:**
- Tom Lyttle EPA, Region IV, Air Management Branch, 345 Courtland Street, Atlanta, Georgia, 404-681-2864 (PNT: 257-2864).

**SUPPLEMENTARY INFORMATION:**

**SUMMARY:** On March 28, 1984 (49 FR 11175), EPA approved North Carolina’s 1982 revision to its carbon monoxide (CO) State Implementation Plan (SIP) for Charlotte except for its I/M plan and commitments to certain transportation control measures (TCM’s) which had been submitted to EPA in draft form only. EPA found that these portions of the plan would meet the requirements of the Clean Air Act if subjected to a public hearing and formally adopted. Furthermore, in the March 20, 1984, notice, the Agency said that it would approve them once they were officially submitted. A public hearing on the two outstanding portions was held on January 31, 1984; they were adopted by the Environmental Management Commission on April 12, 1984, and submitted to EPA on April 17, 1984. Because they are the same as the ones reviewed in draft by EPA, and because EPA had previously announced its
Court of Appeals for the appropriate circuit by [60 days from today]. This action may not be challenged later in proceedings to enforce its requirements. [See sec. 307(b)(2).]

Incorporation by reference of the North Carolina State Implementation Plan was approved by the Director of the Federal Register on July 1, 1982.

List of Subjects in 40 CFR Part 52

Air pollution control, Intergovernmental relations, Ozone, Sulfur oxides, Lead, Nitrogen dioxide, Particulate matter, Carbon monoxide, Hydrocarbons.

[Secs. 110 and 172 of the Clean Air Act as amended (42 U.S.C. 7410 and 7502)]


William D. Ruckelshaus,
Administrator.

PART 52—[AMENDED]

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

Subpart II—North Carolina

Section 52.1770(c) is amended by revising paragraph (c)(37) to read as follows:

§ 52.1770 Identification of plan

(a) The plan revisions listed below were submitted on the date specified.

(37) 1982 revision of the Part D plan for the Mecklenburg County CO nonattainment area, submitted on June 17, 1982, and April 17, 1984, by the North Carolina Department of Natural Resources and Community Development.

[47 FR 44339, Sept. 14, 1982; 49 FR 41717, Sept. 12, 1984]

BILLING CODE 6560-65-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 405

[BOO-030-F]

Medicare Program; Interest Charges on Overpayments and Underpayments to Providers and Suppliers of Services

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

ACTION: Final rule and correction.

SUMMARY: On December 6, 1982, we published a final rule with comment period (47 FR 54811) concerning interest charges on overpayments and underpayments to providers and suppliers of services and indicated that we would consider making revisions to respond to comments received. That rule implemented section 117 of Pub. L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982. The purpose of this final rule is to respond to the comments we received and to make some minor revisions to the rule.

EFFECTIVE DATE: These regulations are effective October 15, 1984.

SUPPLEMENTARY INFORMATION:

I. Background

Section 117 of Pub. L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), was enacted on September 3, 1982. It added a new subsection (d) to section 1815 and a new subsection (j) to section 1833 of title XVIII (Medicare) of the Social Security Act (the Act). These provisions require that once a final determination is made that a provider or supplier of services has received an overpayment or underpayment from Medicare, and payment of the excess or deficit is not made within 30 days of the date of the final determination, interest charges will be applied to the balance due. The regulations at 42 CFR 405.376 implement the legislation and provide specific rules regarding interest on Medicare overpayments and underpayments.

II. Analysis and Response to Comments

1. If a cost report is filed that does not contain an amount is due HCFA, interest will accrue on that overpayment from the date the cost report is filed, unless (i) full payment accompanies the report or (ii) the provider and the intermediary agree in advance to subtract the amount of overpayment from Medicare payments over the next 30-day period. In addition, if the intermediary determines that a further overpayment exists, interest accrues from the date of the final determination with respect to that further overpayment.

2. If a cost report is filed and indicates an amount is due HCFA, interest will accrue on that overpayment from the date the cost report is filed, unless (i) full payment accompanies the report or (ii) the provider and the intermediary agree in advance to subtract the amount of overpayment from Medicare payments over the next 30-day period.

3. In instances when a cost report is not filed timely and the intermediary subsequently determines that an overpayment exists, interest is also assessed.

Under the regulations, interest assessed on overpayments and interest on funds borrowed during a cost reporting period for the purpose of repaying Medicare overpayments is not considered an allowable cost to providers of services. If an overpayment determination is ultimately reversed administratively or judicially in favor of the provider or supplier of services, appropriate adjustments will be made with respect to the overpayment and the interest assessed.

II. Analysis and Response to Comments

We received comments from 35 commenters, who consisted of health facilities, health care associations, Medicare intermediaries, certified public accountant firms, State health agencies, and a law firm.
The comments are discussed below according to the order in which the provisions appear in the regulations.

1. Basic rules: 42 CFR 405.376(b)

Three commenters disagreed with the provision that, for purposes of computing interest, periods of less than 30 days should be treated the same as a full period; they recommended that interest should be calculated on daily balances.

Response: The regulations conform with the requirements of the Treasury Fiscal Requirements Manual, with which we must comply. In addition, calculating interest on a 30-day period is easier for Medicare contractors to administer. The provision will apply to underpayments as well as overpayments, requiring us to pay a provider 30 days’ worth of interest even if we settle the underpayment sooner.

2. Definition of final determination: 42 CFR 405.376(c)

a. Twenty-four commenters believe that the filing of the cost report should not be considered as a final determination nor as a “triggering device” for the accrual of interest when a cost report indicating an overpayment is submitted and payment does not accompany the cost report.

Response: We do not agree with this comment. The filing of a cost report showing an overpayment is an admission by a provider that a debt exists that is therefore due and payable at that time. This has always been our policy. Before sections 1815(d) and 1833(j) of the Act were enacted, there was no incentive for compliance. If a provider filed a cost report without returning any overpayment, we would need to monitor constantly, send a series of demand letters, and possibly suspend program payments. The intent of Congress in adding these interest charges was to encourage more timely settlement.

b. One commenter stated that if a provider receives an extension for filing a cost report, we should not penalize the provider for delinquency.

Response: We agree with this comment. The definition of a timely-filed cost report is confusing in the context of these regulations and that a better term would be “late filed cost report,” since the purpose is to establish the date from which interest accrues, rather than to discuss procedures concerning unfiled cost reports.

Response: We agree with this comment and are changing “unfiled cost report” to “cost report that is not filed on time” in § 405.376(c)(1)(iv) and (c)(5), the two places it appears.

d. Three commenters had difficulty with the definition of final determination because of the possibility that the provider’s cost report would show an underpayment and the intermediary’s review would show an overpayment. Two of the commenters noted that the provider may show an underpayment because of the need to preserve appeal rights. One of the commenters wanted to know whether in such a situation a provider was required to repay the amount overpaid within 30 days of the due date or would be permitted to wait for the NBR. Two commenters concerned the date the interest would start: with the due date of the cost report or with the intermediary’s determination that there is an overpayment. (One of these comments concerned a late filed cost report that showed an underpayment; the intermediary charged interest from the due date of the cost report.)

Response: When adjustments excluding certain appeal items result in an overpayment, interest accrues from the date of notification and demand for repayment. Interest will always accrue on any overpayment, either as filed, or later determined, when a cost report is delinquent. Interest accrues during the period of delinquency even through the amount due is repaid within 30 days from the date of determination.

e. Three commenters wanted to know whether the interest provisions apply to interim payments or lump sum repayments based on interim rate adjustments. The definition of final determination as a written determination of an overpayment when there is no notice of program reimbursement permits, two commenters believed, interest assessment on interim reimbursement; one commenter stated that if that is HCFA’s intention, it should be specified in a future proposed revision and not implemented before providers have a chance to comment.

Response: We agree with the comment. We will not assess interest on overpayments resulting from interim rate adjustments. However, as indicated below, we may assess interest based on an initial retroactive adjustment if the provider does not dispute the adjustment.

f. One commenter requested that the definition of a timely-filed cost report for purposes of assessing interest on an overpayment should be clarified. For an example, he suggested that if a cost report is not filed within 90 days but is filed within 120 days; and the overpayment is not filed within 30 days, no interest should be charged. He stated that the policy on assessment of interest should be consistent with the policy on offset/suspension of interim/PIP payments when a cost report is not timely filed (i.e., the interim/PIP payments are not reduced until after the 120-day period ends).

Response: A cost report is due on the last day of the third month following the close of the cost reporting period with a single 30-day extension granted for good cause. If an overpayment exists when the cost report is filed, it is payable at that time. The suspension of interim payments is a collection procedure. It is not practical to expect the intermediary to begin offset the day after a cost report is late.

g. One commenter stated that our position in considering a provider’s cost report as a “final determination” when there is an overpayment might cause a provider to take and sustain the position that we and our intermediaries would be barred from further audits or adjustments of the report.

Response: We do not agree with this comment. The term “final determination” is defined in regulations as a means of establishing the initial date of interest accrual. It does not prevent further adjustment of an overpayment or underpayment in the usual cost settlement or appeals process.

3. Rate of interest: 42 CFR 405.376(d)

a. Two commenters stated that the interest rate to be charged is vital information and should be available in convenient form to all parties concerned.

Response: We agree and will send the current interest rate each quarter to the HCFA Regional Administrators who will establish procedures to notify the intermediaries and carriers in the region, who in turn will keep the providers and suppliers apprised of interest rates.

b. Two commenters stated that the regulations do not define what constitutes default. They stated that conditions that give rise to declaration of default should be defined.

Response: We agree with this comment. We will explain default and include in our administrative instructions the procedures the intermediary should follow. The provider or supplier is considered in default if he fails to pay two consecutive installment payments of an extended repayment agreement.
c. One commenter believed that there should be a distinction between a delay in repayment for good cause and default: if good cause exists, the interest rate should not be modified. This commenter and another one believed that if there is a default in repayment, the interest rate should match the prevailing rate, whether it is higher or lower.

Response: In response to the first comment: we define default as missing two payments (or more) on a repayment schedule; the balance of the debt then becomes subject to a higher rate of interest (if a higher rate is in effect at that time). This policy will be included in administrative instructions. In response to the second comment: because the Federal Register may publish the interest rate as much as 60 days prior to its effective date, a provider or supplier could delay payment knowing that a future interest rate would be lower than the rate currently being assessed. To assess the lower rate prevailing at the time of default would defeat the purpose of the regulation; i.e., prompt repayment of Medicare overpayments.

4. Accrual of Interest: 42 CFR 405.376(e)

a. Twenty-four commenters expressed their belief that the regulations are not consistent in their treatment of overpayments and underpayments when they appear on a cost report as filed. They stated that if the cost report indicates an overpayment, the balance is due immediately. If it indicates an underpayment when the cost report is filed, the provider must wait until the intermediary reviews it and decides the correct amount due. These commenters felt a provider is deprived of the amount due and does not receive any interest for the period in which the intermediary makes its decision.

Response: Although it may appear that there is an inconsistency in the treatment of overpayments and underpayments when they appear on a cost report; we believe the different treatment is justified. Interim rates are set by the intermediary based primarily upon data submitted by a provider. A cost report showing an underpayment is a claim for funds against the government and cannot be paid until the claim is verified. On the other hand, a cost report showing an overpayment is a statement by the provider (which has received payment during the period of the cost report) that it has been overpaid. Based on that statement, payment should accompany the cost report. It is not reasonable to require either the government to take an additional step to collect the overpayment before interest starts to accrue or to allow the provider an additional period to repay the admitted overpayment before interest is charged. In the latter case a provider has had interest-free funds in excess of those to which it is entitled during part or all of the cost report year (and, in many cases, as long as 16 months). With respect to underpayment, existing regulations (42 CFR 405.454(f)) require the intermediary to make a retroactive adjustment. In either case, the amount of the debt must be reasonably certain before it becomes due and payable.

b. These 24 commenters also stated that if the full amount of an underpayment is not received upon tentative settlement (to which we refer as an initial retroactive adjustment in this preamble), interest to the provider should accrue from the date the cost report is filed. Such a policy would eliminate partial refunds of underpayments based upon a percentage of the claimed underpayment. Providers are being denied a complete return of their costs until the intermediary makes final retroactive adjustments.

Response: We do not agree with this comment. Initial retroactive adjustments (see 42 CFR 405.454(f)(2)) by the intermediary are intended to bring the interim payments into agreement with the reimbursable amount payable to the provider. Regardless of whether there is an overpayment or underpayment, either the provider or the intermediary has 30 days to pay from the date of the determination before interest accrues. Interest is not to be applied to the date of the cost report except in those cases where the provider does not file the cost report timely or does not pay the overpayment when filing a cost report indicating an amount due the Medicare program.

c. The twenty-four commenters also stated that if our findings are reversed on appeal, we should pay interest to the provider to the extent that it has prepaid the overpayment.

Response: We cannot accept this comment. If findings are reversed or changed upon administrative or judicial appeal, we will refund any interest erroneously collected. We can only pay interest or otherwise disburse funds when the payment is authorized by law. Sections 1815(d) and 3333(i) of the Act require only that interest be paid if an underpayment is not paid within 30 days from the date of the final determination; it does not otherwise authorize payment of interest.

d. One commenter stated that when a cost report showing an underpayment is filed late, interest should not be charged for the period beginning with the due date and up to the date the intermediary determines there is an overpayment, since to charge interest from the date the cost report was due penalizes the provider for filing late.

Response: Whenever a cost report is filed late and an overpayment exists, either as initially reported by the provider or as later determined by the intermediary, interest will accrue. The accrual for the delinquent period runs from the due date to the date filed, not to the date of determination. Under section 1815(e) of the Act, all payments previously made constitute an overpayment when a cost report is not timely filed.

e. Three commenters had difficulty with the option to liquidate the overpayment. To one of the commenters the meaning of “agree in advance” was unclear: he wanted to know whether it means in advance of the cost report filing date or in advance of the interest payment reduction. All three did not believe that the intermediary had to agree, as the regulations imply, to a liquidation of the overpayment if the provider repaid the amount within 30 days of a determination of an overpayment.

Response: The agreement to offset interim payments must be reached before the cost report is due since interest will otherwise accrue from the due date of a cost report showing an overpayment when filed. If the intermediary determines the overpayment, no agreement is needed if the amount due is paid within 30 days.

f. One commenter suggested that we change the language in § 405.376(e)(2)(ii) so that there is no confusion because of the difference in the definitions of “final determination” in the law and in our regulations. The commenter suggested we eliminate the term “further overpayment” and change the language so that it is clear that there is a final determination for each overpayment discovered. The commenter also thought the regulations should specify the interest rate for further overpayments.

Response: We agree with these comments and are adopting the pertinent language the commenter included in his comment, with two minor changes. Section 405.376(e)(2)(ii) will read: "If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination." We are adding a subparagraph (iii) to state that the interest rate to be assessed on any determination is the rate that is in effect on the date the determination is made.
Twenty-four commenters believed that the accrual of interest on underpayments is not consistent with the accrual of interest on overpayments once the contractor makes a determination, since interest to the provider or supplier does not begin to accrue until 30 days after the determination.

Response: We agree with this comment. We will eliminate "beginning 30 days" from § 405.376(e)(4) so that interest to us or to the provider or supplier accrues from the date of the determination. We are also amending § 405.376(f)(1)(i) to show that interest will be waived when either the underpayment or overpayment is liquidated within 30 days so that we may benefit from liquidating underpayments.

One commenter wanted to know when interest starts to accrue on amounts owing because of amended NPRs.

Response: When an amended NPR establishes or increases the amount of an overpayment, interest on the overpayment, or the increased amount, accrues from the date the intermediary sends the amended NPR and new demand letters to the provider.

One commenter requested that there be some provision to protect providers and suppliers from assessment of interest charges when the provider has made "good faith" efforts to refund an overpayment; e.g., the provider has sent a check that the intermediary could not locate.

Response: We agree with the comment and we are furnishing the details for determining the date of receipt in our administrative instructions. Generally, we will consider the date of postmark to be the date of "receipt" (postal service regulations consider a letter to be the addressee's after it is postmarked); when other types of delivery are used (such as Federal Express or Overnight Mail), the receipt will establish the date of receipt. Because postmarks are sometimes missing or illegible, we suggest providers using the U.S. mail send letters by certified mail, return receipt requested.

Two commenters stated that one intermediary has indicated that interest will be assessed from the date of an initial retroactive adjustment. The commenter stated that because the regulations appear to provide quite clearly that interest starts with the issuance of a notice of program reimbursement (NPR) and a written demand for payment, the intermediary's position does not appear to be supported by the regulations.

Response: We do not agree entirely with this comment. Although the NPR is the primary basis upon which interest is assessed against providers, the regulations do not require an NPR to be issued before interest may accrue. When an initial retroactive adjustment results in an overpayment, a written determination that an overpayment exists and a written demand for payment is sufficient to start the accrual of interest.

Section 405.376(e)(1)(ii) indicates that a final determination occurs in those cases when an NPR is not utilized upon the issuance of a written overpayment determination and demand for payment. (That section also includes the parenthetical phrase "(primarily under Part B)." This is not meant to be an exclusive phrase limiting this type of determination to Part B overpayments. Provider overpayments and underpayments are the principal subject dealt with in the regulation and the phrase is meant to point out where Part B debts fall in the definition of final determination.) This section, therefore, also defines final determination with regard to provider overpayments and underpayments that are made before the issuance of the NPR.

It is our experience that because the initial retroactive adjustment serves to correct mathematical errors of calculations, or other obvious errors or inconsistencies, it is, for the most part, not disputed by the provider. Accordingly, these adjustments, in effect, create a correct cost report, which if filed accurately when submitted would have indicated a different amount in the provider's overpayment or underpayment. In the case of an overpayment, if this amount had appeared on the cost report, payment would be due when the cost report was filed. This, just as a cost report that indicates an amount is due HCFA constitutes a final determination under 42 CFR 405.376(c)(1), an undisputed initial retroactive adjustment is also a final determination.

Full review and settlement of a provider's cost report can be a very time-consuming process. To implement the processing of the provider's cost report as quickly as possible, the intermediary makes an initial retroactive adjustment as soon as it receives the cost report and reviews it. For this purpose, the intermediary accepts costs as reported except for obvious errors or inconsistencies, subject to a later review. To avoid creating overpayments (later on in the settlement process) while making initial retroactive adjustments, the intermediary reduces the amount due the provider by any amounts claimed that are attributable to obvious errors or inconsistencies, as well as by any monies owed the program (42 CFR 405.454(f)(2)).

The intermediary bases initial retroactive adjustments on the data that it determines will result in the most accurate reimbursement to the provider. Usually the initial retroactive adjustment is performed in conjunction with a desk review of provider costs that includes not only a comparative cost analysis but also a review of all available information about the provider. It also provides the means for resolving as many problems as possible without audit by obtaining additional information and documentation from the provider.

When the intermediary issues a demand letter based on an initial retroactive adjustment, the written determination will set out the basis for the overpayment. The provider will be given 15-days following the date of such notification to contest the determination regarding the existence or amount of the overpayment. In its response, the provider must include, along with any pertinent evidence, a statement concerning why it believes the overpayment determination is wrong. If the provider does not respond within the 15-day period, or the provider's response indicates agreement with the initial retroactive adjustment, interest will accrue from the date of that adjustment, unless the overpayment is liquidated within 30-days. If the provider submits a written statement disputing portions of the initial retroactive adjustment, interest will not be assessed on those disputed amounts based upon the initial retroactive adjustment until the dispute is settled. In case of dispute, the intermediary will either proceed with the audit and an NPR, or issue a separate determination concerning the initial retroactive adjustment based on the evidence submitted together with any other material bearing on the overpayment.

In those cases when the intermediary acts on the provider's response to the notice of the initial retroactive adjustment before the issuance of an NPR, the intermediary must issue a separate determination to the provider. This notice must contain specific findings and an explanation as to why the intermediary's reimbursement decision differs from the amount the provider claimed.

In sum, interest will accrue from the date of the initial retroactive adjustment when the provider does not respond within the 15-day period, or when the
5. Waiver of interest charges: 42 CFR 405.376(h) Three commenters thought that we should establish thresholds of interest to be waived.

Response: We do not agree with this comment. As we stated in the preamble to the final rule with comment period, we will waive the interest when the cost of collecting interest is more than the amount of interest involved. Since the cost of collecting interest may vary, we cannot state a fixed threshold amount in the regulations or in instructions. We will, however, issue instructions so that intermediaries and carriers can determine whether interest should be waived in a given case.

8. Exceptions to applicability: 42 CFR 405.376(h)

a. One commenter stated the term “final decision” as used in paragraph (h)(2) may be confused with the term “final determinations” when a final determination is administratively or judicially reviewed.

Response: We agree with this comment. Instead of stating “... the reversal is the final decision in the case ...”, we will state “the reversal is no longer subject to appeal ...”.

b. One commenter requested a clarification of the phrase “appropriate adjustments will be made” in § 405.376(h)(2).

Response: This phrase means that any interest erroneously collected will be refunded to the paying party.

7. Interest as a nonallowable cost: 42 CFR 405.376(i) and 405.419

a. Twenty-three commenters stated that interest on funds providers borrow in order to repay an overpayment should be an allowable cost since it is related to patient care.

Response: We do not agree. The principal reasons for overpayments are nonallowable and excessive costs that are not related to patient care. Therefore, we cannot allow the interest as an allowable cost.

b. These same commenters believed that interest income received as a result of an underpayment not being timely paid by an intermediary should not be used to reduce allowable interest expense in computing reimbursable costs.

Response: We agree with this comment. Administrative instructions will indicate that the interest income on underpayments will not be offset against interest expense in computing reimbursable costs.

c. One commenter stated that the regulations do not clearly state that interest on funds borrowed solely to repay an overpayment will be disallowed, but rather imply that interest on any borrowings is nonallowable, up to the amount of the overpayment and made during the period in which the overpayment is repaid.

Response: We agree with the comment and we are adding to §§ 405.376(i) and 405.419(a)(1)(C) language that will clarify that interest is nonallowable where the provider cannot show that the borrowing would have been necessary if the overpayment had not occurred.

d. One commenter wanted to know whether interest assessed on an overpayment would be considered an allowable expense if after the cost report is settled there is a determination that there is in fact an underpayment.

Response: We will refund interest assessed on an overpayment and later found to be collected in error. Since no expense will have been incurred the interest is not an allowable cost.

The remainder of the comments, discussed below, did not address specified sections of the regulations.

8. Effective date of regulations.

Three commenters stated that the regulations should only affect those cost reports filed after September 3, 1982.

Response: Section 117 of the TEFRA states that the interest provisions of the Social Security Act apply to “final determinations made on or after the date of enactment” of the TEFRA, September 3, 1982; therefore, we cannot comply with the comment.

9. Miscellaneous

a. Two commenters disagreed with our position that the regulations did not need to be published as a notice of proposed rulemaking.

Response: We published the regulations as final regulations in order to conform as soon as possible with Congress’ intent to reduce the amount and duration of Medicare overpayments, since Congress wanted determinations made on or after the date the law was enacted to be subject to the law. In addition, we did provide the public with an opportunity to comment. We have considered the comments carefully and are making changes as explained in this preamble.

b. One commenter stated that an NPR should include a statement clearly spelling out to the provider its obligation for repayment, the amounts of interest to be charged, the circumstances under which it will be charged, and the provider’s rights to appeal.

Response: We agree with this comment. We are going to list in administrative instructions specific items relating to interest assessment that must be included in future NPRs.

c. One commenter requested a differentiation between Part A and Part B when determining an overpayment. He wanted to know, for example, whether a Part B underpayment would be applied against a Part A overpayment to determine the amount due.

Response: The regulation does not change existing rules for offsetting Part A and Part B overpayments and underpayments in the cost report settlement process.

III. Summary of Changes

As a result of comments, we are making the following changes:

(1) Sections 405.376(c)(1)(iv) and (e)(3): We are revising “unfiled cost report” to “cost report that is not filed in time”.

(2) Section 405.376(c)(1)(i): We are revising this subparagraph so that the definition of “final determination” includes any new determination issued because a provider disputed an initial retroactive adjustment. This revised definition will require that interest begin to accrue when the cost report settlement process.
(3) Section 405.376(e)(2): We are revising subparagraph (ii) to clarify that there is a final determination for each overpayment discovered. We are also adding a new subparagraph (iii) to show that the interest for each final determination will be that in effect on the date of the determination.

(4) Sections 405.376(e)(4) and (f)(1)(i): We are revising these subparagraphs to show that interest accrues from the date of the determination on either an overpayment or underpayment and that interest will be waived for an overpayment or underpayment when liquidated within 30 days.

(5) Section 405.376(h)(2): We are changing the term “final decision” in this subparagraph so that it will not be confused with the term “final determination”.

(6) Sections 405.376(i) and 405.412(e)(1)(iii): We are revising these subparagraphs to clarify that interest on borrowed funds is not an allowable cost if it cannot be shown that the amount was not borrowed to repay an overpayment.

IV. Technical Changes

In addition to revisions prompted by comments, we are making three technical revisions to the regulations.

The first change is to § 405.376(c)(1)(iii). We are revising the phrase “Upon the date of submittal of a timely-filed cost report . . .” to “Upon the due date of a timely filed cost report . . .”. We are changing the language so that no providers will be discouraged from filing a cost report early when the report shows an amount due the program.

We are changing § 405.376(e)(2)(i) for the same reason. We are changing in that paragraph the phrase “interest . . . will accrue from the date the cost report is filed unless . . .” to “interest . . . will accrue from the due date of the cost report unless . . .”.

The third revision is to § 405.412(a)(2). We are deleting the phrase “and interest assessed on an overpayment.” The current language in that paragraph may imply that interest paid on an overpayment that is reversed is an allowable cost. Since we refund any interest paid on overpayment, we are revising these subparagraphs to clarify that interest on borrowed funds is not an allowable cost if it cannot be shown that the amount was not borrowed to repay an overpayment.

In addition, on January 30, 1984 (49 FR 3648), we published a final rule concerning the reduction in the number of providers dealing directly with HCFA.

On page 3659, in the first column, in the amendment to § 405.2001, we erroneously stated that we were revising paragraph (a) instead of stating that we were revising the introductory matter of paragraph (a). As a result, the revision as printed deletes subparagraphs (1), (2) and (3). We are correcting the amending language to § 405.2001 so that subparagraphs (1), (2) and (3) remain part of paragraph (a).

V. Impact Analyses

A. Executive Order 12291

We have determined that this final rule is not likely to result in an annual impact of $100 million annually or meet other threshold criteria of Section 1(b) of the Order. The overall intent of these regulations is to make a few technical and clarifying changes, mostly in response to comments we received on the final rule with comment period we published on December 6, 1982. These regulations changes will have a very minimal, if any, effect.

B. Regulatory Flexibility Act

The Secretary certifies under 5 U.S.C. 605(b), enacted by the Regulatory Flexibility Act of 1980 (Pub. L. 96-345) that these final regulations will not result in a significant impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required. These regulations will affect some providers, physicians and other suppliers of services, most of which are small entities. However, as noted in the Executive Order analysis, since these regulations merely clarify the final regulations published on December 6, 1982, the impact on providers and suppliers will not be significant.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Certification of compliance, Clinics, Contracts (agreements), End-stage renal disease (ESRD), Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers, Home health agencies, Hospitals, Inpatients, Kidney diseases, Laboratories, Medicare, Nursing homes, Onsite surveys, Outpatient providers, Reporting requirements, Rural areas, X-rays.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. 42 CFR Chapter IV, Part 405 is amended as set forth below:

1. Subpart C is amended as set forth below:

Subpart C—Exclusions, Recovery of Overpayment, Liability of a Certifying Officer and Suspension of Payment

The authority citation for Subpart C reads as follows:

Authority: Sec. 1102, 1815, 1833, 1842, 1861, 1862, 1863, 1870, 1871, and 1879 (42 U.S.C. 1320c, 1395f, 1395i, 1395l, 1395n, 1395x, 1395yy, 1395zc, 1395gg, 1395hh and 1395pp) and 31 U.S.C. 3711.

Section 405.376 is amended by reprinting paragraph (c)(1) for the convenience of the reader and by revising paragraphs (c)(1)(i), (c)(1)(ii), (c)(1)(iv), (e)(2), (e)(3), (e)(4), (f)(1)(i), (b)(2) and (i) as follows:

§ 405.376 Interest charges on overpayments and underpayments to providers and suppliers.

(1) For purposes of this section, a final determination is deemed to occur—

• • • •

(ii) When an NPR is not utilized as a notice of determination (primarily under Part B), upon the issuance of either (A) a written determination that an overpayment exists and a written demand for payment, or (B) a written determination of an underpayment.

EXAMPLES OF WHEN AN NPR IS NOT UTILIZED AS A NOTICE OF DETERMINATION

• • • •

(a) Definition of final determination.

(i) When an NPR is not utilized as a notice of determination, a final determination is deemed to have been made if the provider does not dispute the determination within 15 days of the notice of the determination.

• • • •

(ii) When an NPR is utilized as a notice of determination, a final determination is deemed to have been made on those portions where the intermediary issues a new determination in response to the dispute:

(A) Upon the due date of a timely-filed cost report that (A) indicates an amount is due HCFA, and (B) is not accompanied by payment in full. (If an additional overpayment or underpayment is determined by the carrier or intermediary, a final determination on the additional amount will be made in accordance with paragraphs (c)(1)(i) or (c)(1)(ii) of this section): or,
(iv) With respect to a cost report that is not filed on time, the day following the date the cost report was due (plus a single extension of time not to exceed 30 days if granted for good cause), until such time as a cost report is filed. (When such cost report is subsequently filed, there will be an additional determination as specified in paragraphs (c)(1)(i), (ii) or (iii) of this section.)

(e) Accrual of interest.

(2)(i) If a cost report is filed and indicates that an amount is due HCFA, interest on the amount due will accrue from the due date of the cost report unless—

(A) Full payment on the amount due accompanies the cost report; or

(B) The provider and the intermediary agree in advance to liquidate the overpayment through a reduction in interim payments over the next 30-day period.

(ii) If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination.

(iii) The interest rate on each of the final determinations of an overpayment will be the rate of interest in effect on the date the determination is made.

(3) In the case of a cost report, that is not filed on time, interest also will accrue on a determined overpayment from the day following the due date of the report (plus a single extension of time not to exceed 30 days if granted for good cause, as specified in §405.453(f)), to the time the cost report is filed.

(4) If an intermediary or a carrier makes a final determination that an underpayment exists, interest to the provider or the supplier will accrue from the date of notification of the underpayment.

(f) Waiver of interest charges.

(1) When an intermediary or a carrier makes a final determination that an overpayment or underpayment exists, as specified in paragraphs (e)(1), (e)(2)(ii), and (e)(4)—

(i) Interest charges will be waived if the overpayment or underpayment is completely liquidated within 30 days from the date of the final determination.

(ii) Exceptions to applicability.

(2) If an overpayment or an underpayment determination is reversed administratively or judicially, and the reversal is no longer subject to appeal, appropriate adjustments will be made with respect to the overpayment or underpayment and the amount of interest charged.

(i) Non-allowable cost. As specified in §405.419, interest accrued on overpayments and interest on funds borrowed specifically to repay overpayments are not considered allowable costs, up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (e.g., capital improvements).

(See section 405.419(a)(2) for exceptions based on administrative or judicial reversal.)

2. Subpart D is amended as set forth below:

Subpart D—Principles of Reimbursement of Providers, Outpatient Dialysis, and Services by Hospital-Based Physicians

The authority citation for Subpart D reads as follows:

Authority: Secs. 1102, 1814(b), 1815, 1833(a), 1861(v), 1871, 1881, 1886, and 1887 of Social Security Act as amended (42 U.S.C. 1302, 1305(b), 1385, 1385(a), 13851(v), 1385hh, 1385r, 1385ww, and 1395x).

Section 405.419 is amended by reprinting paragraphs (a)(1) (i) and (ii) for the convenience of the reader and revising paragraphs (a)(1)(iii) and (a)(2) as follows:

§405.419 Interest expense.

(a) (1) Principle. Necessary and proper interest on both current and capital indebtedness is an allowable cost. However, interest costs are not allowable if incurred as a result of—

(i) Judicial review by a Federal court (as described in §405.454(f)),

(ii) An interest assessment on a determined overpayment (as described in §405.376), or

(iii) Interest on funds borrowed to repay an overpayment (as described in §405.454(l) or §405.376), up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (e.g., capital improvements).

(2) Exception. In those cases of administrative or judicial reversal, interest paid on funds borrowed to repay an overpayment is an allowable cost, in accordance with this section.

B. In Federal Register document 84-2424, appearing at page 3659 in the issue of January 30, 1984, the amending language of paragraph "2" is corrected to read as follows:

"Section 405.2001 is amended by revising the introductory text of paragraph (a) to read as follows:"
subject to the 1984 Act. This Interim Rule became effective on June 18, 1984. Interested persons were given 90 days from the date of publication in the Federal Register in which to comment on the interim rules.

The Commission has now been requested by certain conferences to immediately suspend the requirement in §572.704 that conferences maintain and file with the Commission an index of documents, and the related requirement in §572.703(b) that meeting reports:

shall specify any documents distributed by the conference or other agreement to inform or assist the members on such matters . . . occurring within the scope of the agreement and which are being discussed or considered by the membership. 

Section 704 of the Interim Rule provides:

(a) Each agreement required to file minutes pursuant to §572.703 shall maintain an index of all reports, circulars, notices, statistics, analytical studies, or other documents, not otherwise filed with the Commission pursuant to this subpart, which are distributed to the member lines. (b) Each index required by paragraph (a) of this section shall be filed with the Commission on a quarterly basis, the first to be filed for the period ending September 30, 1984, and for each succeeding quarterly period thereafter. Each index must be certified by an official of the agreement as true and correct.

Upon consideration of the emergency comments, we have determined to grant the interim relief requested, and defer implementation of these requirements pending issuance of a Final Rule. This action is not a determination on the ultimate merit of these comments which will be considered in connection with the issuance of a final rule. Accordingly, §572.704 is being amended to provide that for the index of documents the first period to be reported is that ending "March 31, 1985" rather than "September 30, 1984." Also, §572.703 is amended to provide that minutes need not specify documents which are distributed until January 1, 1985.

List of Subjects in 46 CFR Part 572

Antitrust, Contracts, Maritime carriers, Administrative practice and procedure, Rates and fares, Reporting and record keeping requirements.

PART 572—[AMENDED]

Therefore, pursuant to 5 U.S.C. 553, and sections 5, 6, and 17 of the Shipping Act of 1984 (46 U.S.C. app. 1704, 1705 and 1716), The Commission amends

Title 46, Code of Federal Regulations, Part 572, Subpart G, as follows:

1. In §572.703 revise paragraph (b) to read as follows:

§572.703 Filing of minutes.

(b) Content of Minutes. Conferences, interconference agreements, agreements between a conference and one or more ocean common carriers, pooling agreements, equal access agreements, discussion agreements, marine terminal conferences, and marine terminal rate fixing agreements shall, through a designated official, file with the Commission a report of each meeting describing all matters within the scope of the agreement which are discussed or considered at any such meeting, shall specify any documents distributed by the conference or other agreement to inform or assist the members on such matters, and shall indicate the action taken. These reports need not disclose the identity of parties that participated in discussions, or the votes taken.

Reports of meetings filed with the Commission in accordance with this requirement need not specify documents that were distributed until January 1, 1985.

§572.704 [Amended]

2. In §572.704, Index of Documents, in paragraph (b), remove "September 30, 1984" and insert "March 31, 1985."

By the Commission.

Francis C. Hurney,
Secretary.

FEDERAL COMMUNICATIONS COMMISSION

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 83

Communications equipment, Marine safety, Radiodetermination, Ship stations.

Order

In the matter of amendment of Part 83 of the Commission's rules regarding radar stations on ships between 500 and 1,600 gross tons. Adopted: September 5, 1984.

By the Commission.


1. This Order amends the Commission's rules to implement the portion of the first set of amendments to the International Convention for the Safety of Life at Sea, 1974 (SOLAS), that pertains to the installation of radar equipment on ships between 500 and 1,600 gross tons.

2. An amendment to Regulation 12 of Chapter V of SOLAS requires ships between 500 and 1,600 gross tons constructed on or after September 1, 1984, to carry radar. The performance standards of the radar equipment must not be inferior to those adopted by the International Maritime Organization (IMO). We are amending Section 83.465 of the Commission's rules to apply the IMO specifications for compulsory radar systems to ships between 500 and 1,600 gross tons.

3. Authority for this amendment is contained in Section 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 303(r). Since this amendment implements a treaty provision, prior notice and comment is not required 5 U.S.C. 553(a)(1). In addition, because this provision should be noncontroversial, we find good cause to dispense with the prior notice and comment procedure of the Administrative Procedure Act, 5 U.S.C. 553(b)(B).

4. Accordingly, it is ordered, That effective October 15, 1984, the Commission's rules are amended as set forth in the attached Appendix.

1 For the purpose of SOLAS "constructed" means a stage of ship construction where: (a) The keel is laid or (b) construction is identifiable with a specific ship begins; or (c) assembly of that ship has commenced comprising at least 50 tons or 1 percent of the estimated mass of all structural material, whichever is less.

2 The International Maritime Organization (IMO) is responsible for administering the SOLAS Convention. The applicable radar standards are contained in the IMO resolution A. 477 (XII).

Federal Communications Commission.


William J. Tricarico.
Secretary.

Appendix

Part 83 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

§ 83.465 [Amended]

In § 83.465 the introductory paragraph is amended by adding a new first sentence and revising the present first sentence to read as follows:

On ships between 500 tons and 1,600 gross tons that are constructed on or after September 1, 1984, and are engaged in international voyages all compulsorily installed ship radar must comply with the specifications in Regulation 12, Chapter V of the International Convention for the Safety of Life at Sea, 1974 (SOLAS), as amended. On ships over 1600 gross tons all compulsorily installed shipboard stations shall, in addition to meeting all other relevant provisions of this chapter, comply with the applicable radar specifications issued by the Radio Technical Commission for Marine Communications equipment, Great Lakes.

Order

Amendment of part 83 to correct the record keeping requirements applicable to vessels subject to the Great Lakes Agreement and to add a technical specification applicable to survival craft radios.

EFFECTIVE DATE: October 17, 1984.


SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 83

Communications equipment, Great Lakes.

IN THE MARITIME SERVICE

Part 83 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICE

§ 83.368 [Amended]

In § 83.368 the first sentence is revised to read as follows:

The Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 303(r).[1] Since these amendments make minor changes which are likely to be noncontroversial, we find good cause to dispense with the notice and comment procedures of the Administrative Procedure Act 5 U.S.C. 553(b)(3)(B).

4. In view of the above, it is ordered, that §§ 83.368 and 83.556 of the rules are amended, as set forth in the attached Appendix effective October 17, 1984.


Federal Communications Commission.

William J. Tricarico.
Secretary.

Appendix

Part 83 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICE

1. In § 83.368(a) the first sentence is revised to read as follows:

§ 83.368 Radiotelephone station log.

(a) Ship radiotelephone stations subject to Title III, Part II of the Communications Act, the Safety of Life at Sea Convention or the Great Lakes Agreement shall maintain a station log.

2. Section 83.556 is amended by adding a new paragraph (c) to read as follows:

§ 83.556 General requirements for survival craft radio equipment.

(c) Survival craft radio equipment to be type approved under this part shall be tested with ambient temperature variation from −20° to +50° Celsius.

Federal Communications Commission.

William J. Tricarico.
Secretary.

Appendix

Part 83 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICE

4. In view of the above, it is ordered, that §§ 83.368 and 83.556 of the rules are amended, as set forth in the attached Appendix effective October 17, 1984.


Federal Communications Commission.

William J. Tricarico.
Secretary.

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(c) Survival craft radio equipment to be type approved under this part shall be tested with ambient temperature variation from −20° to +50° Celsius.

Federal Communications Commission.

William J. Tricarico.
Secretary.

Appendix

Part 83 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICE


Federal Communications Commission.

Appendix


Federal Communications Commission.

Appendix


Federal Communications Commission.

Appendix


Federal Communications Commission.

Appendix


Federal Communications Commission.
power of private land mobile stations operating on TV-shared frequencies in the band 470-512 MHz. Without this action, licensees would be required to increase their system complexity while incurring additional costs.

**EFFECTIVE DATE:** October 17, 1984.

**FOR FURTHER INFORMATION CONTACT:** Keith Plourd, Private Radio Bureau, Washington, D.C. 20554, (202) 634-2443.

**SUPPLEMENTARY INFORMATION:**
List of Subjects in 47 CFR Part 90

- Administrative practice and procedure, Business and industry, Industrial radio services, Land transportation radio services, Private land mobile radio services, Public safety radio services, Radiolocation radio service, Special emergency radio service.

**Report and Order**

In the matter of amendment of § 90.307(f) of the Commission's rules and regulations to delete a table limiting the effective radiated power of stations at elevations exceeding 1500 feet ASL in the Band 470-512 MHz in the Los Angeles urbanized area (PR Docket No. 82-244, RM-3451).

By the Commission.

**Introduction**

1. Section 90.307(f) of the Commission's Rules limits the effective radiated power (ERP) of private land mobile radio stations operating in the 470-512 MHz band in Los Angeles, California. Licensees are required to adjust their system power according to the height of their transmitting antennas. Higher antennas required lower radiated powers. In theory, this enhances spectrum efficiency by permitting frequency re-use under certain circumstances in this particular geographic area. In practice, this power restriction appears to have little if any positive impact on spectrum efficiency and it operates to limit the communications quality of private land mobile radio systems.

**Background**

2. On January 27, 1975, the Commission amended its Rules to limit the ERP of private land mobile radio stations operating in the Los Angeles area according to their antenna height.¹

Licensees operating systems at that time were allowed until January 1, 1980 to comply with the new ERP limitations. On June 29, 1978, the Commission received a Petition for Rule Making from the California Mobile Radio Association (now the National Mobile Radio Association or MNRA) requesting that the Commission delete the ERP table.² In view of this petition, the Chief of the Private Radio Bureau extended the date for grandfathered systems to comply with these limitations to December 31, 1980.

3. On October 21, 1980, the Commission denied the Petition for Rule Making stating that NMRA's arguments were essentially the same arguments which the Commission previously considered and denied in Docket 20109.³ NMRA filed a Petition for Reconsideration on December 2, 1980, arguing that the limitation on system ERP would not achieve the Commission's goal of increased frequency re-use.

On January 29, 1980, NMRA submitted a Motion for Stay of the October 21, 1980, decision arguing that conformance with the ERP table would cause imminent disruption to radio systems including critical public safety. On May 19, 1981, the Chief of the Private Radio Bureau stayed indefinitely the requirement that grandfathered stations conform with the ERP restrictions pending Commission action on NMRA's Petition for Reconsideration.⁴

4. On April 29, 1982, the Commission adopted a Notice of Proposed Rule Making (NPRM) in response to the NMRA petition.⁵ The Notice proposed to delete § 90.307(f) because the ERP limitations did not appear to be achieving the goal intended but rather were burdening licensees and limiting the effectiveness of their systems. The Commission expresses its concern that requiring present systems to reduce their ERP would disrupt communications with potentially serious impact on critical public safety systems. The Commission indicated that it would delay final action on this matter until the completion of its study of propagation in Southern California.

**Comments**

5. Formal comments on the Notice were received from Teletech, Inc. (Teletech), the County of Los Angeles (LA County), the Manufacturers Radio Frequency Advisory Committee (MRFAC), and Palomar Communications Co., Inc. (Palomar). Approximately fourteen informal comments supporting the Commission's proposal to delete the ERP table were received from various radio users in the Los Angeles area. Reply comments were filed by the National Mobile Radio Association (NMRA).

6. Only Palomar and Teletech opposed the proposal to delete the ERP table. Palomar expressed concern that removal of the ERP restrictions would foreclose the possibility of allocating the same frequencies in the future to San Diego. Teletech argued that the proposal was contrary to the Commission's objective of promoting channel re-use and that an increase in ERP would increase the potential for intermodulation interference.

7. MRFAC supported the Commission's proposal without qualification. LA County stated that the ERP restriction severely limits the effectiveness of large local public safety systems. As an example, one of the eighteen major mountain top repeaters used in the County was limited to 25 watts ERP, although it must serve an area of approximately 2000 square miles.

8. NMRA focused on the system imbalance which the current rule promotes. While base stations are often limited to 125 watts ERP, NMRA points out that mobile units are allowed to use 200 watts ERP which results in weak, interference-prone base to mobile communications and increased interference from mobile units to base station receivers of other systems.

9. The Commission recognized in Docket No. 20109 that many licensees in the 470-512 MHz band were employing mountain重复ers located on mountain peaks which surround Los Angeles.⁷ The Commission observed that there are serious potential for interference in base systems using higher effective radiated powers.

**Discussion**

The Commission recognized in 20109 that many licensees in the 470-512 MHz band were employing community repeaters located on mountain peaks which surround Los Angeles. The Commission observed that these stations blanket the Los Angeles area and might impair local frequency re-use. Therefore, the
Commission proposed to limit the effective radiated power at these sites to encourage intercarrier frequency re-use. In theory, this action would reduce signal levels from these high sites sufficiently to permit multiple co-channel systems to operate simultaneously within the Los Angeles area.

10. Although we remain committed to encouraging frequency re-use in general, we are also aware that the application of a forced re-use policy to the Los Angeles area creates significant problems which impact licensees operating in the area. The Los Angeles urban area extends over 50 miles in diameter and is bounded on three sides by tall mountains. Most licensees require coverage throughout the complete area. The tall mountains are natural antenna locations providing line-of-sight coverage of the entire Los Angeles area. Most of the developed antenna sites are located on these mountain peaks. The majority of licensees in all services regulated by the Commission operate from these natural antenna locations.

11. Since the developed antenna sites are removed from the center of Los Angeles, sufficient power is necessary to cover effectively the entire service area. The ERP table, however, was designed to limit the very coverage these licensees require. The County of Los Angeles states that the reduced communications effectiveness for both the Sheriff’s Department and the County Fire Department. The imposition of the ERP table would require licensees with grandfathered systems to secure additional transmission sites and redundant facilities to maintain their present service area, raising the procurement and operating costs of their communication systems.

12. Therefore, while frequency re-use is a goal, we must seek to encourage re-use in a practical manner. Our ERP table does not appear to have fostered frequency re-use in the Los Angeles area. It appears that the locations of antenna sites are influenced far more by local real estate conditions than by the Commission’s Rules. In Docket No. 18262, we expected the Los Angeles area from similar ERP restrictions in the 800 MHz private radio band in recognition of the unique topography of the area. Again, we must strike a balance between frequency re-use and communications effectiveness. As before, we believe the public interest would be best served in these unique circumstances by deleting the table in its entirety and allowing licensees to employ the powers they need to achieve adequate communications service.

13. We have decided to move forward with this proceeding absent the final results of our study of propagation anomalies in southern California. The intent of the study is to examine signal enhancement due to ducting. We recognize that signal enhancement due to ducting can increase the potential for interference between land mobile transmissions and distant television receivers. However, stations grandfathered when the ERP table was adopted in 1974 continue to operate at higher powers without any indication of interference to television reception. We do not anticipate that the elimination of the ERP restrictions will create significant additional interference. 10

14. In regard to Palomar’s concern that the elimination of the ERP table may foreclose the allocation of additional frequencies to San Diego, we must point out that our action in this proceeding affects only television channels 14 and 20, which have been allocated in Los Angeles for the use of land mobile systems. This should not adversely affect our options in San Diego. If it becomes necessary to allocate additional spectrum for use in San Diego, we could consider other frequencies in the 470-512 MHz band. We do agree with Teltech that increased ERP could result in an increase in the potential for intermodulation interference at the mountain top antenna sites. Intermodulation interference, however, is best controlled on a case-by-case basis at the actual transmitting site, rather than by a federal restriction on system ERP. We do caution licensees to be aware of this potential problem and to take appropriate steps to control it if they increase their radiated powers. See 47 CFR 90.173(b).

15. In view of the foregoing, the Commission finds that it is in the public interest to amend the Rules as proposed. Therefore, it is ordered, pursuant to the authority contained in sections 4(i) and 303(r) of the Communications Act of 1934, as amended, that effective October 17, 1984, Part 90 of the Commission’s Rules and Regulations is amended as set forth in the attached Appendix.

16. It is further ordered that this proceeding is terminated.

Federal Communications Commission.
William J. Tricario, Secretary.

Appendix

PART 90—[AMENDED]

Part 90 of the Commission’s Rules and Regulations (47 CFR Part 90) is amended as follows:

§ 90.307 [Amended]
1. Section 90.307(f) is removed and reserved, including the associated notes.

§ 90.309 [Amended]
2. In § 90.309(b), Figure “A”, the effective radiation power table applying to Los Angeles is removed.

§ 90.307 [Amended]
3. The reference to § 90.307(f) in § 90.307(b) is removed.

[FR Doc. 84-4303 Filed 9-13-84; 8:45 am]
BILLING CODE 6712-01-M

47 CFR Part 97

[84-413; PR Docket No. 82-624]

Definition and Measurement of Transmitting Power in the Amateur Radio Service

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the FCC rules regarding maximum allowable power in the Amateur Radio Service to correct a typographical error. It also denies three Petitions for Reconsideration of the Report and Order in this proceeding because: (1) This proceeding is not mutually exclusive with or determinative of the issues raised in General Docket No. 83-114; and (2) petitioners raise no other facts or issues not previously considered. This document also clarifies that the maximum allowable power in the amateur radio service will not be changed without further rule making.

DATE: Effective October 17, 1984.

FOR FURTHER INFORMATION CONTACT:
SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 97
Radio.

Memorandum Opinion and Order

In the matter of definition and measurement of Transmitting Power in the Amateur Radio Service; PR Docket No. 82-624.


By the Commission.


1. On July 22, 1983 the Commission adopted a Report and Order, 48 FR 34746 (August 1, 1983) in this proceeding replacing the former input power measurement standard in the Amateur Radio Service with a power measurement standard based upon peak envelope power output. This Report and Order was later modified by two Errata, 48 FR 37224 (August 17, 1983) and 48 FR 44814 (September 30, 1983).

2. The Society for Promotion of Amplitude Modulation (Society), Kevin Alfred Strom (Strom) and Donald B. Chester (Chester) filed Petitions for Reconsideration. 1 The American Radio Relay League (ARRL) filed a Motion for Clarification. Arthur E. Provan (Provan) and Byron H. Kretzman (Kretzman) filed reply comments in support of Chester's comments.

3. The ARRL, in its Motion for Clarification, addressed the language in paragraph five of the Report and Order. In this paragraph we set forth the methods we intend to employ in determining the output power of an amateur radio station. We also stated: "Should we decide upon other standards in the future, we will release them in public notices." The ARRL sought clarification on whether this statement was meant to include the actual output power limitation, the methods used for measurement of output power, or both. Further, the ARRL maintained that in either case public notice would be inappropriate, and that such changes require notice and comment rule making proceedings as described in section 553 of the Administrative Procedure Act (5 U.S.C. 553).

4. The last sentence of paragraph five of the Report and Order, regarding release of future standards by public notice, dealt only with the procedures used for measurement of output power. This sentence was not meant to include the actual output power limitation. We anticipate that any revision of the 1500 watt peak envelope power output limit in § 97.67(b) of the Rules would be the subject of a notice and comment rule making proceeding. 2

5. We do not view announcement of changes in measurement methods as within the purview of 5 U.S.C. 553. These methods merely reflect Field Operations Bureau practice for measuring power. Because improved testing equipment and techniques may become available, there may be a need to change these power measurement methods at some time in the future. Should the Field Operations Bureau change its method of measuring amateur radio transmitting power, we intend to inform the public of this change in method by public notice. This matter is a general statement of procedure not subject to the Administrative Procedure Act. See 5 U.S.C. 553(a)(3)(A).

6. Chester, Provan and Kretzman all expressed the view that the instant proceeding is inconsistent with General Docket No. 83-114. We disagree. General Docket No. 83-114 is both a Notice of Inquiry and a Notice of Proposed Rule Making. Notice of Inquiry and Proposed Rule Making, General Docket No. 83-114, 48 FR 14299 (April 4, 1983). The rule changes at issue in that Notice of Proposed Rule Making are limited to Parts 15 and 73 of our Rules. The Notice of Inquiry in that proceeding in a broad discussion of possible rationale for reducing the Commission's technical regulations and adopting alternative approaches. The instant proceeding is not mutually exclusive with nor a pretermination of the outcome of the Inquiry in General Docket No. 83-114. If, in that proceeding, we determine that deregulatory alternatives in the areas of interoperability, efficiency or interference should be adopted, we will then see whether they have particular applicability to rules in the Amateur Radio Service.

7. Further, the inquiry proceeding does not address the question of whether input power or output power measurements are more appropriate in the Amateur Radio Service. Rather, it addresses the overall question of whether rules limiting power are necessary to control interference. We have a power limitation in the Amateur Radio Service and the question of whether that limitation should be upon input or output power and of how to properly measure the power were properly reached in this docket.

8. Each of the filings requesting reconsideration other than the ARRL's deal with the impact of this proceeding upon AM DSB operations in the Amateur Radio Service. In the Report and Order we recognized that this docket would have an impact on AM DSB operations. We estimated that use of output power measurement standards would typically limit AM DSB operations to half of their previous maximum allowable operating power. We stated that in the worst case this would result in an actual power reduction of 3dB, which should be insignificant in terms of actual communications effectiveness. We concluded that we could not justify a permanent and continuous expense, both for equipment and training, to make a special power measurement for amateurs who happen to engage in AM DSB operations, particularly where they constitute only approximately one percent of the U.S. amateur population.

9. Strom commented that variations in amplifier efficiency for AM DSB operations may cause variations in average output for a given input power, but that these variations are within a calculable range of efficiencies. This is true, but we estimate the variation range in average output power calculated on the basis of input power for AM DSB operations in the Amateur Radio Service to be between 45% and 90%. AM DSB operation is in fact a primary example of the inapplicability of input power measurement to certain operating methods. This issue illustrates the extent to which input power standards were archaic. Moreover, the input power measurement standard failed to indicate radiated power or interference potential.

10. The only new facts or analysis presented by Chester and Strom are allegations of quantifiable peak envelope power measurements (PEP) as functions of d.c. plate input power measurements. We have rejected these estimates for the reasons stated in paragraph nine. Chester argues that the 14% of U.S. amateur operators using AM transmitters. The Amateur Radio Service is one of the few remaining services that had not, until this proceeding, been modified to adopt this approach. We long ago decided that power measurement standards in most radio services in favor of output power measurement standards.
§ 97.67 Maximum authorized transmitting power.

(b) Each amateur radio transmitter may be operated with a peak envelope power output (transmitter power) not exceeding 1500 watts, except as provided in other limitations of these rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
48 CFR Ch. 3

Acquisition Regulation; Amendments

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule; amendments.

SUMMARY: This rule amends the final rule published in the Federal Register on April 9, 1984 (49 FR 13959-14051) that established the Department of Health and Human Services Acquisition Regulation (HHASAR) as Chapter 3 of Title 48, Code of Federal Regulations. The HHASAR implements and supplements the Federal Acquisition Regulation (FAR), Title 48 CFR Chapter 1. The amendments being made in this rule to 48 CFR Chapter 3 reflect comments made by the two respondents, as well as administrative, clerical, and typographical corrections disclosed by the Department.

EFFECTIVE DATE: September 14, 1984.

FOR FURTHER INFORMATION CONTACT: E.S. Lanham, Procurement Analyst, Division of Procurement Policy, telephone (202) 245-6901.

SUPPLEMENTARY INFORMATION: The final rule published on April 9, 1984 requested comments from interested parties, and comments were received from two organizations. The amendments being made in this rule to 48 CFR Chapter 3 reflect comments made by the two respondents, as well as administrative, clerical, and typographical corrections disclosed by the Department.

One amendment redesignates Appendix A, Single Letter of Credit Recipients and Central Point Addresses, and Appendix B, HHASAR Subject Index (not published in the Federal Register of April 9, 1984 but to appear in the Code of Federal Regulations) as Attachment I and Attachment II, respectively. This is being done to accommodate the forthcoming Public Health Service Acquisition Regulation (PHSAR) (published elsewhere in this issue of the Federal Register), which will implement and supplement the HHASAR, as Appendix A to Chapter 3 of Title 48, Code of Federal Regulations, to comply with a recent decision from the Office of the Federal Register concerning the treatment of lower tier Department/Agency implementations and supplementations under the FAR System. Accordingly, a change is also being made to paragraph (d) of section 301.304 to explain the designation of lower tier implementations and supplementations to the HHASAR.

Another amendment removes the term "[Reserved]", and the CFR paragraph designation to which the term refers, throughout Chapter 3 of Title 46 CFR. The purpose of this action is to eliminate any concern that the HHASAR may be disregarding or negating the corresponding text in the FAR. The intent was to present a sequential flow within the sections where the term appears to make it easier for the user to follow the text, and to eliminate possible user confusion that paragraphs might be mislabeled. However, since the term denotes a meaning other than that intended, it is being removed from the entire regulation.

A third amendment removes section 303.302 Reporting identical bids, and section 303.302-2 Reporting requirements, as a result of an amendment to the FAR transmitted by Federal Acquisition Circular Number 84-1, dated March 26, 1984 (49 FR 12972, March 30, 1984), eliminating the requirement for Federal agencies to report identical bids to the Attorney General.

A fourth amendment removes Subpart 305.2—Synopses of Proposed Contracts, also as a result of new FAR coverage transmitted by Federal Acquisition Circular Number 84-1 eliminating the need for HHASAR coverage on time of synopsisizing, and special situations—research and development advance notices (sections 305.203 and 305.205, respectively.)

The remaining amendments correct administrative, clerical and typographical errors. Several comments by the respondents addressed internal administrative guidance which were not incorporated because the guidance has little or no bearing on outside parties.

The provisions of this regulation are issued under 5 U.S.C. 301; 40 U.S.C. 486(c).

List of Subjects in 48 CFR Ch. 3

Government procurement.

Accordingly, the Department amends 48 CFR Chapter 3 as set forth below.
Henry G. Kirschenmann, Jr.,
Deputy Assistant Secretary for Procurement,
Assistance and Logistics.

As indicated in the preamble, Chapter 3 of Title 48, Code of Federal
Regulations is amended as shown.

1. Title 48 CFR Chapter 3 is amended
by removing the term "[Reserved]," and
the CFR designation that precedes it,
wherever they appear within the
Chapter.

2. Paragraph (d) of section 301.304 is
amended by adding the following after
the table showing the organizational
prefixes:

301.304 Agency control and compliance
procedure.

Each OPDIV or lower level acquisition
regulation will be included in its entirety
as a separate appendix to 48 CFR
Chapter 3. The Director, Division of
Procurement Policy will assign the
appendix designation upon approval of
the initial request to establish the
OPDIV or lower level acquisition
regulation.

301.501 [Amended]

3. In the first sentence of paragraph
(b) of section 301.501, the phrase "a
direct" is removed and replaced by the
word "an".

Subpart 303.3—Report of Suspected
Antitrust Violations

4. The heading of Subpart 303.3 is
revised to read as set forth above.

303.302 and 303.302-2 [Removed]
5. Sections 303.302 and 303.302-2 are
removed.
6. Section 304.201 is revised to read as
follows:

304.201 Procedures.
The signed original of bilateral
contracts and modifications shall be
placed in the contract file, and duplicate
originals shall be furnished the
contractor, the appropriate accounting
point, the project officer, and other
individuals or offices, as applicable.
Purchase orders, delivery orders, and
other unilateral contracts and
modifications shall be distributed the
same as bilateral contracts except the
original shall be furnished the contractor
or seller. Copies of unilateral contracts
and modifications with carbon
impressed signatures may be used
must be stamped "DUPLICATE
ORIGINAl" (see 304.101).

305.102 [Amended]
7. Section 305.102 is amended by
revising the dollar threshold in the third
sentence from "$5,000" to "$10,000".

Subpart 305.2 [Removed]
8. Subpart 305.2, consisting of sections
305.203 and 305.205, is removed.

307.105-2 [Amended]
9. In section 307.105-2[3][8], remove
the word "involve" and insert in its
place "concern the subjects of".

313.107 [Amended]
10. Paragraph (6) of section 313.107 is
removed.

315.406-5 [Amended]
11. In the last sentence of section
315.406-5[3][3][I][B] which begins
"However, care should be taken", add a
comma between the words "necessary"
and "to".

315.413-2 [Corrected]
12. Section 315.413-2 (p. 13986), the
introductory text, is amended by
correcting the reference to "315.215-12"
to read "352.215-12," and by correcting
the reference to "FAR 15.215-12" to read
"FAR 52.215-12".

315.670 [Corrected]
13. Section 315.670 (page 13991) is
corrected so that the section number
reads "315.670." Paragraph (d) of that
section is corrected by removing the
word "should" and inserting in its place
the word "shall."

315.7008 [Corrected]
14. Section 315.7008 is amended by
correcting the word "should" in the first
and second sentences to read "shall."

330.7000 [Corrected]
15. In section 330.7000, the references
to "FAR 32.205-10" in the first and last
sentences are corrected to read "FAR
31.205-10."

330.070-1 [Amended]
16. In the first sentence of section
335.070-1, add a comma and the phrase
"when authorized," between the phrases
"this type of contract" and "should also
be considered".

335.070 [Corrected]
17. The third section heading (Method
of cost sharing) under section 335.070
Cost sharing (p. 14021) is corrected to
read "335.070-3."

352.215-70 [Corrected]
18. In the text of the clause in section
352.215-70 (p. 14032), the word
"changes" is corrected to read
"charges."

Appendix A—[Redesignated as
Attachment I]
Appendix B—[Redesignated as
Attachment II]

19. Appendix A, Single Letter of
Credit Recipients and Central Point
Addresses, is redesignated Attachment
I, and Appendix B, HHSAR Subject
Index (not published in the April 9, 1984
dition of the Federal Register but to
appear in the Code of Federal
Regulations), is redesignated
Attachment II.

(5 U.S.C. 301; 40 U.S.C. 486(c))
[FR Doc. 84-24188 Filed 9-13-84; 8:45 am]
BILLING CODE 4150-04-M
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.

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 656

Labor Certification Process for the Permanent Employment of Aliens in the United States; Certification of Canadian Railway Workers; Withdrawal of Proposed Rule

AGENCY: Employment and Training Administration, Labor.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Department of Labor (DOL) is withdrawing a proposed rule for the certification of certain immigrant Canadian aliens for permanent employment in railway work in the United States. It has been determined that the labor certification process and rulemaking by DOL are inappropriate means for resolving this immigration issue.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Bruening, Telephone: 202-375-4228.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 102

Common or Usual Names for Nonstandardized Foods; Diluted Fruit or Vegetable Juice Beverages; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is providing another 45 days for interested persons to submit their comments on its proposal that would amend the regulation establishing common or usual names for diluted fruit or vegetable juice beverages. FDA is granting this extension based on requests for the extension of the comment period.

Comment date: October 29, 1984.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.


SUPPLEMENTARY INFORMATION: In the Federal Register of June 1, 1984 (49 FR 22831), FDA proposed to amend the regulation establishing common or usual names for diluted fruit or vegetable juice beverages—to exempt cranberry juice products from percent ingredient labeling requirements. The proposal would also allow manufacturers of other diluted high-acid juice beverages to request a similar exemption for their products. Additionally, FDA proposed to eliminate the requirement for the declaration of the percentage of individual juices in diluted multiple-juice beverages. FDA said it would retain the requirement that the total percentage of juice in multiple-juice beverages be declared in the labeling.

In that same issue of the Federal Register, FDA proposed to extend the effective date of 21 CFR 102.33 for affected products until the completion of this rulemaking (49 FR 22834). In the Federal Register of June 27, 1984 (49 FR 36541), FDA published a final rule extending the effective date of 21 CFR 102.33.

Additionally, based on two requests, in the Federal Register of July 31, 1984 (49 FR 30528), FDA extended the comment period for 45 days on its proposal to amend the regulation establishing common or usual names for diluted fruit or vegetable juice beverages.

The agency has received two requests to extend the comment period an additional 45 days. One request was submitted on behalf of the Processors Council of the California-Arizona Citrus League and the other was submitted by the National Juice Products Association. The associations seek the additional time to discuss the proposal at the National Juice Products Association’s mid-year meeting. The associations intend to use the meeting as a means of reaching a consensus regarding the position to be taken concerning the proposed rule.

The agency believes that, under these circumstances, extending the comment period an additional 45 days is reasonable and is likely to result in more informed and focused comments on the proposed rule. Therefore, interested persons may, on or before October 29, 1984, submit to the Dockets...
MANAGEMENT BRANCH (address above)
written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-24527 Filed 9-13-84; 8:45 am]
BILLING CODE 4160-01-M

DEPARTMENT OF AGRICULTURE
Forest Service
36 CFR Part 281

Land Disposal; Sale of Lands Pursuant to Section 10 of the Act Approved March 1, 1911

AGENCY: Forest Service, USDA.

ACTION: Proposed rule.

SUMMARY: The regulations at 36 CFR Part 281 were promulgated in 1955 to implement section 10 of the Weeks Act of March 1, 1911 (36 Stat. 961; 16 U.S.C. 490). Section 10 provides for the sale of small areas of land that are chiefly valuable for agriculture which may have been acquired as part of a larger tract for National Forest purposes. Since the regulations were promulgated, the Forest Service has not had a single instance requiring application of these regulations, and there is no foreseeable need for them. Therefore, the Agency proposes to remove Part 281 from the Code of Federal Regulations.


ADDRESS: Comments in the proposed rule may be sent to R. Max Peterson, Chief (5450), Forest Service, USDA, P.O. Box 2417, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Paul R. Haarala, Lands Staff, (202) 235-2161.

SUPPLEMENTARY INFORMATION: Over 27 million acres have been acquired for National Forest purposes under the authority of the Weeks Act. Over 20 million acres of those lands, which were acquired prior to 1961, were in poor condition because of excessive timber cutting, fire damage, and erosion from tillage of lands unsuitable for agriculture. Under Federal ownership, the productivity of these lands has been restored.

The Agency anticipates no future use of the Weeks Act sale regulations, since current Federal land acquisition programs preclude acquiring lands that are chiefly valuable for agricultural purposes.

This proposed action to revoke Part 281 has been reviewed under relevant USDA procedures, Executive Order 12291, and the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et. seq.), and it has been determined that:

(1) This rule is not a major rule;
(2) No effect on the economy will result from the repeal of this regulation;
(3) This action will not have a significant economic impact on a substantial number of small entities;
(4) It does not directly or indirectly result in information collection requirements or requests or impose any paperwork burden; and
(5) It does not affect the environment; therefore, an environmental assessment or impact statement is not required.

Therefore, for the reasons set forth in the preamble, it is proposed that Part 281 of Title 36 be removed from the Code of Federal Regulations.

List of Subjects in 36 CFR Part 281

Administrative practice and procedure, National forests, Public lands—sales.

Douglas W. MacCleery,
Deputy Assistant Secretary for Natural Resources and Environment.

[FR Doc. 84-24547 Filed 9-13-84; 8:45 am]
BILLING CODE 0410-11-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

(Docket No. 21323)

The Use of Subcarrier Frequencies in the Aural Baseband of Television Transmitters; Order Extending Time for Filing Comments and Reply Comments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment/reply period.

SUMMARY: Action taken herein extends the time for filing comments and replies to comments in response to the Second Further Notice of Proposed Rule Making in Docket No. 21323. This Further Notice requested additional information on the issue of whether to require cable television systems to retransmit program-related aural subcarriers of broadcast television stations.

Therefore, the Commission is interested in expeditiously completing the process of reviewing a proposal for allowing cable television systems to retransmit program-related aural subcarriers of broadcast television stations and ask for comments on a proposal for resolving it that was submitted jointly by the National Association of Broadcasters and the Association of Maximum Service Telecasters. The extension of time was requested by several parties.

DATES: Comments are due on or before October 4, 1984 and replies to comments are due on or before October 19, 1984.


FOR FURTHER INFORMATION CONTACT: Alan Stillwell, Mass Media Bureau, (202) 512-5302.

SUPPLEMENTARY INFORMATION:

Order Extending Time for Filing Comments to Second Further Notice of Proposed Rule Making

In the matter of the use of subcarrier frequencies in the aural baseband of television transmitters; Docket No. 21323.


By the Chief, Mass Media Bureau.

1. On July 26, 1984 the Commission adopted a Second Further Notice of Proposed Rule Making in Docket No. 21323 (49 FR 32619) to consider the issue of whether to require cable television systems to carry program-related aural subcarriers of broadcast television stations. The Further Notice was released on August 13, 1984 with a comment period due by September 19, 1984 and reply comments due by October 4, 1984.

2. On August 23, 1984, the National Association of Broadcasters, the Association of Maximum Service Telecasters, and the Corporation for Public Broadcasting submitted a joint petition to extend the comment period 15 days. Petitioners base their request on a plea that the Further Notice presents many complex questions some of which are complex, and the brevity of the comment period would prevent themselves and other parties from fully addressing the matter.

3. The Commission is interested in expeditiously completing the process of reviewing a proposal for allowing cable television systems to retransmit program-related aural subcarriers of broadcast television stations.

4. Accordingly, it is ordered that the time for filing comments and replies to comments to the above referenced Further Notice is extended to and including October 4, 1984 for comments and October 19, 1984 for reply comments.

In the matter of the use of subcarrier frequencies in the aural baseband of television transmitters; Docket No. 21323.


By the Chief, Mass Media Bureau.

1. On July 26, 1984 the Commission adopted a Second Further Notice of Proposed Rule Making in Docket No. 21323 (49 FR 32619) to consider the issue of whether to require cable television systems to carry program-related aural subcarriers of broadcast television stations. The Further Notice was released on August 13, 1984 with a comment period due by September 19, 1984 and reply comments due by October 4, 1984.

2. On August 23, 1984, the National Association of Broadcasters, the Association of Maximum Service Telecasters, and the Corporation for Public Broadcasting submitted a joint petition to extend the comment period 15 days. Petitioners base their request on a plea that the Further Notice presents many complex questions some of which are complex, and the brevity of the comment period would prevent themselves and other parties from fully addressing the matter.

3. The Commission is interested in expeditiously completing the process of reviewing a proposal for allowing cable television systems to retransmit program-related aural subcarriers of broadcast television stations.

4. Accordingly, it is ordered that the time for filing comments and replies to comments to the above referenced Further Notice is extended to and including October 4, 1984 for comments and October 19, 1984 for reply comments.
AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of reply comment period.

SUMMARY: This document extends the reply comment period in PR Docket No. 84-279 concerning Narrowband Technologies in the Private Land Mobile Radio Services; Order Extending Time for Filing Reply Comments.

DATE: Reply comments are now due by October 1, 1984.


SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 90

Administrative practice and procedure, Business and industry, Industrial radio services, Land transportation radio services, Public safety radio services.

Order

1. On April 4, 1984, the Commission released a Notice of Proposed Rule Making to propose the introduction of narrowband technologies in the Private Land Mobile Radio Services. Comments were originally due June 11, 1984, and reply comments July 11, 1984. The Land Mobile Communications Council (LMCC) requested an extension of time for filing comments. In an Order released June 5, 1984, the Commission granted LMCC's request, extending the comment period to August 10, 1984, and reply comment period to September 10, 1984. LMCC has now requested that the reply comment period be extended until October 1, 1984.

2. On August 10, 1984, LMCC submitted comments which contained a preliminary report prepared by a consulting firm evaluating the potential use of narrowband technologies. The final version of that report was submitted to the Commission on August 31, 1984. LMCC argues that the current reply period is not sufficient for interested parties to have an adequate opportunity in which to respond to the report and, therefore, an additional extension of time is warranted.

In order to develop a complete record on which to base our decision, it appears that a further extension of time is now necessary to provide all parties sufficient opportunity to address all comments in this proceeding. Accordingly, it is ordered, pursuant to the authority set forth in § 0.331 of the Commission's Rules, that interested persons are to file reply comments by October 1, 1984.

Federal Communications Commission.

Robert S. Foosener,
Chief, Private Radio Bureau.

[PR Doc. 84-2493 Filed 7-13-84; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 97

Request for Federal Preemption of Local Amateur Radio Antenna Zoning

AGENCY: Federal Communications Commission.

ACTION: Request for comments.

SUMMARY: This notice requests comments on a Request for Issuance of Declaratory Ruling filed by the American Radio Relay League seeking Federal preemption of state and local zoning laws and regulations in matters of amateur radio antennas and transmitters. While it is not required that this notice be published in the Federal Register, the Register is being used in this instance as one additional method of seeking comments from the public because of the potential impact this matter could have on persons outside of the field of communications.

DATES: Comments must be filed on or before November 9, 1984. Reply comments must be filed on or before December 14, 1984.


SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 97

Amateur radio, Antennas.


August 30, 1984.

On July 16, 1984, the American Radio Relay League, Incorporated (the ARRL) filed a Request for Issuance of Declaratory Ruling requesting the Commission to exercise federal preemptive authority over state and local zoning regulations which affect transmitters and antennas used by amateur radio operators. Specifically, the ARRL seeks a declaratory ruling preempting all local ordinances which unreasonably or significantly inhibit effective, reliable amateur communications, and which are not clearly necessary to assure the safety of a proposed antenna installation.

The Private Radio Bureau seeks comments on this filing. Parties wishing to file formal comment on the issues raised therein should do so by filing an original and four copies with the Secretary, Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554, on or before November 9, 1984. Reply comments may be filed on or before December 14, 1984. Comments and reply comments should refer to the following number: PRB-1.

Copies of the ARRL's Request for Issuance of Declaratory Ruling and any subsequently filed documents in this matter may be obtained from International Transcription Services, Inc., 1270 Fairfield Road (Route 116 West), Gettysburg, Pennsylvania 17325, (717) 337-1433 or 4006 University Drive, Fairfax, Virginia 22030, (703) 352-2400 or (202) 296-7322. Any documents related to this matter will also be available for inspection and copying in the Private Radio Bureau Public Reference Room, 1270 Fairfield Road (Route 116 West), Gettysburg, Pennsylvania 17325.

For further information contact John J. Borkowski at (202) 632-4964.

William J. Tricarico,
Secretary, Federal Communications Commission.

[FR Doc. 84-24380 Filed 8-13-84; 8:45 am]

BILLING CODE 6712-01-M
Amendments to GSA Board of Contract Appeals Rules of Procedure

AGENCY: Board of Contract Appeals, GSA.

ACTION: Request for comments.

SUMMARY: This notice invites written comments on proposed amendments to the rules of procedure of the GSA Board of Contract Appeals which will govern proceedings before the Board in protests involving automatic data processing equipment (ADP) procurements.

DATE: Comments must be submitted on or before October 15, 1984.

ADDRESS: Copies of the proposed rules may be obtained from and written comments submitted to: Office of the Clerk of the Board, c/o Ms. Beatrice Jones, Rm. 7204, GSA Board of Contract Appeals, 18th & F Sts., NW, Washington, DC 20435, (202) 566-0716.

FOR FURTHER INFORMATION CONTACT: James J. Regan, Chief Counsel, GSA Board of Contract Appeals, (202) 566-0890.

SUPPLEMENTARY INFORMATION: Section 2713 of the Competition in Contracting Act of 1984, 40 U.S.C. 759(h), provides that protests involving procurement of ADP may be filed with the Board on or after January 15, 1985. The Act also provides that the Board is to adopt and issue rules and procedures necessary for the expeditious resolution of such protests. Amendments have been made to the Board's rules of procedure for contract disputes and appeals, effective June 1, 1984, which appear in Appendix B to 48 CFR Chapter 5.

Impact

The Director, Office of Management and Budget (OMB), by memorandum dated October 4, 1982, exempted agency procurement regulations from Executive Order 12291. The General Services Administration certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.); therefore, no regulatory flexibility analysis has been prepared. The rules do not contain information collection requirements which require the approval of OMB under 44 U.S.C. 3501 et seq.

List of Subjects in 48 CFR Chapter 5

Government procurement.
DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

1985 Wheat Program; Determinations Regarding the Proclamation of 1985-Crop Program Provisions for Wheat

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice of Determinations of the 1985-crop wheat loan and purchase rate, established (target) price, combined acreage reduction and land diversion program, payment-in-kind diversion program, grazing and haying provisions, and other program provisions.

SUMMARY: The purpose of this notice is to affirm the following determinations which were announced by the Secretary of Agriculture on June 14, 1984 with respect to the 1985 crop of wheat: (1) The loan and purchase rate will be $3.30 per bushel; (2) the established (target) price will be $4.38 per bushel; (3) an acreage reduction program for wheat will be in effect with a uniform reduction of 20 percent combined with a land diversion program of 10 percent; (4) the 1985 acreage base will be the average acreage planted and considered planted to wheat for the 1983 and 1984 crops; (5) the land diversion payment rate will be $2.70 per bushel; (6) there will be no optional land diversion program with payment-in-kind compensation; (7) there will be no haying and only limited grazing of acreage devoted to acreage conservation reserve; (8) the decision on whether entry will be permitted into the farmer-owned reserve will be made at a later date; (9) offsetting compliance will not apply; and (10) summer fallow land will be eligible for designation as acreage conservation reserve, and (11) binding contracts must be executed by producers in order to participate in the 1985 Wheat Program. These determinations are made in accordance with sections 107B, 107C, 109 and 110 Act of 1949, as amended (hereinafter referred to as the “1949 Act”).

EFFECTIVE DATE: June 14, 1984.

ADDRESS: Dr. Howard C. Williams, Director, Commodity Analysis Division, USDA-ASCS, Room 3741, South Building, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT: Bruce R. Weber, Agricultural Marketing Specialist, Commodity Analysis Division, USDA-ASCS, P.O. Box 2415, Washington, D.C. 20013 or call (202) 447-4146. The Final Regulatory Impact Analysis describing the options considered in developing this Notice of Determinations is available on request from the above-named individual.

SUPPLEMENTARY INFORMATION: This notice has been reviewed under USDA procedures established in accordance with Executive Order 12291 and Department Regulation No. 1512-1 and has been designated as “major”. It has been determined that these program provisions will result in an annual effect on the economy of $100 million or more.

The title and number of the federal assistance program to which this notice applies is: TITLe—Commodity Loans and Purchases: Number 10.051, as found in the Catalog of Federal Domestic Assistance.

It has been determined that the Regulatory Flexibility Act is not applicable to this notice since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of these determinations. This notice sets forth determinations with respect to the following issues which are briefly described.

1. The Loan and Purchase Level

Section 107B(a) of the 1949 Act provides that the Secretary shall make available to producers loans and purchases for the 1983 crop of wheat at such level, not less than $3.55 per bushel, as the Secretary determines will maintain the competitive relationship of wheat to other grains in domestic and export markets after taking into consideration the cost of producing wheat, supply and demand conditions, and world prices for wheat. If the Secretary determines that the average price of wheat received by producers in any marketing year is not more than 105
percent of the level of loans and purchases for wheat for such marketing year, the Secretary may reduce the level of loans and purchases for the next marketing year by the amount the Secretary determines necessary to maintain domestic and export markets for grain, except that the level of loans and purchases shall not be reduced by more than 10 percent in any year nor below $3.00 per bushel.

2. The Established (Target) Price Level

Section 107B(b)(1)(C) of the 1949 Act provides that the established (target) price for wheat shall not be less than $4.38 per bushel for the 1985 crop. Any such established price may be adjusted by the Secretary as the Secretary determines to be appropriate to reflect any change in (i) the average adjusted cost of production per acre for the two crop years immediately preceding the year for which the determination is made from (ii) the average adjusted cost of production per acre for the two crop years immediately preceding the year previous to the one for which the determination is made.

3. Acreage Reduction Program and Cash Land Diversion Program

Sections 107B(e)(1)(D) and (2) of the 1949 Act require that the Secretary provide for a combination of an acreage reduction program (ARP) and a cash land diversion (CLD) program for the 1985 crop of wheat under which the acreage planted to wheat for harvest on the farm would be limited to the acreage base for the farm reduced by not more than 30 percent, consisting of an acreage reduction program of not more than 20 percent and a reduction of 10 percent under the cash land diversion program. As a condition of eligibility for loans, purchases, and payments on the 1985 crop of wheat, the producers on a farm must comply with the terms and conditions of the combined ARP and CLD program. The Secretary shall announce any such wheat acreage reduction program not later than July 1 prior to the calendar year in which the crop is harvested. Such limitation shall be achieved by applying a uniform percentage reduction to the acreage base for each wheat-producing farm. Producers who knowingly produce wheat in excess of the permitted wheat acreage for the farm shall be ineligible for wheat loans, purchases, and payments with respect to that farm. In addition, a number of acres on the farm determined by dividing (1) the product obtained by multiplying the number of acres required to be withdrawn from the production of wheat times the number of acres actually planted to wheat by (2) the number of acres authorized to be planted to wheat under a limitation established by the Secretary shall be devoted to conservation uses in accordance with regulations issued by the Secretary.

4. Establishment of Acreage Bases

Section 107B(e)(2) of the 1949 Act provides that the acreage base for any farm for the purpose of determining any reduction required to be made for any year as a result of a limitation shall be the acreage planted on the farm to wheat for harvest in the crop year immediately preceding the year for which the determination is made or, at the discretion of the Secretary, the average acreage planted to wheat for harvest in the two crop years immediately preceding the year for which the determination is made. The Secretary may make adjustments to reflect established crop-rotation practices and to reflect such other factors as the Secretary determines should be considered in determining a fair and equitable base.

5. Cash Land Dimension Payments

Section 107B(e)(5) of the 1949 Act provides that the Secretary shall implement a CLD program for the 1985 crop of wheat under which the Secretary shall make crop retirement and conservation payments to any producer whose acreage planted to wheat for harvest on the farm for such crop is reduced so that it does not exceed the wheat acreage base for the farm, less an amount equivalent to 10 percent of the wheat acreage base, in addition to the ARP reduction, and who devotes this acreage to approved conservation uses. Such payments shall be made in an amount computed by multiplying (1) the diversion payment rate by (2) the farm program payment yield for the crop by (3) the additional acreage diverted under the cash land diversion program. The CLD payment rate for the 1985 crop of wheat shall be established by the Secretary at not less than $2.70 per bushel. The Secretary shall make not less than 50 percent of the CLD program payments to producers of the 1985 crop of wheat as soon as practicable after a producer enters into a cash land diversion contract and in advance of any determination of performance.

8. Optional Land Diversion Program

An additional land diversion program with compensation being made available in the form of commodities (i.e., Payment-In-Kind) to participating producers is authorized by the 1949 Act and the CCC Charter Act.

The 1949 Act authorizes the Secretary to make diversion payments to producers of wheat if the Secretary determines that such payments are necessary to assist in adjusting the total national acreage of wheat to desirable goals. The CCC Charter Act (15 U.S.C. 714 et seq.) also gives the Commodity Credit Corporation (CCC) broad authority to support the price of agricultural commodities, stabilize agricultural commodity markets and remove and dispose of agricultural surpluses.

7. Haying and Grazing of Acreage

The Secretary may authorize haying and grazing of acreage devoted to the acreage conservation reserve (ACR).

8. Provisions of the Farmer-Owned Reserve (FOR)

Section 110 of the 1999 Act provides that the Secretary shall formulate and administer a program under which producers of wheat will be able to store wheat when it is in abundant supply and extend the time for its orderly marketing. The Secretary shall provide for original or extended price support loans at such level of support as the Secretary determines appropriate, except that the loan rate shall not be less than the current level of price support provided for under the wheat program established in accordance with section 107B(e) of the 1949 Act.
1. Loan and Purchase Level

With respect to the loan and purchase level, a total of 40 comments were received with 16 favoring a higher loan and purchase level than in 1984, 7 favoring the same level and 17 favoring a lower loan and purchase level. Most farmers (52 percent) favored increasing the loan and purchase level for the 1985 crop while nearly three-quarters of the farmers organizations submitting comments favored a lower level.

2. Established "Target" Price

With respect to the established (target) price, a total of 27 comments were received with 12 favoring a higher target price than in 1984, and 15 supporting the same target price. Comments favored a target price in the $4.36 to $7.00 range.

3. Acreage Reduction/Cash Land Diversion Program

A total of 27 comments were received with 21 favoring a 20-percent ARP/10-percent CLD program. Other comments supported either a 15-percent ARP/10-percent CLD or a 10-percent ARP/10-percent CLD.

4. Cash Land Diversion Payment

A total of 15 comments were received with 6 favoring a $2.70 per bushel payment rate. The others favored a higher rate ranging from $2.74 to $4.00 per bushel.

5. Optional Land Diversion Program With Payment-In-Kind (PIK) Payments

A total of 29 comments were received with 21 favoring an optional 10-20 percent land diversion program with PIK payments ranging from 80 to 90 percent of farm program payment yield. Two comments opposed an optional diversion program while six recommended other types of optional programs.

6. Haying and Grazing of Acreage Conservation Reserve (ACR) Land

Over 80 percent of the 52 comments received favored the haying and grazing of ACR acreage. The majority also favored the option of allowing State ASC committees to determine whether or not haying or grazing should be authorized. The National Hay Association and several State Hay organizations opposed the haying of ACR land.

7. Provisions of the Former-Owned Reserve (FOR)

A total of 18 comments were received. The majority favored (1) having the same loan level for reserve loans as the loan level for regular price support loans; (2) a storage payment rate at 26.5 cents per bushel; and (3) entry into the reserve at maturity of the regular 9-month price support loan.

8. Offsetting Compliance

A total of 31 comments were received with 20 opposed to implementation of offsetting compliance requirements.

9. Summer Fallow Rules

A total of 37 comments were received with 32 favoring designation of summer fallow acreage as ACR.

10. Binding Program Contracts

A total of 31 comments were received with 26 favoring binding contracts for the 1985 Wheat Program. A large majority favored the binding contract at conclusion of the signing period, while others felt the contract should be binding at a later date.


a. Offsetting Compliance

Section 107B(g) of the 1949 Act provides that the Secretary may issue such regulations as the Secretary determines to be necessary to carry out the wheat program. The Secretary may promulgate regulations providing for offsetting compliance requirements. If such regulations are implemented, operators and owners of farms would have to ensure that all of the farms in which they had an interest were either in compliance with the program requirements or the acreages of wheat planted for harvest on each of such farms did not exceed the wheat acreage bases which were established for such farms.

b. Summer Fallow Rules

The Secretary may authorize the designation of summer fallow land as ACR acreage.

c. Binding Program Contracts

The Secretary may require that program contracts between producers and CCC be binding. These contracts may also provide for liquidated damages in the event producers do not fulfill the terms and conditions of the contracts.

Summary of Public Comments

A proposed notice of determination with respect to the 1985 crop of wheat was published in the Federal Register on May 11, 1984, (49 FR 20037) and provided for a 30-day comment period. The comment period was limited to 30 days to allow the Secretary sufficient time to properly consider the comments received before the final program determinations were made. A total of 67 comments were received. Comments were received on all issues discussed above. Following is a summary of the comments received:
1984/85 marketing year is not expected to be more than 105 percent of the level of loans and purchases for the 1984/85 marketing year. Accordingly, to provide producers with the same total returns as if the loan and purchase rate had not been reduced, it has been determined that any established price "deficiency" payment above 83 cents per bushel (the difference between the target price of $4.38 per bushel and the statutory minimum loan price of $3.55 per bushel) will not be included in the determination of payments which are subject to the $50,000 maximum payment limitation imposed by Section 1101 of the Food and Agriculture Act of 1981.

3. Acreage Reduction/Cash Land Diversion Program

In accordance with section 107B[e][2][D] of the 1949 Act, it has been determined that a 30 percent reduction shall be implemented consisting of a 20 percent ARP combined with a 10 percent CLD. Producers will be required to reduce their 1985 acreage of wheat for harvest from the established acreage base by at least 30 percent to be eligible for loans, purchases, and payments. It has been determined that the total supply of wheat, in the absence of such limitations, will be excessive.

4. Establishment of 1985-Crop Acreage Bases

In accordance with section 107B[e][2] of the 1949 Act, it has been determined that the 1985 wheat acreage bases shall be established using the average of the acreage planted and considered planted to wheat for the 1983 and 1984 crops. For farms where crop rotation practices are utilized, the acreage base shall be the acreage planted and considered planted to wheat in the immediately prior years that correspond to the farm's rotation practice. This method was selected to moderate the impacts of overplantings on farms not participating in the commodity production adjustment programs in prior years.

5. Cash Land Diversion Payment

In accordance with section 107B[e][5] of the 1949 Act, it has been determined that the CLD payment rate shall be $2.70 per bushel, which is the minimum statutory level. Producers entering into a land diversion contract may receive one-half of the diversion payment in advance of any determination of performance of the contract.

6. Optional Land Diversion Program With Payment-In-Kind (PIK) Compensation

It has been determined that no optional land diversion program with PIK compensation will be offered to producers for the 1985 crop of wheat. When the PIK program was implemented for the 1983 crops it was announced as a short-term measure for the 1983 crops and, perhaps, the 1984 crops. To extend this program into the 1985 crop would run counter to the efforts to regain our competitiveness in the world markets. A more aggressive acreage reduction program would signal to the rest of the world that the U.S. was willing to continue to assume the world supply adjustment burden while allowing our competitors in world markets to expand their production and reap the benefits of any resultant price strength.

7. Haying and Grazing of Acreage Conservation Reserve (ACR) Acreage

In accordance with section 107B[e][4] of the 1949 Act, it has been determined that haying of cover crops on ACR acreage will not be permitted. However, ACR acreage may be grazed except during the six principal growing months as designated by county Agricultural Stabilization and Conservation (ASC) committees. In the event of a natural disaster, emergency haying and grazing may be approved as needed on a county-by-county basis.

The unrestricted haying and grazing of ACR acreage, which was permitted for the 1984 crop, was not extended for the following reasons: (1) Haying of ACR creates a new supply of hay and can adversely impact the established hay industry; (2) the 1985 program was announced well in advance of the fall seedings of winter wheat thereby allowing farmers sufficient time to plan their fall seedings based on full knowledge of the applicable program provisions; and (3) the announced grazing provisions will allow county ASC committees to permit grazing of ACR acreage through the end of April, a time period which is considered to be adequate to provide maximum grazing benefits from the ACR cover and still properly protect the land from wind and water erosion.

It is further determined that the planting of alternative crops for harvest on ACR acreage will not be permitted.

8. Provisions of the Farmer-Owned Reserve (FOR)

In accordance with section 110 of the 1949 Act, the Secretary has determined that there will be no immediate entry into the farmer owned reserve program for the 1985 crop. Further, the Secretary intends to review the size of the reserve before regular price support loans for the 1985 crop reach maturity. A determination whether to impose a limitation on the size of the reserve will be made accordingly.

9. Offsetting Compliance

In accordance with section 107B[g] of the 1949 Act, it has been determined that offsetting compliance will not be required as a condition of eligibility for program benefits on a farm where a producer has an interest in more than one farm.

10. Summer Fallow Rules

With respect to farms with a summer fallow rotation, acreage designated as ACR must be cropland that was devoted to row crops or small grains in one of the last two crop years. It has been determined that this action was necessary to achieve a high level of participation in the 1985 Wheat Program in the summer fallow regions.

11. Binding Program Contracts

Contracts signed by program participants for the ARP and CLD program will be considered binding at the end of the signup period and will provide for liquidated damages if producers do not comply with contractual arrangements. It has been determined that binding contracts will ensure a high level of compliance by those producers enrolling into the program and will also result in a more effective program.


Everett Rank, Executive Vice President, Commodity Credit Corporation.

[FR Doc. 84-24424 Filed 9-13-84; 8:45 am]

BILLING CODE 3410-05-48

Forest Service

Joint Interchange Order Between Department of the Army and Department of Agriculture; Interchange of Administrative Jurisdiction of Department of the Army Lands and National Forest Lands

This is a notice of an interchange order which describes the interchange of administrative jurisdiction of 17.27 acres of land within the boundaries of the Daniel Boone National Forest, Kentucky, from the Department of Agriculture to the Department of the Army and the interchange of administrative jurisdiction of 5,766.07 acres of land
This order will be effective as of the date of publication in the Federal Register.

Dated: July 2, 1984.

John O. Marsh, Jr.
Secretary of the Army.

This order will be published as follows:


E. Max Peterson,
Chief.

DEPARTMENT OF AGRICULTURE
DEPARTMENT OF THE ARMY
Cave Run Lake, KY, Joint Order
Interchanging Administrative Jurisdiction of the Department of the Army Lands and National Forest Lands

Interchange Order No. 3

By virtue of the authority vested in the Secretary of Agriculture and the Secretary of the Army by the Act of July 26, 1956 (70 Stat. 656; 16 U.S.C. 505a, 306), it is ordered as follows:

(1) The lands under the jurisdiction of the Department of the Army described in Exhibit A, attached hereto and made a part hereof, which are a part of the Daniel Boone National Forest, Kentucky, are hereby transferred from the jurisdiction of the Secretary of Agriculture to the jurisdiction of the Secretary of Agriculture, subject to outstanding rights or interests of record and to such continued use by the Corps of Engineers as is necessary for the construction, protection, and unrestricted operation, maintenance, and administration of the water storage and flood-control facilities and functions of the Cave Run Lake.

(2) The National Forest lands described in Exhibit B, attached hereto and made a part hereof, which are a part of the Daniel Boone National Forest, Kentucky, are hereby transferred from the jurisdiction of the Department of the Army for or in connection with the Cave Run Lake project, in Bath, Rowan, Menifee, and Morgan Counties, Kentucky.

Dated: April 17, 1984.

John R. Block,
Secretary of Agriculture.

Exhibit A.—Lands Transferred From the Secretary of the Army to the Secretary of Agriculture
The following listed tracts acquired by the Department of the Army for or in connection with the Cave Run Lake project, in Bath, Rowan, Menifee, and Morgan Counties, Kentucky, are hereby transferred from the Department of the Army to the Department of Agriculture.

Dated: July 2, 1984.

This final interchange of lands at the Cave Run Lake project includes (1) all mineral interests acquired or extinguished, since been acquired or extinguished. This final interchange of lands at the Cave Run Lake project includes (1) all mineral interests acquired or extinguished.

Exhibit B.—Lands Transferred From the Secretary of Agriculture to the Secretary of the Army

A portion of U.S. Forest Service Tract 172 consisting of 17.27 acres, more or less, in Rowan County, Kentucky, acquired by the Department of Agriculture as a part of the Daniel Boone National Forest.

A complete legal description and plat are on file in the office of the District Engineer, U.S. Army Engineer District, Louisville, Kentucky, of the office of the District Engineer, U.S. Army Engineer District, Louisville, Kentucky.

BILLING CODE 3410-11-M
DEPARTMENT OF COMMERCE
International Trade Administration

[52x743]36120

Federal Register / Vol. 49, No. 180 / Friday, September 14, 1984 / Notices

International Trade Administration

[53x630]A-588-045

Agency:

Review of Antidumping Finding
Preliminary Results of Administrative
Commerce.

SUMMARY: The Department of Commerce has conducted an administrative review of the antidumping finding on steel wire rope from Japan. The review covers 102 of the 121 known manufacturers and/or exporters and two of the four known third-country resellers of this merchandise to the United States and generally the period October 1, 1982, through September 30, 1983. The review indicates the existence of dumping margins for certain firms during the period.

As a result of the review, the Department has preliminarily determined to assess dumping duties equal to the calculated differences between United States price and foreign market value on each of their shipments during the period.

When company-supplied information was inadequate or no information was received in response to our questionnaire, we used the best information available for assessment and estimated antidumping duties cash deposit purposes.

Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: September 14, 1984.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:
Background

On March 29, 1984, the Department of Commerce ("the Department") published in the Federal Register (49 FR 12294) the final results of its last administrative review of the antidumping finding on steel wire rope from Japan (39 FR 28571, October 15, 1973) and announced its intent to conduct the next administrative review. As required by section 751 of the Tariff Act of 1930 ("the Tariff Act"), the Department has now conducted that administrative review.

Scope of the Review

Imports covered by the review are shipments of steel wire rope, except brass electroplated steel truck tire cord of cable construction specially packaged for protection against moisture and atmosphere. Such steel wire rope is currently classifiable under items 642.1200, 642.1400, 642.1500, 642.1600, and 642.1700 of the Tariff Schedules of the United States Annotated.

The review covers 102 of the 121 known manufacturers and/or exporters and two of the four known third-country resellers of Japanese steel wire rope to the United States and generally the period October 1, 1982, through September 30, 1983. We are deferring our review of the remaining 21 firms until a subsequent administrative review.

Fifty-five firms did not ship Japanese steel wire rope to the United States during the period. The estimated antidumping duties cash deposit rates for those firms will be the most recent rate for each firm. Twenty-six firms failed to respond to our questionnaire or provided inadequate responses to our questionnaire, and one firm did not permit the Department to conduct an on-site verification of its response to our questionnaire. For those 27 firms we used the best information available to determine the assessment and estimated antidumping duties cash deposit rates. The best information available is the most recent rate for each firm or the highest rate among responding firms with shipments in the period, whichever is higher.

United States Price

In calculating United States price the Department used purchase price, as defined in section 772 of the Tariff Act. Purchase price was based either on the f.o.b. or c.i.f. packed price to unrelated purchasers in the United States or to unrelated trading companies for export to the United States. Where applicable, we made deductions for foreign inland freight, f.o.b. charges, ocean freight, insurance, and quantity discounts. No other adjustments were claimed or allowed.

Foreign Market Value

In calculating foreign market value the Department used home market price, the price to a third country (Australia), or the constructed value, all as defined in section 773 of the Tariff Act. Home market and third-country prices were based on the packed delivered price to unrelated purchasers. We made adjustments, where applicable, for inland freight, f.o.b. charges, ocean freight, and differences in the cost of packing, warranty, and credit. Constructed value was calculated as the sum of materials, fabrication costs, general expenses, profit, and the cost of packing. The amount added for general expenses was one percent of the sum of materials and fabrication costs, or actual general expenses, whichever was higher. The amount added for profit was eight percent of the sum of materials, fabrication costs, and general expenses, or actual profit, whichever was higher.

Due to an allegation by the petitioner, the Committee of Domestic Steel Wire Rope and Specialty Cable Manufacturers, in order to determine the producers of the dump product, we requested those firms that were not shown in a previous review to be selling substantially all of their wire rope in the home market at prices above their costs of production to provide cost of production information. We did not receive adequate cost of production data from any such firm.

Preliminary Results of the Review

As a result of our comparison of United States price to foreign market value, we preliminarily determine that the following margins exist for the period October 1, 1982, through September 30, 1983:

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<th>Manufacturer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ace Industrial Co., Ltd.</td>
<td>9.38</td>
</tr>
<tr>
<td>Asahi Rope, K.K.</td>
<td>7.95</td>
</tr>
<tr>
<td>Asahi Mini Rope Co., Ltd.</td>
<td>9.38</td>
</tr>
<tr>
<td>Chrysanthemum Nippon Wire Rope Co., Ltd.</td>
<td>11.61</td>
</tr>
<tr>
<td>Chrysanthemum Nippon Wire Rope Co., Ltd./Fuji Trading Co., Ltd.</td>
<td>0.68</td>
</tr>
<tr>
<td>Chrysanthemum Nippon Wire Rope Co., Ltd./Kurt Moore, Inc.</td>
<td>11.61</td>
</tr>
<tr>
<td>Chuo Senkakusho Ltd./Koshin Co., Ltd.</td>
<td>10.36</td>
</tr>
<tr>
<td>Chuo Senkakusho Ltd./all other exporters</td>
<td>1.21</td>
</tr>
<tr>
<td>Dieco Corp.</td>
<td>7.29</td>
</tr>
<tr>
<td>Daisen Kogyo</td>
<td>5.95</td>
</tr>
<tr>
<td>Dasawa Wire Co., Ltd. (also known as Dasawa Kogyo K.K.)</td>
<td>6.68</td>
</tr>
<tr>
<td>Deyu Kogyo Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Dia Enterprises, Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>J. Gebrer &amp; Co. (Japan)</td>
<td>10.75</td>
</tr>
<tr>
<td>Goto Tessen Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Hakko Sangyo Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Hamann Wire Rope Mfg. Co., Ltd./Far East Industrial Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Hamann Wire Rope Mfg. Co., Ltd./Higashinaka &amp; Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Hidaka Wire Mfg. Co., Ltd./Hori Trading Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Iga Wire Rope Co., Ltd./Amitani Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Iga Wire Rope Co., Ltd./Kumamoto Shokan (formerly known as Osaka Ship Supply Center)</td>
<td>11.21</td>
</tr>
<tr>
<td>Inaba Wire Rope Mfg. Co., Ltd./Motsumi &amp; Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Kasuga Seiko Co., Ltd./Higashinaka &amp; Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Kasuga Seiko Co., Ltd./Kohshin Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Kasuga Seiko Co., Ltd./Kohshin Co., Ltd.</td>
<td>11.21</td>
</tr>
<tr>
<td>Kasuga Seiko Co., Ltd./Sunimoto Corporation (also known as Sumimoto Shop Kabushiki Kaisha)</td>
<td>11.21</td>
</tr>
<tr>
<td>Kawashima Trading Co., Ltd.</td>
<td>8.65</td>
</tr>
<tr>
<td>Kawataku Wire Products Ltd./Mitsui &amp; Co., Ltd.</td>
<td>8.31</td>
</tr>
<tr>
<td>Kikai Steel Wire Rope Co., Ltd./Walisemra Trading Co., Ltd.</td>
<td>11.21</td>
</tr>
</tbody>
</table>
Interestingly, parties may submit written comments on these preliminary results within 30 days of the date of publication of this notice and may request disclosure and/or a hearing within 10 days of the date of publication. Any hearing, if requested, will be held 45 days after the date of publication or the first workday thereafter. Any request for a hearing shall be made no later than 5 days after the date of publication. The Department will publish the final results of the administrative review including the results of its analysis of any such comments or hearing. The Department shall determine, and the Customs Service shall assess, dumping duties on all appropriate entries. Individual differences in United States price and foreign market value may vary from the percentages stated above. The Department will issue appraisement instructions directly to the Customs Service.

Further, as provided for by § 353.46(b) of the Commerce Regulations, a cash deposit of estimated antidumping duties based on the most recent of the above margins shall be required for those firms. Since the weighted-average margin for Marusen Wire Rope Mfg. Co., Ltd. /Yutoku & Co., Ltd. is less than 0.50 percent and, therefore, de minimis for cash deposit purposes, the Department shall waive the deposit requirement for that manufacturer/exporter combination. For any future entries from a new exporter not covered in this or prior reviews, whose first shipments of Japanese steel wire rope occurred after September 30, 1983, and who is unrelated to any reviewed firm, a cash deposit of 11.21 percent shall be required. These deposit requirements are effective for all shipments of Japanese steel wire rope entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1673a(a)(1)) and § 353.53 of the Commerce Regulations (19 CFR 353.53).

Dated: September 6, 1984.

Alan F. Holmer,
Deputy Assistant Secretary for Import Administration.

[FR Doc. 84-24490 Filed 9-13-84; 8:45 am]
BILLING CODE 3510-05-M

Licensing Procedures Subcommittee of the Computer Systems Technical Advisory Committee; Open Meeting

AGENCY: International Trade Administration, Commerce.


Previously announced time and date of the meeting: 1:00 p.m., September 25, 1984.

Changes in the Meeting:

9:30 a.m., September 26, 1984, Herbert C. Hoover Building, Conference Room A, 14th Street and Constitution Avenue N.W., Washington, D.C.


Milton M. Ballas,
Director of Technical Programs, Office of Export Administration.

[FR Doc. 84-24497 Filed 9-13-84; 8:45 am]
BILLING CODE 3510-26-M
Case History

On March 29, 1984, we received a petition filed by AMAX Chemicals Inc., Lakeland, Florida, and Kerr-McGee Chemical Corporation, Oklahoma City, Oklahoma, on behalf of U.S. producers of potassium chloride who represent a major portion of that industry. In compliance with the filing requirements of § 355.26 of our regulations (19 CFR 355.26), the petition alleges that manufacturers, producers, or exporters in Israel of potassium chloride receive, directly or indirectly, bounties or grants within the meaning of section 303 of the Act and that these imports are materially injuring or threatening to materially injure, a U.S. industry.

We found the petition to contain sufficient grounds upon which to initiate a countervailing duty investigation and, on April 13, 1984, we initiated such an investigation (49 FR 18001).

Israel is not a “country under the Agreement” within the meaning of section 701(b) of the Act; therefore, section 303 of the Act applies to this investigation. Section 303(a)(2) of the Act requires an injury determination by the ITC, since the merchandise enters the United States duty-free and the international obligations of the United States so require.

We presented questionnaires concerning the allegations to the government of Israel and Dead Sea Works Ltd. (DSW), the only known Israeli producer or potassium chloride, in Washington, D.C., on April 23, 1984, and requested a response by May 23, 1984. In a letter dated May 2, 1984, DSW requested an extension until June 8 to submit its response. We granted an extension until May 29. On that date we received responses from the Israeli government and DSW. On May 17, 1984, we denied a government of Israel request that we consider this case extraordinarily complicated.

On June 25, 1984, we preliminarily determined that benefits that constitute bounties or grants within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters in Israel of postassium chloride. For purposes of this investigation, the following programs are found to confer bounties or grants:

- Investment Grants under the Encouragement of Capital Investment Law 5719-1959 (ECIL).
- Export Shipment Fund Under ECIL.
- Export Production Fund Under ECIL.
- Imports-For-Exports Fund Under ECIL.

The bounty or grant is 3.64 percent ad valorem.

Analysis of Programs

Based upon our analysis of the petition, the responses to our questionnaires, our verification, and the parties’ comments we determine the following:

I. Programs Determined to Confer Bounties or Grants

We determine that bounties or grants being provided to DSW under the following programs:

A. ECIL Investment Grants

The purpose of “The Encouragement of Capital Investments Law, 5719-1959 (ECIL)” is to attract capital to Israel with a view toward developing the productive capacity of the national economy, improving the balance of payments, absorbing immigration, and offsetting the economic disadvantages in Israel’s development areas.

Investment grants are given as a percentage of the investment. The percentage varies according to the location of a project. “Approved projects” located in Zone A are entitled to receive a grant amounting to 30 percent of the total investment in fixed assets; “approved projects” in Zone B are entitled to receive a grant amounting to 15 percent of the total investment; and those in Zone C are not entitled to receive grants. Any company located in Zone A, regardless of the industry, is eligible for grants. Only projects that demonstrate economic viability are approved. After the Investment Center approves a project, it instructs a commercial bank to disburse the grant funds to the grant recipient.

DSW, which is located in Zone A, received various ECIL grants during the years 1972 through 1982 for the purposes of plant enlargement and the construction of dikes and canals used in the production of potassium chloride. DSW received additional ECIL grants in fiscal years 1979 through 1982 for the expansion of potassium chloride production under its Makleff Stage A and Stage B projects.

Because ECIL investment grants are limited to companies located in specific regions, we determine that grants benefiting the production of potassium chloride of the grades marketable by DSW in the United States confer countervailable bounties or grants. We have included in our calculations all grants for the construction of the hot leach and flotation plants and the portions of those grants used to build the dikes, ponds, and canals that benefit which we are measuring benefits is April 1, 1982, through March 31, 1983.
the hot leach and flotation plants. We have not considered as countervailable benefits those portions of the grants for the plant expansion, machinery, and equipment received for Stages A and B of the Makleff Project since DSW has provided convincing evidence that it is not selling, and cannot sell, potassium chloride produced by the Makleff “Cold Crystallization” process to the U.S. However, we have included in our calculations those portions of the Makleff grants used for the construction of dikes, evaporating ponds, and canals which benefit the hot leach and flotation plants. We have allocated the grants for all ponds, dikes canals based on the hot leach and flotation plants’ percentage of potassium chloride production during the period of review. If in future circumstances change and potassium chloride from the Makleff plant is sold to the United States, we will reevaluate this determination.

We calculated the countervailable benefit of these grants by using the grant methodology set out in the “Subsidies Appendix,” 49 FR 18016 (April 26, 1984).

In determining the discount rate, we concluded that suitable company-specific long-term borrowing rates were not available. Consequently, we used the national average bond rate and the national average rate of return on equity. These numbers were based on Bank of Israel statistics. We allocated the grants over eleven years, which is the average asset depreciation range for assets used in the manufacture of chemicals, as determined by the 1977 Internal Revenue Service guidelines (Rev. Proc. 77-10). We then allocated the benefits during the period of review over the total sales (less the sales from the Makleff plant) by DSW during the period of review. We thus determined a bounty or grant in the amount of 1.18 percent ad valorem exists.

In January, 1984, the ECIL law was amended to include export performance requirements as one of its criteria for eligibility. Since this requirement was not in effect when the grants relevant to the period for which we are measuring benefits in this investigation were received, we have treated this program as a domestic bounty or grant. B. Export Credit Funds

During the period of review the Bank of Israel provided short-term financing to DSW through three export credit funds: the Export Production Fund (for working capital loans), the Export Shipments Fund (for accounts receivable), and the Imports-for-Exports Fund (for financing of imported materials used for export production).

We calculated the countervailable benefit of these export credit funds using the short-term loan methodology set out in the “Subsidies Appendix,” 49 FR 18016 (April 26, 1984).

We find short-term export loans (one year or less) to be countervailable to the extent that they are given at rates less than those for comparable commercial loans. To determine the amount of the bounty or grant from loans, we compare the terms of the loan at issue with a benchmark, that is, a comparable commercial loan. We included in our calculations all loans for which DSW paid interest during the review period. For our benchmark, we used the rates of the most appropriate national average commercial method of short-term financing. The benchmark used for each of the export funds is included in our description of each program.

1. Export Production Fund

Preferences financing is provided in Israeli shekels and in certain foreign currencies to exporters through the Export Production Fund (EPF) to finance the production process for items to be exported. The Bank of Israel manages this fund. Financial institutions which offer credit to exporters according to the terms established for this fund by the Bank of Israel may receive credit from the Bank of Israel for the financing which they provide.

During the period of review DSW received EPF loans in shekels at a quarterly interest rate of 10.5 percent. In our preliminary determination, we annualized the EPF quarterly interest rate of 10.5 percent and compared that number with our benchmark which was the effective annual cost of overdraft accounts published by the Bank of Israel.

We have changed our calculation to take into account the fact that DSW pays interest on its EPF loans at the end of each 3 months and not on an annualized basis. Accordingly, we are now using as the basis of our benchmark the average quarterly cost of overdraft accounts published by the Bank of Israel. This figure includes the interest rate, commitment fees, management fees, and penalties.

We determined the benefits from these loans based on a comparison of the cost of the EPF financing and the cost of the comparable commercially available financing. This benefit was allocated over the value of DSW’s total potassium chloride exports during the review period. On this basis, we calculated a bounty or grant in the amount of 1.966 percent ad valorem.

2. Export Shipments Fund

The preferential financing designed to afford exporters the possibility of extending credit in foreign currency to their customers abroad is provided by the Export Shipments Fund (ESF). The Bank of Israel manages this fund. Financial institutions which offer credit to exporters according to the terms established for this fund by the Bank of Israel are discharged from certain payment obligations to the Bank of Israel and are exempt from the credit ceiling fixed by the Bank of Israel.

Exporters are required to pay the Euro-currency interest rate plus a premium on loans obtained through the ESF. Financing is granted after the merchandise is shipped upon the presentation by the exporter of particular export documents. Up to 90 percent of the export value of the merchandise shipped may be financed through this fund for a period not to exceed 6 months. Credit from this fund is provided in the currency indicated on the export documentation.

In our preliminary determination, we used as the best available benchmark for dollar loans the sum of the interest rate and the applicable surcharge, in dollar terms, available in Israel on non-directed United States dollar credit. We obtained these figures from Bank of Israel statistics. We were not able to obtain the interest rates available in Israel on non-directed credit in other foreign currencies. For those loans, we used as the benchmark the interest rates on comparable commercial loans, the interest rates DSW received on foreign currency loans adjusted (on a quarterly basis) by the percentage difference by which the interest rate on the non-directed United States dollar benchmark (surcharge excluded) exceeded the interest rates DSW received on United States dollar loans. The applicable surcharge was then added to the foreign currency benchmark interest rates.

Based on our verification, we have determined that during the review period, non-directed foreign currency credit liable to surcharge is not the most appropriate commercial method of foreign currency borrowing for large companies since it represents only a narrow segment of foreign currency borrowing that is not commonly utilized by Israeli companies. At verification, we determined that Israeli companies were able to borrow in the international financial markets at Euro rate plus an appropriate premium. Consequently, we are using as our foreign currency benchmark the Euro rate in effect on the date DSW obtained its foreign currency loans plus a spread of 2 percent which we determined to be the most representative premium paid by Israeli companies during the review period.
We calculated the benefit of the loans by comparing the appropriate benchmark to the preferential rates of interest obtained by DSW on its ESF loans. This benefit was allocated over the value of DSW's total potassium chloride exports during the review period. On this basis, we calculated a bounty or grant in the amount of 0.41 percent ad valorem.

3. Imports-for-Exports Fund. Through the Imports-for-Export Fund, preferential financing is provided in foreign currency to exporters in order to finance imported material used for export production. The Bank of Israel manages this fund. Financial institutions which offer credit to exporters through this fund may receive credit from the Bank of Israel for the financing which they provide. In its response, the government of Israel states that financial institutions grant credit to exporters in foreign currency at a rate of interest equal to 60 percent of the Euro-currency interest rate for the currency in which the loan is given for a period not to exceed 1 year. The Bank of Israel then credits the financial institution's account with an amount equal to the difference between the rate of interest paid by the exporter (60 percent of the Euro-currency rate) and the Euro-currency rate plus 3/8.

As with the ESF, we have amended the benchmarks used in the preliminary determination to represent the interest rate on comparable commercial loans. We used as our benchmark for this fund the foreign currency benchmark described in the "Export Shipments Fund" section.

We calculated the benefit of these loans by comparing the appropriate benchmark to the preferential rates of interest obtained by DSW on its Imports-for-Exports Fund loans. This benefit was allocated over the value of DSW's total potassium chloride exports during the review period. On this basis, we calculated a bounty or grant in the amount of 0.083 percent ad valorem.

II. Programs Determined Not To Confer Bounties or Grants

We determine that bounties or grants are not being provided to DSW under the following programs:

A. Exchange Insurances Scheme

During the period for which we are measuring bounties or grants, DSW's exports were covered under the "Exchange Rate Risk Insurance Scheme" (EIS) offered by the government-owned "Israel Foreign Trade Risks Insurance Corporation Ltd." (IFTRIC). EIS, which is optional for all exporters, is a mixture of exchange rate risk insurance and cost escalation coverage. It is designed to insure the exporter against decreased payments in its foreign currency receivables resulting from a delay in devaluation of the shekel with respect to a market basket of exchange rates, relative to the appreciation of the consumer price index.

IFTRIC structured the EIS program so that it contains certain fundamental economic principles. First, IFTRIC designed EIS to be self-balancing. Under EIS, if the change in the consumer price index is larger than the changes in the rate of the shekel depreciation, the exporter is indemnified by an amount equal to the difference between the changes multiplied by the "added value" of the imports. When the depreciation is higher than the change in the consumer price index, EIS requires the exporter to compensate IFTRIC. Second, IFTRIC set up a premium schedule and compensation formula based on economic projections. Based on these projections, IFTRIC established separate premium schedules for three areas: (1) The U.S., (2) the European Communities, and (3) the rest of the world. Based on the economic projections, the premium rate for exporters of merchandise to the U.S. was the highest. Third, IFTRIC made EIS insurance optional. Those Israeli exporters who chose to participate in the program could choose EIS coverage for all three areas or for all areas other than the U.S. This policy was established due to pressure from exporters who felt that premiums to the U.S. were higher than the risks warranted. Lastly, the EIS is required to pay a premium to the government of Israel which acts as a reinsurer. Under paragraph J of the Annex to the Agreement on Interpretation and Application of Articles VI, XVI and XXIII of the General Agreement on Tariffs and Trade (the Subsidies Code), an export subsidy is

[t]he provision by governments (or special institutions controlled by governments) . . . of insurance or guarantee programmes against increase in the costs of exported products or of exchange risk programmes, at premium rates, which are manifestly inadequate to cover the long-term operating costs and losses of the programmes.

Under this standard, the premiums must be manifestly inadequate to cover long-term operating costs and losses. As described above, EIS is structured to be self-balancing. It is designed to prevent losses and take away any gains that arise because of non-commensurate movements in the domestic inflation rate and the currency appreciation/depreciation rate. Under the compensation formula, if inflation equals devaluation, then the insured receives no payment under EIS. If inflation is greater than devaluation, then the insured is paid. If inflation is less than devaluation, the insured pays EIS.

In the long run, it would not be expected that either of the latter two situations would be sustained since movements in inflation rates and exchange rates are generally correlated. With floating exchange rates, the adjustment would be more rapid. With fixed rates, the rate of adjustment would depend on how often and to what extent the government of Israel devalues the currency. Even with fixed rates, it is unlikely that an overvalued or undervalued currency could be maintained indefinitely.

Thus, in the long term, it should be expected that the inflation rate and the devaluation rate will correspond. As a result, a scheme such as EIS should operate at about the break-even level over the long-term. Any premiums paid would be necessary only to cover operating costs.

In the short-run period examined, EIS has not attained the break-even point. While actual loss figures are only available for the first six months of operation, there are indications that the program has suffered continuing losses. However, the program has been in operation only for a short period and it is impossible to ascertain, on the basis of the data available, whether the extent of the losses make the premiums manifestly inadequate to cover long-term losses.

For these reasons, we are unable at this time to determine whether the premiums are manifestly inadequate to cover long-term operating costs and consequently do not currently find this program to confer a countervailable benefit. However, we will continue to review the financial performance of this program during our first review under section 731 of the Act. If at this time sufficient information is available to permit a judgment as to whether the premiums are adequate to meet long-term operating costs, and if that judgment results in a conclusion that the program confers a bounty or grant, countervailing duties to offset the bounties or grants will be issued on all entries of the subject merchandise from the effective date of the initial suspension of liquidation in the investigation.

B. ECIL Partial Non-Payment of Employer's Tax

The petition alleges that DSW benefits from the partial non-payment of the employer's tax which normally
amounts to 7 percent of payroll. The extent of non-payment depends on the ratio between “approved” assets and total assets.

On January 1, 1980, the employer’s tax law was amended. Since April 1, 1980, the employer’s tax has not been applicable to the productive sectors, including industrial manufacturing firms, agricultural farms, operation of hotels, and the building of housing or civil engineering related to the above activities. As a result, DSW has not paid an employer’s tax since 1980.

We determine that non-payment of the employer’s tax as a result of the 1980 amendment is so broad that the 1980 amendment is no longer a selective exemption from a tax. Further, this domestic program is not provided by government action to a specific enterprise or industry, or a group of enterprises or industries. Thus, it does not confer a countervailable benefit.

C. Preferential Ocean Freight Rates

The petition alleges that most potassium chloride exported from Israel to the United States (back-haul) is shipped by Zim Navigation which is 40 percent owned by the government of Israel, at rates which are charges on bulk (grain) shipments from the United States to Israel (front-haul). Petitioners add that the enormous difference between the front-haul and back-haul rates cannot be accounted for simply as the result of the imbalance in shipments into and out of Israel. They are deliberately structured, at the government of Israel’s direction, to cross-subsidize lower freight rates on potassium chloride exports to the United States by higher freight rates on grain imports (by the government of Israel) from the United States.

We verified that there are three Israeli bulk carriers: Zim Navigation Company Ltd. (Zim), El Yam Ships Ltd. (El Yam), and Rosenfeld Company (Rosenfeld), the most recent entrant in the bulk freight business. While Zim is partially owned by the government of Israel, El Yam and Rosenfeld are both privately owned. Although unrelated, Zim and El Yam have an informal agreement to share their bulk freight business, including grain and potassium chloride shipments. We verified that Zim and El Yam negotiated their contracts directly with DSW to carry potassium chloride at the rate charged by Zim and El Yam.

DSW has also provided evidence of lower spot market rates which it had received but did not utilize, preferring instead to stick with reliable long-term contracts.

For these reasons, we conclude that the shipping rates to carry potassium chloride paid by DSW to Zim and El Yam are set on a commercial basis and that the government is not paying higher grain shipment rates to cross-subsidize lower potassium chloride shipment rates. Consequently, ocean freight rates do not constitute a countervailable benefit.

D. Preferential Wharfage Charges

Petitioners allege that the “Israeli Ports Dues and Charges” schedule is designed to subsidize exports by disproportionately raising wharfage revenue from imports and vastly undercharging exports.

We determine that the following provisions that allow eligible enterprises a 5 year exemption from payment of 5% of property taxes on buildings. The petition states that this program was repealed by Amendment 17 of the ECIL on August 1, 1978.

The last year that DSW used this program was 1980. The property tax on buildings was abolished for all taxpayers on April 1, 1981.
B. Property Tax Exemption on Equipment

The petition alleges that the government of Israel provides a 10 year exemption from payment of 1/4 of the property taxes on equipment approved prior to repeal of this program. The program was repealed by Amendment 17 of ECIL on August 1, 1976. The last year for which DSW used this program was 1980. This program was abolished for all taxpayers as of April 1, 1981.

Petitioners Comments

Comment 1: The four grades of potassium chloride produced by all of DSW's plants are fungible, "like" products not only to each other but to the grades produced and sold in the United States. Based on the chemical and physical data provided by DSW, there is no obvious unresolvable technical reason why the fine grade potassium chloride product of the Makleff plant is not suitable for sale in the United States market either as is or as a compacted granular grade. Thus, the ECIL grants relating to the Makleff plant are countervailable.

DOC Position: After reviewing all the technical evidence on the record, we find that DSW cannot sell potassium chloride produced by the Makleff plant to the U.S. Although all grades of potassium chloride are essentially chemically fungible, there uses in the market place are largely grade-specific. The Makleff plant primarily produces a fine grade of potassium chloride and there is persuasive evidence that this product technically is not saleable in the United States. Further, there is no evidence on the record to refute DSW's contention that the Makleff fine grade has not been sold as is or as a compacted granular grade in the United States market. Accordingly, we determine that ECIL grants for the Makleff plant are not countervailable because they do not benefit the production of exports of potassium chloride to the United States. Since the technical evidence supporting this position is proprietary information we are unable to elaborate on our position in this notice.

Comment 2: The ITC determined that potassium chloride is a "like product." In determining its preliminary determination that grants for the construction of the Makleff plant are not countervailable, it was improper for the Department to conclude that Makleff produced potassium chloride is excluded from the concept of "like product."

DOC Position: As stated above, the Department excluded these grants because the Makleff produced potassium chloride is not, and cannot be, sold to the U.S. The definition of a "like product" is a criterion the Department must consider in determining "interested party" status. The concept of "like product," however, has no bearing on our determination of which ECIL grants to include in our calculations of countervailable benefits.

Comment 3: The preliminary determination which did not treat the grants relating to the Makleff plant as countervailable is inconsistent with Certain Steel Products from Italy, 47 FR 38556 (Sept. 7, 1982) and Congressional intent.

DOC Position: Certain Steel Products from Italy is inapposite. Unlike the present case, the steel products from both factories could be sold to the United States. There were no technical difficulties prohibiting the sale of steel from either factory to the U.S. The comment about Congressional intent is irrelevant to this issue. A countervailable grant must be conferred with respect to the manufacture, production, or exportation of a class or kind of merchandise imported into the United States. As stated above, we are satisfied that potassium chloride produced by the Makleff plant is not, and cannot be, sold to the U.S.

Comment 4: Even if potassium chloride produced in the Makleff plant cannot be sold to the U.S., it is sold to Europe and other markets. Sales to markets other than the U.S. can release output from other DSW plants for sale in the U.S. Thus, the grants to Makleff indirectly subsidize the sale of potassium chloride in the U.S. market.

DOC Position: There is no evidence on the record that the grants to Makleff indirectly subsidize the sale of DSW's potassium chloride in the U.S. The evidence shows the DSW has penetrated the European market with potassium chloride produced by the Makleff plant. However, the amount of granular or standard grades sold to Europe had remained fairly constant. The record does not show that DSW has substituted fine for granular or standard grades in the European market.

Comment 5: The Department should (1) allocate ECIL grant benefiting all DSW assets put in service after 1980 over 5 years (based on IRS ACRS guidelines) and (2) allocated ECIL grants put in service prior to 1981 over 9.5 years (based on IRS Class Life Asset Depreciation Range System (ADRS) (Rev. Prac. 77-10) guidelines.

DOC Position: We have allocated ECIL grant over 11 years based on the average depreciation range for assets used in the manufacture of chemicals and allied products as reflected by category 28 of the 1977 ARDS guidelines. The use of this table is consistent with our Subsidies Appendix published at 49 FR 18008, 18016 (April 26, 1984). The fact that U.S. taxpayers may elect accelerated depreciation or may use the 1993 IRS table for assets put into service prior to 1981 is not determinative. As stated in the Subsidies Appendix, "we have concluded that there are no economic or financial rules that mandate the choice of an allocation period." The ITA has selected the 1977 IRS guidelines as the standard to apply.

Comment 6: With regard to the calculation of the weighted cost of capital, the Department should use actual interest rates incurred by DSW to calculate the marginal cost of debt. Also, the Department should include dividends paid on shares as part of the marginal cost of equity.

DOC Position: We concluded that DSW's long-term loan rates were not suitable as benchmarks for the marginal cost of debt because they contained restrictive terms. For reasons more fully set out in the Subsidies Appendix, we cannot calculate a company's actual marginal cost of equity. As a surrogate, we have used the company's marginal cost of debt, plus the difference between the national average rate of return on equity and the national average cost of debt. Further, the company specific refinements are not possible because of the aggregate (i.e. nationwide) nature of the figures which adjust the marginal cost of debt to the marginal cost of equity.

Comment 7: Petitioners suggest that the Department's allocation formula for grants lacks a compounding term in the discount rate terms. Moreover, they recommend a different valuation formula which would measure the benefit to the recipient by calculating the future value of the grant.

DOC Position: We do not believe that the allocation formula should include a compounding term. The formula used by ITA is designed to ensure that the present value (in the year of grant receipt) of the amounts allocated over time does not exceed the face value of the grant. In this way, we are consistent with the Act and our international obligations in that the amount countervailed will not exceed the total net subsidy. This result will not necessarily be obtained using the petitioner's methodology. Only if the discount rate remains constant throughout the allocation period will the petitioners' methodology lead to the present value of...
the amounts countervailed (measured in the year of receipt) being equal to the grant. We note that were we to apply their formula (using the same discount rate throughout), the effect would be to allocate a disproportionate share of the benefit to later years of the allocation period. This result, while not unreasonable, has been rejected in favor of a declining balance methodology that allocates higher benefits to those years immediately following the receipt of the grant.

Comment 8: ECIL grants are export subsidies.

**DOC Position:** The ECIL program was changed in January 1984 to include as one of its criteria certain export performance requirements. Since all the grants relevant to our investigation were received prior to 1984, we have treated those ECIL grants as domestic subsidies.

Comment 9: The appropriate benchmark for determining the subsidy element for the export credit funds is the actual commercial borrow experience of DSIF. If DSW's credit experience is unavailable, credits denominated in U.S. dollars and French francs should be measured against LIBOR plus an appropriate premium for foreign currency loans. For Israeli shekel loans, the appropriate benchmark should be a reasonable positive real rate of return plus the increase in the CPI.

**DOC Position:** For short-term loan benchmarks, the Subsidies Appendix provides that we will use the most appropriate national average commercial method of short-term financing, rather than company specific experience. For reasons elaborated in that appendix we agree that foreign currency loans should be measured against interest rates offered in the international financial market.

Comment 10: Since 1978, the U.S. has taken the position before GATT that export inflation insurance schemes are subsidies. The ECIL exchange risk program is a variant of these subsidies.

**DOC Position:** The standard under the GATT for whether such schemes constitute subsidies, as set forth above, is whether premiums collected are manifestly inadequate to cover long-term operating costs and losses. Available information does not permit us to reach that conclusion in the present investigation.

Comment 11: With regard to the EIS program, the Department should segregate long-term operating costs of IFTRC from those to a specific insurance product line.

**DOC Position:** For the purposes of this investigation, based upon all the facts available, we have done so. Whether this would be appropriate in future cases will be determined upon the facts of those cases.

Comment 12: The gross subsidy from EIS should be the difference between the lag in devaluation of the shekel behind inflation. The net subsidy is the difference between the gross subsidy and the premiums.

**DOC Position:** Since we did not determine that the EIS program is countervailable at this time, we do not have to reach the issue of how to measure the value of the alleged benefit.

Comment 13: Under Bethlehem Steel Corp. v. United States, 6 CIT --, Slip Op. 84-67, June 8, 1984, the preliminary determination that the exemption from the employer's tax is not countervailable because it is generally available is erroneous as a matter of law.

**DOC Position:** In Bethlehem, the court's broad opinion that the Department cannot apply rule that "generally available" benefits are not subsidies is dictum. The Department continues to interpret the language in section 771(5)(B) of the Act that the term subsidy includes "domestic subsidies, if provided or required by government action to a specific enterprise or industry, or group of enterprises or industries . . ." to mean that benefits broadly or "generally available do not constitute countervailable benefits or grants. In this case we determined that the exemption from the tax program is "generally available." Further, our position does not conflict with the holding of Bethlehem which states that tax laws become bounties or grants to the taxpayer only if the elimination or reduction of the tax is selective. In this case, the 1980 amendment to the tax law was so broad as to cover nearly every sector of the economy. Consequently, the program no longer operates as a selective exemption from the employer's tax.

Comment 14: The amount of countervailable benefit attributable to the corporation income tax program is the difference between the ordinary 61 percent and the special 30 percent rate linked to ECIL benefits. Further, the Department should examine intra-corporate transfers of funds.

**DOC Position:** DSW's eligibility under the ECIL program to pay a reduced corporate income tax rate is an insufficient basis to conclude that DSW has received a countervailable benefit. Where DSW paid no tax because of its combined return with its parent company, it has not, in fact, received the benefit of a lower tax rate. We are not concerned with intra-corporate transfers of funds but rather with corporate income taxes paid by DSW through ICL to the government.

Comment 15: The government is subsidizing potassium chloride shipments to the extent it is paying more than $17.00 per MT for the grain haul to Israel. The facts on the record indicate that Zim and El-Yam carry both potassium chloride and grain, the contracts for import and export are between these carriers and the government and no others, and the rates for import carriers of grain to Haifa are contingent upon a reciprocal agreement for export charter of potassium chloride from Ashdod. When the GOL exclusively negotiates all grain import rates and the shipment of potassium chloride and phosphates are linked in reciprocal contracts with all carriers, there are no market rates by leg of voyage. Thus, the Department should look to surrogates rates supplied by the petitioner to determine market rates.

**DOC Position:** See our discussion of these issues under Section II.C. of this notice.

Comment 16: The "Israeli Port Dues and Charges" schedule is designed to subsidize exports in general and potassium chloride in particular. Further, the Department should analyze the contract between DSW and the Israeli Port Authority to determine the extent to which the land and equipment lease payments have actually been adjusted through exchange rate or consumer price linkages to reflect the current market value of the lease services to DWS.

**DOC Position:** The "Israeli Port Dues and Charges" schedule does not apply to DSW. We verified that the rental charges paid by DSW are linked to the cost of building index and that the operation charges are paid on a cost plus basis.

**Respondent's Comments**

**Comment 1:** It was inappropriate for ITA to consider as countervailable the grants for the construction of ponds and dikes relating to the plant. DSIF's pond capacity prior to the construction of the Makleff plant was more than adequate to produce sufficient raw material for the hot leach and flotation plants. But for the construction of the Makleff plant, the new ponds would not have been constructed. If ITA insists on including grants to Makleff-related ponds, dikes, and canals, ITA should calculate the benefit by dividing the grant benefit by total sales and not excluding exports of the Makleff product.

**DOC Position:** We have countervailed the grants for the construction of ponds.
and dikes relating to Makleff because those ponds and dikes do not exclusively benefit the Makleff plant. Rather, raw material used for the production of potassium chloride in the hot leach and flotation plants also pass through those ponds. The larger capacity of the ponds increases the efficiency of the production of raw material for all potassium chloride produced by DSW. We therefore have included in our calculations those portions of the Makleff grants used to construct canals, ponds, dikes and calculated the benefit by multiplying the grants by the proportion that potassium chloride from the hot leach and flotation plants represent of total potassium chloride production and allocating this amount over the sales of the hot leach and flotation plants.

Comment 2: ITA’s allocation of grants over 10 years is inappropriate. Although DSW’s production is a type of mining, it is not the type envisioned by the IRS depreciation guidelines. If ITA uses the IRS guidelines, grants for land improvements should not be spread over the life of the equipment when the grants were specifically tied to land improvements and when the IRS guidelines provide specifically that land improvements shall be spread over 20 years.

DOC Position: As discussed previously, we have concluded that there are no economic or financial rules that mandate the choice of an allocation period and we have selected the 1977 IRS guidelines as the standard to apply. Consistent with the Subsidies Appendix, we have selected Category 28-Chemicals and Allied Products which reflects the type of business activities involved in DSW’s manufacture of potassium chloride.

Comment 3: The preliminary determination vastly overstates the benchmarks used to calculate the benefits from the export funds. DSW’s own experience should be used as a benchmark. Since DSW is one of the most efficient and largest revenue producing companies in Israel, it is unfair, inappropriate, and violative of the statute to use benchmark rates which include small and unprofitable companies.

DOC Position: As explained more fully in the Subsidies Appendix, we use as our benchmark for short-term financing the most appropriate national average commercial method of short-term financing, instead of company-specific experience.

Comment 4: The benchmark for export production fund loans should be the quarterly (not annualized and not compounded) shekel overdraft rate. Further, the overdraft rate includes components not attributable to export production fund loans which are term loans. Since ITA is using the overdraft as proxy for a term loan, it must eliminate those elements of the revolving credit not attributable to term loans. Those elements are a negotiated commitment fee for the credit line, penalty interest for exceeding the credit line, and a management fee.

DOC Position: We agree that the benchmark for export production fund loans should be the quarterly shekel overdraft rate. In choosing a benchmark, we are seeking the national average commercial method of short-term shekel financing. The benchmark selected for the EFP is the average cost of overdraft accounts. Since the management fees, commitment fees, and penalty interest are components of the national average experience of overdraft borrowing, they are properly included in the benchmark.

Comment 5: With regard to the benchmark used in the preliminary determination for the Export Shipments Fund and the Import-for-Export Fund, non-directed foreign currency credit liable to the surcharge is unrepresentative of any national average because it represents only a narrow segment of foreign currency borrowing, is highly restrictive, and includes a surcharge intended to discourage borrowing. Further, ITA’s addition of the surcharge to the Bank of Israel figure used as the benchmark double-counted the surcharge. Lastly, the Bank of Israel demonstrated that commercial loans exist which should be used as a benchmark. Companies can discount accounts receivable at the Euro rate plus a certain percent.

DOC Position: We agree and have modified our foreign currency benchmarks accordingly.

Comment 6: The EIS is an internationally accepted type of insurance and does not provide a subsidy.

DOC Position: As stated above, section 771(5)(B) of the Act incorporates the Annex to the Subsidies Code into U.S. law. Paragraph j of that Annex sets forth the standards for determining when exchange rate insurance schemes, such as EIS, constitute export subsidies.

Verification

In accordance with section 776(a) of the Act, we verified all information used in making our final determination. During verification we followed normal procedures, including meetings with government officials, inspection of government documents and on-site inspection of the records and operations of DSW.

Suspension of Liquidation

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-confidential information relating to this investigation. We will allow the ITC access to all privileged and confidential information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Deputy Assistant Secretary for Import Administration.

The ITC will make its determination whether these imports are materially injuring, or threatening to materially injure, a U.S. industry within 45 days of the publication of this notice.

If the ITC determines that material injury or the threat of material injury does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or cancelled. If however, the ITC determines that such injury does exist, we will issue a countervailing duty order, directing Customs officers to assess a countervailing duty on potassium chloride from Israel entered, or withdrawn from warehouse, for consumption after the suspension of liquidation, equal to the net bounty or grant amount indicated in the “Suspension of Liquidation” section of this notice.

This notice is published pursuant to section 705(d) of the Act (19 U.S.C. 1671d(d)).
**Dated:** September 10, 1984.

William T. Archey,

 Acting Assistant Secretary for Trade Administration.

**FORWARDING INFORMATION CONTACT:**

Michael C. Fuchs, Agreements Compliance Division, Import Administration, Room 3709, Department of Commerce, Washington, D.C. 20230, telephone: (202) 377-1102.

**SUPPLEMENTARY INFORMATION:**

The Department of Commerce announces that fourth quarter 1984 monitoring price bases and extras for stainless steel round wire products will not change from their third quarter levels. Increases in cost of production were offset by the yen value relative to the dollar.

The Department uses these prices to monitor imports of stainless steel wire and cold-drawn bar under 0.703 inches in diameter for possible initiation of antidumping or countervailing duty investigations. Each quarter the Department reviews Japanese steel production and delivery costs and revises monitoring prices accordingly. The fourth quarter monitoring prices apply to those products exported to the United States on or after October 1, 1984.


Alan F. Holmer,

Deputy Assistant Secretary for Import Administration.
National Bureau of Standards

National Fire Codes: Request for Proposals for Revision of Standards

AGENCY: National Bureau of Standards, DOC.

ACTION: Notice of request for proposals.

SUMMARY: The National Fire Protection Association (NFPA) proposes to revise some of its fire safety standards and requests proposals from the public to amend existing NFPA fire safety standards. The purpose of this request is to increase public participation in the system used by NFPA to develop its standards. The publication of this notice of request for proposals by the National Bureau of Standards (NBS) on behalf of NFPA is being undertaken as a public service. NBS does not necessarily endorse, approve, or recommend any of the standards referenced in the notice.

DATES: Interested persons may submit proposals or on or before the dates listed with the standards.

ADDRESS: Secretary, Standards Council, NFPA, Batterymarch Park, Quincy, Massachusetts 02269.

FOR FURTHER INFORMATION CONTACT: Secretary, Standards Council, at above address, (617) 770-3000.

SUPPLEMENTARY INFORMATION:

Background

The National Fire Protection Association (NFPA) develops fire safety standards which are known collectively as the National Fire Codes. Federal agencies frequently use these standards as the basis for developing Federal regulations concerning fire safety. Often, the Office of the Federal Register approves the incorporation by reference of these standards under 5 U.S.C. 552(a) and 1 CFR Part 51.

Request for Proposals

Interested persons may submit amendments, supported by written data, views, or arguments to Secretary, Standards Council, NFPA, Batterymarch Park, Quincy, Massachusetts 02269. Each person who submits a proposal must include his or her name and address, and a request for a hearing must be received by the Director, Certification Division, Office of Trade Adjustment Assistance, U.S. Department of Commerce, Washington, D.C. 20230, no later than the close of business of the tenth calendar day following the publication of this notice.

The Catalog of Federal Domestic Assistance identifies the program number and title of the program under which each request for a hearing must be submitted. TheCatalog of Domestic Assistance is available from the Office of the Federal Register, U.S. Government Printing Office.


Ernest Ambler,

Director, National Bureau of Standards.

Committees Soliciting Proposals

The following Committees are planning to meet to begin preparation of their respective reports. In accordance with the Regulations Governing Committee Projects, Committees are now accepting proposals for recommendations on documents content on the documents listed below. Proposals received by the closing date...
indicated will be acted on by the Committee, and that action will be published in the Committee's Report. Proposals must be submitted to Assistant Vice President Arthur E. Cote on Proposal Forms [available from Mr. Cote].

Bolier Fuirncs Explosions:

Systenis:

Chemical Processes:

Motion Picture Film:

Vehicle Terminals:

Dust Explosion Hazards:
NFPA 61A-1984, Manufacturing and (open).

Handling of Storches:

Bulk Grain Handling Facilities:

NFPA 610-1984, Dust Explosions in (open).

Feed Mills:


safety Conception Tree.

Proposed NFPA 14-1983, Standpipe and (open).


Water Sprinkler Systems.

Water Sprinkler Systems.


Batterymarch Park, Quincy, Massachusetts 02269.

FOR FURTHER INFORMATION CONTACT:
Secretary, Standards Council, at above address, (607) 770-3900.

SUPPLEMENTAL INFORMATION:
Background

Standards developed by the technical committees of the National Fire Protection Association (NFPA) have been used by various Federal Agencies as the basis for Federal regulations concerning fire safety. The NFPA standards are known collectively as the nationa Fiqe Codes. Often, the Office of the Federal Register approves the incorporation by reference of these standards under 5 U.S.C. 552(a) and 1 CFR Part 51.

Revisions of existing standards and adoption of new standards are reported by the technical committees at the NFPA's Full Meeting in November or at the Annual Meeting in May of each year. The NFPA invites public comment on its Technical Committee Reports.

Request for Comments

Interested persons may participate in these revisions by submitting written data, views, or arguments to Secretary, Standards Council, NFPA, Batterymarch Park, Quincy, Massachusetts 02269.

Commentors may use the forms provided for comments in the Technical Committee Reports. Each person submitting a comment should include his or her name and address, identify the notice, and give reasons for any recommendations. Comments received on or before November 2, 1984, will be considered by the NFPA before final action is taken on the proposals.

Copies of all written comments received and the disposition of those comments by the NFPA committees will be published as the Technical Committee Documentation by March 22, 1985, prior to the Annual Meeting.

A copy of the Technical Committee Documentation will be sent automatically to each commenter. Action on the Technical Committee Reports [adoption or rejection] will be taken at the Annual Meeting, May 13-17, 1985, at the Hyatt Regency in Chicago, Illinois, by NFPA members.


Ernest Ambler,
Director, National Bureau of Standards.

Action at the NFPA Annual Meeting in May 1985 is being proposed on the NFPA standards listed below:
COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1984; Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped. ADDITION: Additions to Procurement List 1984. SUMMARY: This action adds to Procurement List 1984 commodities to be produced by and services to be provided by workshops for the blind and other severely handicapped.

EFFECTIVE DATE: September 14, 1984.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: C.W. Fletcher, (703) 557-1145.

SUPPLEMENTARY INFORMATION: On March 16, May 11, June 22, June 29, 1984, the Committee for Purchase from the Blind and Other Severely Handicapped published a notice (49 FR 9941, 49 FR 20048, 49 FR 20780, 49 FR 25664) of proposed addition to Procurement List 1984, October 13, 1983 (48 FR 40415).

Additions

After consideration of the relevant matter presented, the Committee has determined that the commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c, 85 Stat. 77.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered were:

a. The actions will not result in any additional reporting, recordkeeping or other compliance requirements.

b. The actions will not have a serious economic impact on any contractors for the commodities and services listed.

c. The actions will result in authorizing small entities to produce or provide the commodities and service procured by the Government.

Accordingly, the following commodities and services are hereby added to Procurement List 1984:

Class 7929

Cloth, Wiping: 7929-LL-103-5134

(REquirements for Pearl Harbor Naval Shipyard, Pearl Harbor, Hawaii only)

SIC 7349

Janitorial/Custodial, Federal Building and Courthouse, 5th and Okmulgee, Muskogee, Oklahoma

Janitorial/Custodial, U.S. Courthouse, Broadway and Main, Portland, Oregon

SIC 7369

Commissary Shelf Stocking and Custodial, Lowry Air Force Base, Colorado

SIC 9199

Administrative Services, DCASR Building B-95, 805 Walker Street, Marietta, Georgia

C.W. Fletcher, Executive Director.

Supplementary Information: Proposed additions to and deletions from procurement list.

SUMMARY: The Committee has received proposals to add to and delete from Procurement List 1984 commodities and a military resale commodity to be produced by and services to be provided by workshops for the blind and other severely handicapped.

DATE: Comments must be received on or before October 17, 1984.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202.

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. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodities, military resale commodity and service listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities, military resale commodity and service to Procurement List 1984, October 18, 1983 (48 FR 48415):
DEPARTMENT OF DEFENSE
Office of the Secretary
Privacy Act of 1974; Deletion and Amendments to Systems of Records Notices

AGENCY: Office of the Secretary, DoD.

ACTION: Notice of deletion and amendments to systems of records.

SUMMARY: The Office of the Secretary of Defense proposes to delete one and amend two notices for systems of records subject to the Privacy Act of 1974. The specific changes to the notices being amended are set forth below followed by the system notices, as amended, published in their entirety.

DATES: This shall be effective without further notice October 15, 1984, unless comments are received which would result in a contrary determination.

ADDRESS: Send any comments to the System Manager identified in the system notice.

FOR FURTHER INFORMATION CONTACT: Norma Cook, Privacy Act Officer, OSASD(A), Room 5C-315, Pentagon, Washington, D.C. 20301-1155 Telephone: 202/855-0370.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense (OSD) systems of records notices as prescribed by the Privacy Act of 1974, Title 5, United States Code 552a (Pub. L. 93-579; 48 Stat. 1896 et seq.) have been published in the Federal Register at:

FR Doc. 84-4418 (49 FR 6145) February 17, 1984
FR Doc. 84-17736 (49 FR 27602) July 5, 1984
FR Doc. 84-20096 (49 FR 30560) July 31, 1984
FR Doc. 84-22589 (49 FR 33700) August 24, 1984

The proposed amendments are not within the purview of the provisions of 5 U.S.C. 552a(o) of the Act which requires the submission of an altered system report.

Patricia H. Meons,
OSD Federal Register Liaison Officer.
Department of Defense.

AMENDMENTS
DUSDRE 03
System Name:
Inventor's File, Office Under Secretary of Defense (Research and Engineering) (49 FR 25861, June 8, 1983).

Reason: This system is no longer being maintained as a system of records.

AMENDMENTS
DUSDRE 02
System Name:
OUSDRE Personnel Administration files (48 FR 25860, June 8, 1983).

Changes:
Add the heading "PURPOSE(S)" before the heading Routine Uses of Records Maintained in the system, including Categories of Users and purposes of such uses.

Add the following paragraph under the heading PURPOSE(S):
The information contained in these personnel files is used by the office manager, supervisory personnel and the Under Secretary of Defense for Research and Engineering in the management of his/her organization. Specific uses include determining eligibility for appointment to positions; reviewing financial interest and background of individual applying for appointments; comparing individual resumes and job requirements; keep account of time worked; travel performed; orders issued, awards given to personnel and security clearance grant.

Delete the heading "Routine Uses (disclosure) of records Maintained in the System Including Categories of Users, Uses, and the purpose of Such Uses."

Delete the heading "Internal Users, Uses, and Purposes."

Delete the paragraph following the above heading.

Delete the heading "External, Users, Uses, and Purpose" and add the heading "Routine Uses of Records Maintained in the System, Including Categories of Users and the purposes of Such Uses."

Delete the paragraph under the heading "Safeguards" and add the paragraph "Building Guards and Secure (Vault) Area. Records are maintained in an area accessible only to authorized personnel."

Delete third line under heading "Notification Procedure" and add "Room 3E1065."

Systems DUSDRE 02 and DUSDRE 04 read as follows:

DUSDRE 02
SYSTEM NAME:
OUSDRE Personnel Administration Files.

SYSTEM LOCATION:
CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All employees assigned to or considered for positions in OUSDRE including civilian and military personnel and consultants.

CATEGORIES OF RECORDS IN THE SYSTEM:

These files contain position descriptions; biographical résumés, qualification statements (SD 171, SD 173, SD 598, SF 161, etc.); Confidential Statement of Affiliations and Financial Interests, Department of Defense Personnel (DD Form 1555); requests for personnel actions (SD 52, 108); notification of Personal Action (SD 50); appointments affidavits (SF 61, 61B); award recommendations; appraisals and efficiency reports; time and attendance records (SF 1135); travel orders and vouchers; and security clearance information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 133.

PURPOSE(S):

The information contained in these personnel files is used by the office manager, supervisory personnel and the Under Secretary of Defense for Research and Engineering in the management of his organization. Specific uses include: Determining eligibility for appointment to positions; reviewing financial interest and background of individual applying for appointments; comparing individuals résumés with job requirements; keeping account of time worked; travel performed; orders issued; awards given to Personnel and Security Clearances granted.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See Office of the Secretary of Defense (OSD), Blanket Routine Uses at the head of this Component's published system notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

Filed alphabetically by last name of individual.

SAFEGUARDS:

Building guards and locked file containers. Records are maintained in areas accessible only to authorized personnel.

RETENTION AND DISPOSAL:

Records are temporary in nature and are destroyed after individuals leave employment of OUSDRE or are no longer under consideration for employment.

SYSTEM MANAGER(S) AND ADDRESS:

Executive Assistant to USDRE, Office of the Secretary of Defense, Washington, D.C. 20301.

NOTIFICATION PROCEDURE:

Information may be obtained from: Personnel Assistant, Office of the Executive Assistant to USDRE, Room 3E1006, Pentagon, Washington, D.C. 20301-3000, Telephone: 202-695-6556.

Written requests for information should contain the full name of the individual, current address, telephone number, and any other information which would help in identifying the desired information.

For personal visits, the individual must be able to provide acceptable identification, that is, driver's license, employing office's identification card, and give verbal information that could be verified with his "case folder."

RECORD ACCESS PROCEDURES:

Requests should be addressed to System Manager as shown above.

CONTESTING RECORD PROCEDURES:

The Agency's rules for access to records and for contesting contents and appealing initial determinations by the individual concerned are contained in 32 CFR Part 286b and OSD Administrative Instruction No. 81.

RECORD SOURCE CATEGORIES:

Information is provided by the Directorate for Personnel and Security, Security Division, Washington Headquarters Services, Department of Defense, individuals concerned, travel vouchers, security forms, travel orders, individual's supervisors, and time and attendance clerks.

EXEMPTION CLAIMED UNDER THIS SYSTEM:

None.

DUSDRE 04

SYSTEM NAME:

Requests for Two-Year Foreign Residence Waiver Files.

SYSTEM LOCATION:

Security Policy and Review Division—Office of the Director, Program Control and Administration, Office of the Under Secretary of Defense for Research and Engineering, Office of the Secretary of Defense.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any foreigner applying for a Waiver of Foreign Residency.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files contain requests for waiver of foreign residency.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:


PURPOSE(S):

Data is used by Under Secretary of Defense for Research and Engineering, Security Policy and Review Division officials to evaluate requests of foreigners requesting waiver of Foreign Residency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See Office of the Secretary of Defense (OSD) Blanket Routine Uses at the head of this Component's published system notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

Filed alphabetically by last name of individual.

SAFEGUARDS:

Building guards and secure (vault) area. Records are maintained in an area accessible only to authorized personnel.

RETENTION AND DISPOSAL:

Records are permanent. Retained in active file for ten years.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Program Control and Administration, OUSDRE, Office of the Secretary of Defense, Washington, D.C. 20301-3000.

NOTIFICATION PROCEDURE:

Information may be obtained from: Security Policy and Review Division, Room 3D1065, Pentagon, Washington, D.C. 20301-3000, Telephone: 202-697-3459.

RECORD ACCESS PROCEDURES:

Requests from individuals should be addressed to: Under Secretary of Defense for Research and Engineering, Office of the Secretary of Defense, Pentagon, Washington, D.C. 20301-3000.

Written requests for information should contain full name of individual.
DoD Advisory Group on Electron Devices; Advisory Committee Meeting

Working Group D (Mainly Laser Devices) of the DoD Advisory Group on Electron Devices (AGED) will meet in closed session on October 8, 1984 at M/A COM Omni Spectra, 2628 South Hardy Drive, Tempe, AZ 85282.

The mission 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 D meeting will be limited to review of research and development programs which the military 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 Pub. L. No. 92-463, as amended (5 U.S.C. App. II § 10(d) (1976)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552(b)(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

Patricia H. Means,
OSD Federal Register Liaison Officer,
Department of Defense.
Department of the Air Force

USAF Scientific Advisory Board Ad Hoc Committee on Military Aerospace Platform; Meeting

The USAF Scientific Advisory Board Ad Hoc Committee on the Military Aerospace Platform will meet in the ANSER Building, 3 Crystal Gateway, Arlington, VA on October 4–5, 1984.
The purpose of the meeting is to review contractor proposals for military aerospace platform/transatmospheric vehicle concepts. The meeting will convene from 8:30 to 5:00 p.m. on October 4 and from 8:30 a.m. to 3:00 p.m. on October 5.
The meeting concerns matters listed in Section 552(b)(c) of the Title 5, United States Code, specifically subparagraphs(1) and (4) thereof, and accordingly, will be closed to the public.
For further information, contact the Scientific Advisory Board Secretariat at 202–697–8845.
Harry C. Waters,
Alternate Air Force Federal Register Liaison Officer.

USAF Scientific Advisory Board Ad Hoc Committee on Application of Artificial Intelligence (AI);

The USAF Scientific Advisory Board Ad Hoc Committee on the Application of Artificial Intelligence (AI) will meet in the Pentagon, Washington, DC on October 15–16, 1984.
The purpose of the meeting will be to review Air Force planning, distribution of funding, and current programs for AI.
The committee will also review DARPA vehicle concepts. The meeting will convene from 8:30 to 5:00 p.m. on October 5.
The meeting considers matters listed in Section 552(b)(c) of the Title 5, United States Code, specifically subparagraphs (1) and (4) thereof, and accordingly, will be closed to the public.
For further information, contact the Scientific Advisory Board Secretariat at 202–697–8845.
Harry C. Waters,
Alternate Air Force Federal Register Liaison Officer.

DEPARTMENT OF EDUCATION

Advisory Council on Dependents' Education; Meeting

AGENCY: Advisory Council on Dependents' Education.

ACTION: Notice of open meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Advisory Council on Dependents’ Education and of two standing committees concerning education programs and administration. This notice also describes the functions of the council. Notice of these meetings is required under section 10(1)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of its opportunity to attend.

DATE: The Advisory Council on Dependents’ Education: October 15, 9:30 a.m. to 5:00 p.m.; and October 17, 9:00 a.m. to 5:00 p.m. The committees: October 16, 9:00 a.m. to 4:00 p.m.

ADDRESS: Rosslyn Westpark Hotel, The Club Room, 1900 Fort Myer Drive, Rosslyn, Virginia 22209.

FOR FURTHER INFORMATION CONTACT: Dr. William F. Keough, Administrator of Education for Overseas Dependents, 400 Maryland Ave., S.W., Washington, D.C. 20202, (202) 245-8011.

SUPPLEMENTARY INFORMATION: The Advisory Council on Dependents’ Education is established under section 1411 of the Defense Dependents’ Education Act of 1976, as amended (20 U.S.C. 929). The Council is established to recommend to the Director general policies for operation of the defense dependents’ education system with respect to curriculum selection, administration, and operation of the system.
The meeting of the Council is open to the public. The proposed agenda for the full Council on October 15 includes: A report of the Administrator on Council matters, a progress report by the Director, a report by the Director on previously expressed ACDE concerns, and presentations by DoDDS staff members on the talented and gifted program, the opportunity for input and problem-solving in curriculum development at the local level, trends for the SIMS/RIMS (information management) program, the pilot master teacher program, military construction of small schools, and the certification/recertification program. The proposed agenda for the full Council on October 17 includes reports by the two standing committees, with discussion and voting on proposed recommendations.

The proposed agenda for the Education Program Committee on October 16 includes standardized test results, functional literacy vocabulary in elementary host nation programs, continued DoDDS response to the National Commission on Excellence in Education Report, the TAG program and the demographic study, the kindergarten entrance age, and the opportunity for input and problem-solving in curriculum development at the local level.
The proposed agenda for the Administration Committee includes projections of school enrollment, and addition to end-of-year reports by local school advisory committees, trends for the SIMS/RIMS program, the pilot master teacher program, military construction of small schools, and the certification/recertification program.

Records are kept of all Council proceedings and are available for inspection at the office of the Advisory Council on Dependents’ Education, Room 3047, 400 Maryland Ave., S.W., Washington, D.C., from the hours of 8:30 a.m. to 5:00 p.m.


A. Wayne Roberts,
Deputy Under Secretary for Intergovernmental and Interagency Affairs.

DEPARTMENT OF ENERGY

Office of the Secretary

International Atomic Energy Agreement; European Atomic Energy Community: Proposed Subsequent Arrangement

The subsequent arrangement to be carried out under the above mentioned agreement involves approval of the following sale:

Contract Number S-EU-818, to Omnium Scientifique Industriel, Paris, France, one gram of uranium enriched to 0.99 percent in U-235, one gram of uranium enriched to 4.95 percent in U-235, and one gram of uranium enriched to 1.51 percent in U-235, for use as standard reference materials.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended.
it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen (15) days after the date of publication of this notice.

For the Department of Energy.  

Harold Jaffe,  
Acting Deputy Assistant Secretary for International Affairs.  

BILLING CODE 6450-01-M

International Atomic Energy Agreement; European Atomic Energy Community Proposed Subsequent Arrangement

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 Additional Agreement for Cooperation Between the Government of the United States of America and the European Atomic Energy Community (EURATOM) Concerning Peaceful Uses of Atomic Energy, as amended. The subsequent arrangement to be carried out under the above mentioned agreement involves approval of the following sales:

Contract Number S-EU-817, to CEA, Office des Rayonnements, France, 5 milligrams of thorium-230 for measurement of thorium concentrations in volcanic minerals.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen (15) days after the date of publication of this notice.

For the Department of Energy.  

Harold Jaffe,  
Acting Deputy Assistant Secretary for International Affairs.  

BILLING CODE 6450-01-M

International Atomic Energy Agreement; European Atomic Energy Agency and Brazil; Proposed Subsequent Arrangement

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 Additional Agreement for Cooperation Between the Government of the United States of America and the European Atomic Energy Community (EURATOM) Concerning Peaceful Uses of Atomic Energy, as amended, and the Agreement for Cooperation Between the Government of the United States of America and the Government of Brazil Concerning Civil Uses of Atomic Energy. The subsequent arrangement to be carried out under the above mentioned agreements involves approval of the following retransfer:

RTD/EU(BR)-4, from Brazil to Kernforschungsanlage Julich GmbH, the Federal Republic of Germany, uranium oxide pellets containing 502 grams of uranium enriched to 1.98% in U-235 for irradiation testing.

In accordance with Section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

For the Department of Energy.  

Harold Jaffe,  
Acting Deputy Assistant Secretary for International Affairs.  

BILLING CODE 6450-01-M

International Atomic Energy Agreement; European Atomic Energy Community et al.; Proposed Subsequent Arrangements


The subsequent arrangements to be carried out under the above mentioned agreements involve approval for the conversion of uranium enrichment service contracts to the new utilities service contracts form for the following nuclear power stations:

Japan—Chugoku Electric Power Co.—Shimane No. 1, and Chugoku No. 3 and No. 4

—Tohoku Electric Power Co.—Onagawa No. 1, Namie Odaka No. 1, Tohoku No. 4 and No. 5, and Maki No. 1

—Philippines—National Power Corp.—PNPP No. 1

—Sweden—Swedish State Power Board—Ringhals Nos. 1, 2, 3, and 4, and Forsmark Nos. 1, 2, and 3

—Switzerland—Kernkraftwerk Leibstadt—Leibstadt No. 1

—IAEA—Yugoslavia—KRSKO No. 1

—European Atomic Energy Community—Fessenheim No. 2 and Bugey No. 2

—The Federal Republic of Germany—Ems, Unterweser, Isar, Grohnde No. 1, Obrigheim, Brunsbuettel, Philippsburg No. 1, THTTR, and Stade

—The Netherlands—Borssele No. 1
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 (15) days after the date of publication of this notice.

For the Department of Energy.
Harold Jaffe,
Acting Deputy Assistant Secretary for International Affairs.

[FR Doc. 84-24342 Filed 9-13-84; 8:45 am]
BILLING CODE 6450-01-M

International Atomic Energy Agreement; Switzerland; Proposed Subsequent Arrangement

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 Agreement for Cooperation Between the Government of the United States of America and the Government of Switzerland Concerning Civil Uses of Atomic Energy, as amended.

The subsequent arrangement to be carried out under the above mentioned agreement involves approval for the conversion of uranium enrichment contracts to the new utilities services contracts for the Graben and Muehleberg power reactors in Switzerland.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen (15) days after the date of publication of this notice.

For the Department of Energy.
Harold Jaffe,
Acting Deputy Assistant Secretary for International Affairs.

[FR Doc. 84-24340 Filed 9-13-84; 8:45 am]
BILLING CODE 6450-01-M

National Petroleum Council, Distribution Task Group of the Committee on the Strategic Petroleum Reserve; Meeting

Notice is hereby given that the Distribution Task Group of the Committee on the Strategic Petroleum Reserve will meet in September 1984.

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 Committee on the Strategic Petroleum Reserve will address various aspects of the Strategic Petroleum Reserve and the long-term availability and movement patterns of tankers worldwide. Its analysis and findings will be based on information and data to be gathered by the various task groups.

The Distribution Task Group will hold its fourth meeting on Monday, September 17, 1984, starting at 7:30 a.m., in the Conference Room of the National Petroleum Council, 1625 K Street, NW., Washington, D.C.

The tentative agenda for the Distribution Task Group meeting follows:

1. Opening remarks by the Chairman and Government Cochairman.
2. Review preliminary SPR draft report.
3. Discuss any other matters pertinent to the overall assignment from the Secretary of Energy.

The meeting is open to the public. The Chairman of the Distribution Task Group is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Distribution Task Group will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements should inform Carolyn Klym, Office of Oil, Gas, Shale and Coal Liquids, Fossil Energy, 301/353-2709, prior to the meeting and reasonable provision will be made for their appearance on the agenda.

Summary minutes of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room 1E–190, DOE Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C., between the hours of 8:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, D.C., on September 6, 1984.
Donald L. Bauer,
Principal Deputy Assistant Secretary for Fossil Energy.

[FR Doc. 84-24338 Filed 9-13-84; 8:45 am]
BILLING CODE 6450-01-M

Energy Information Administration

Agency Forms Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration, DOE.
ACTION: Notice of submission of request for clearance to the Office of Management and Budget.

SUMMARY: Under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), Department of Energy (DOE), notices of proposed collections under review will be published in the Federal Register on the Thursday of the week following their submission to the Office of Management and Budget (OMB). Following this notice is a list of the DOE proposals sent to OMB for approval. The listing does not contain information collection requirements contained in regulations which are to be submitted under 5504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by DOE.

Each entry contains the following information and is listed by the DOE sponsoring office: (1) The form number; (2) Form title; (3) Type of request, e.g., new, revision, or extension; (4) Frequency of collection; (5) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (6) Type of respondent; (7) An estimate of the number of respondents; (8) Annual respondent burden, i.e., an estimate of the total number of hours needed to fill out the form; and (9) A brief abstract describing the proposed collection.

DATES: Last notice published Thursday, July 26, 1984 (49 FR 30008).

FOR FURTHER INFORMATION CONTACT:
John Gross, Director, Forms Clearance and Burden Control Division, Energy Information Administration, M.S. 1H-023, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 232-2308
Varikos Broussalian, Department of Energy Desk Officer, Office of Management and Budget, 728 Jackson Place NW., Washington, DC 20503, (202) 395–7313.

SUPPLEMENTARY INFORMATION: Copies of proposed collections and supporting documents may be obtained from Mr.
Office of Energy Research

Energy Research Advisory Board, Supply Subpanel of the Energy R&D Strategy Panel; Open Meeting

Notice is hereby given of the following meeting:


Date and Time: October 9, 1984—9:30 a.m.—4:00 p.m.

Place: O'Hare Hilton, O'Hare International Airport, Room 2019, Chicago, IL 60666.

Contact: Charles E. Cathey, Deputy Director, Science and Technology Affairs Staff, Office of Energy Research.

Purpose of the Parent Board: To advise the Department of Energy on the overall research and development conducted in DOE and to provide long-range guidance in these areas to the Department.

Tentative Agenda:

• Follow-up discussion to August 2, 1984, meeting on general issues facing energy supply R&D.
• Progress reports on supply sector issues.
• Progress reports on staff studies previously identified and discussion of additional studies needed.
• Planning of future activities of the Supply Subpanel.
• Public comment (10 minute rule).

Public Participation

The meeting is open to the public. Written statements may be filed with the Panel either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Charles E. Cathey at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provisions will be made to include the presentation on the agenda. The Chairperson of the Subpanel is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Transcripts

Available for public review and copying at the Freedom of Information Public Reading Room, 1E—190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC between 8:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC on August 31, 1984.

Charles E. Cathey,
Deputy Director, Science and Technology Affairs Staff, Office of Energy Research.

Economic Regulatory Administration

[Docket No. ERA-FC-80-013 (OFC Case No. 55041-0731-01-12)]

Proposed Modification of an Order Granting Permanent Fuels Mixture Exemption to Brunswick Pulp and Paper Company

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) has commenced a proceeding under 10 CFR Part 501, Subpart G to modify the permanent fuels mixture exemption granted by Order ("Order") to a new major fuel burning installation (MFBI), a package boiler identified as Boiler No. 5 owned and operated by Brunswick Pulp and Paper Company (Brunswick) at its Brunswick, Georgia facility, under the Powerplant and Industrial Fuel Use Act of 1978, 42 U.S.C. 8301 et seq. ("FUA" of "The Act").

Based upon its review of Brunswick's application for modification, ERA is proposing to modify the Order on the basis of its determination that significantly changed circumstances, as defined in 10 CFR 501.102(f), exist with respect to the applicability of the original exemption. Accordingly, ERA is hereby giving notice to all parties to the original proceeding of their right, pursuant to 10 CFR 501.101(d), to file a written response to ERA's proposal within 30 days of the publication of this Notice in the Federal Register (see DATES section, below).

If no responses are received within the established period, the Order modification, as proposed, shall become final upon the expiration of that period without further action by ERA. A detailed discussion of the Order and Brunswick's request for modification thereof is provided in the SUPPLEMENTARY INFORMATION section below.

DATES: Written responses to ERA's proposed modification of the Brunswick Order must be received no later than October 15, 1984.

Unless ERA receives comments adverse to its proposed action within the established comment period, the modification order shall become effective on December 14, 1984.

ADDRESS: Written responses are to be addressed to Department of Energy, Economic Regulatory Administration, Office of Fuels Programs, Case Control Unit, GA-007, 1000 Independence Avenue, SW, Washington, D.C. 20585. OCF-55041-0731-01-12 should be printed on the outside of the envelope and the documents contained herein.

FOR FURTHER INFORMATION CONTACT:
Anthony Wayne, Office of Fuels Programs, Economic Regulatory
Steven E. Ferguson, Office of the General Counsel, Department of Energy, Forrestal Building, Room 5D-033, 1000 Independence Avenue, SW., Washington, D.C. 20585, Telephone (202) 252-1730.

SUPPLEMENTARY INFORMATION: On December 31, 1980, ERA exempted, by Order, Brunswick’s new package boiler, identified as Boiler No. 5, at its Brunswick, Georgia plant facility from the prohibitions of section 202 of FUA. The Order was published in the Federal Register on January 7, 1981 (46 FR 1768).

Subject to the terms and conditions set forth in the Order, the permanent fuels mixture exemption permitted, in a mixture with hydrogen, the use of No. 6 fuel oil in the package boiler in an amount not to exceed 25 percent of the total annual Btu heat input of the primary energy sources used in that unit. Brunswick’s exemption request was filed under the then-effective 10 CFR §503.38 (45 FR 38276, June 6, 1980) and was granted pursuant to section 212(d) of FUA. 

Subsequently, via letter dated June 1, 1982, Brunswick requested ERA to modify the subject Order to permit the use of either natural gas or No. 6 oil in the mixture with hydrogen as the primary energy source for Boiler No. 5. The modification request was initiated when Georgia Natural Gas Company (OFC Case No. 55041-0731-033, 1000 Independence Avenue, SW., Washington, D.C. 20585, Telephone (202) 252-6947).

Accordingly, ERA hereby modifies the Order in Docket Number ERA-FC-80-013 to delete therefrom the annual certification reporting requirement.

Based upon its review of the whole record in the proceeding, ERA has determined that the revision of §503.38 in the final rules published on December 7, 1981, described supra, constitutes significantly changed circumstances warranting the modification of the original exemption Order, as provided by 10 CFR 501.102 and 501.103.

Procedures

Parties to the original Order proceeding in Docket No. ERA-FC-80-013 are hereby notified of ERA’s proposed modification of the Order exempting Brunswick’s Boiler No. 5, Brunswick, Georgia from the prohibitions in section 202 of FUA and of their right pursuant to 10 CFR §501.101(d) to file a response thereto within 30 days after the publication of this Notice in the Federal Register. If ERA receives no adverse responses within the allotted comment period, the Order modification shall become final as proposed, without further ERA action, upon expiration of that period.


Robert L. Davies,
Director, Coal & Electricity Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 84-24314 Filed 9-13-84; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

Arizona Public Service Co.: Notice of Filing

September 11, 1984.

The filing Company submits the following:


Any persons desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 24, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb, Secretary.

[FR Doc. 84-24314 Filed 9-13-84; 8:45 am]

BILLING CODE 6171-01-M

Carolina Power & Light Co.: Notice of Filing

September 11, 1984.

The filing Company submits the following:
Take notice that on August 27, 1984, Carolina Power & Light Company (Carolina) tendered for filing changes outlined below in its agreement with Randolph EMC.

Randolph EMC—Provisions include the installation of special metering facilities required to provide metering pulse information at the New Robbins 23 KV Point of Delivery and the addition of hydroelectric generating facilities located on the Deep River at High Falls, North Carolina, the portion of the electrical system served from this Point of Delivery. Customer has allowed the Company to purchase the capacity and energy generating from the hydroelectric facility.

The above Supplement is proposed to be effective ninety days after filing.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capital Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 24, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb, Secretary.

[FR Doc. 84-24315 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M

(Docket No. CP84-664-000)

Commonwealth Edison Co.; Notice of Filing

September 11, 1984.

The filing Company submits the following:


Edison states that the Letter Agreement provides for Commonwealth Edison Company to stand ready to supply Wabash Valley Power Association, Incorporated with 49,000 kW (an increase of 4,000 kW over present agreement) of Standby Power from July 1, 1984 through December 31, 1984.

Edison requests an effective date of July 1, 1984, and therefore requests waiver of the Commission’s notice requirements.

Copies of this filing were served upon Wabash Valley Power Association, Incorporated Indianapolis, Indiana and the Illinois Commerce Commission, Springfield, Illinois.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capital Street N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motion or protests should be filed on or before September 25, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb, Secretary.

[FR Doc. 84-24317 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M

(Docket No. ER84-636-000)
filing a Supplement to its Rate Schedule FERC No. 66, an agreement to provide transmission service to the Power Authority of the State of New York (the Authority). The Supplement provides for an increase in the monthly transmission charge of $0.84 to $1.12 per kilowatt for transmission of power and energy sold by the Authority of Grumman Corporation. The Supplement would increase annual revenues from jurisdictional service during Period I by $17,683.68.

Con Edison states that a copy of this filing has been served by mail upon the Authority.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 625 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 24, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb, Secretary.

[Docket No. CP84-626-000]

Florida Exploration Co., Petitioner and Houston Natural Gas Company, Black Marlin Pipeline Company, Industrial Natural Gas Company and Houston Pipe Line Company, Respondents; Petition for Institution of Proceedings

September 11, 1984.

Take notice that on July 27, 1984, Florida Exploration Company (FEC), 3040 Post Oak Boulevard, Houston, Texas 77056 filed in Docket No. CP84-626-000, a petition for the institution of proceedings pursuant to Rule 207 of the Commission's Rules of Practice and Procedure (18 CFR 385.207) and Sections 5(e) and 5(f) of the Outer Continental Shelf Lands Act (OCS Act) (43 U.S.C. 1334 and (f)) to determine the appropriate proportionate amounts of natural gas produced from the High Island Area, Blocks A-6 (HI A-6) and 201 (HI 201), offshore Texas, which should be purchased from the several working interest owners and transported by Houston Natural Gas Company (HNG) and its wholly-owned subsidiaries,\(^*\) all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

FEC alleges that Industrial has contracted with Shell Offshore, Inc. (Shell), to purchase its production from HI A-6 and HI 201. FEC states that it has offered to sell its share of the production to Industrial under the same terms and conditions as in the Shell/Industrial contract; however, Industrial has refused to purchase either FEC's gas or to enter into a preliminary agreement to purchase FEC's gas at a later date. FEC contends that Industrial's refusal to purchase FEC's share of the production from HI A-6 and HI 201 on a non-discriminatory basis violates the OCS Act and the Sherman Antitrust Act (15 U.S.C. 1, et seq.).

It is submitted that, in order to transport the volumes of gas purchased by Industrial from Shell, Black Marlin filed on April 18, 1984, an application in Docket No. CP84-354-000, requesting authorization to construct and operate, among other things, a 13-mile extension of its offshore pipeline system to the Shell platform in HI A-6 and to transport up to 37,000 Mcf of gas per day for Industrial.

FEC filed simultaneously a motion to consolidate Black Marlin's application in Docket No. CP84-354-000 with the instant petition alleging the two proceedings involve common questions of fact, law and policy that could be evaluated and resolved more efficiently in a single proceeding.

As a basis for its petition to institute proceedings in the said Docket, FEC states that Section 5(e) of the OCS Act requires a pipeline that is both purchasing and transporting OCS gas cannot fulfill its obligations merely by either purchasing or transporting gas on a non-discriminatory basis but rather Section 5(e) requires that pipelines must perform "without discrimination" all of the functions in which they have chosen to engage in OCS lands. FEC alleges the language and concept of the OCS Act of 1953, as amended in 1978, was not original but derived from Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185) which provided in part that pipeline rights-of-way through public lands could be issued subject to the requirement that pipelines be "constructed, operated and maintained as common carriers." It is explained that in 1935 to this stipulation was added that "[pipelines] shall accept, convey, transport or purchase without discrimination oil or natural gas produced from government lands in the vicinity of the pipeline in such proportionate amounts—determined to be reasonable—" (49 Stat. 679–79 (1935)). Based upon these statements, FEC contends, therefore, Section 5(e) of the OCS Act requires that the HNG/Hi/Industrial/Black Marlin entity (HNG Entity) which is both transporting and purchasing goes from OCS lands must perform both functions without discrimination.

FEC further alleges that the HNG Entity is not fulfilling its obligations as it is not purchasing the OCS gas in proportionate amounts as the HNG Entity has arranged to purchase 100 percent of Shell's production and has refused to purchase any of the production owned by the remaining working interests, including FEC's interests. Further, FEC states while Black Marlin has asserted that it is willing to transport gas from HI 8 and HI 201, for buyers other than Industrial, for the same fee that it proposes to charge for the Shell production, the proffered transportation service is inferior to the service Black Marlin offered Industrial as it is circuitous and more expensive.

FEC summarizes its instant petition stating that Section 5(e) of the OCS Act requires, in the absence of voluntary compliance, that the Commission must institute proceedings to determine the reasonable proportionate amounts of natural gas which must be purchased and transported "without discrimination" by pipelines located in OCS lands. FEC states that whatever volumes the HNG Entity chooses to buy from the area of HI 8 and HI 201 in whatever terms, it must purchase pro rata from all the working interest owners who are willing to sell on those terms.

FEC states that a hearing before the Commission is the proper forum for the airing of differences on this subject and for the on-the-record investigation of all pertinent facts.

Any person desiring to be heard or to make any protest with reference to said petition should file a motion to intervene or a protest in accordance with the
requirements of the Commission’s Rules of Practice and Procedure (18 CFR 385.214 or 385.211). 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 motion to intervene in accordance with the Commission’s Rules.

Kenneth F. Plumb,
Secretary.

[Docket No. ER84-635-000]
Florida Power Corp.; Notice of Filing
September 11, 1984.
The filing Company submits the following:
Take notice that on August 29, 1984, Florida Power Corporation (Florida Power) tendered for filing Service Schedule X providing for extended economy interchange service between Florida Power and the City of Kissimmee, Florida. Florida states that Service Schedule X is submitted for inclusion as a supplement under the existing contract for interchange service between Florida Power and the City of Kissimmee, designated as Florida Power’s Rate Schedule FERC No. 94.
Florida Power requests an effective date of September 1, 1984, and therefore requests waiver of the Commission’s notice requirements.
Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 25, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[Docket No. CP74-134-005]
Natural Gas Pipeline Company of America; Notice of Petition to Amend
September 11, 1984.
Take notice that on August 17, 1984, Natural Gas Pipeline Company of America (Natural), 701 East 22nd Street, Lombard, Illinois 60148, filed in Docket No. CP74-134-005 a petition to amend further the order issued May 29, 1975, in Docket Nos. CP74-134 and CP74-145, as amended, pursuant to Section 7(c) of the Natural Gas Act so as to authorize the addition of a delivery point in Custer County, Oklahoma, for an existing exchange arrangement between Natural and Northern Natural Gas Company, a Division of InterNorth, Inc. (Northern), all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Natural requests authorization to add an additional exchange delivery point to permit the delivery of gas to Northern for the account of Natural at the existing interconnection of Northern’s gathering and measurement facilities and the Smith “B” No. 1-21 well in Custer County. It is stated that Natural has a supply of gas available from this well under an existing gas purchase agreement. It is further stated that the use of existing facilities at this delivery point precludes the need for any construction. Natural asserts that the addition of the Custer County delivery point would not change the maximum daily volume exchanged, which would remain at 5,000 Mcf, and would have no adverse impact on Natural’s customers.

Natural states that deliveries at the Custer County delivery point have commenced under the provisions of Order No. 60 and Natural’s blanket certificate issued in Docket No. CP90-123, as reported in Docket Nos. ST84-221 (Natural) and ST 84-210 (Northern).

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before Oct. 2, 1984, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission’s Rules of Practice and Procedure (18 CFR 385.214 or 385.211) 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
motion to intervene in accordance with
the Commission’s Rules.
Kenneth F. Plumb,
Secretary.

[FR Doc. 84-24323 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. EC84-20-000]
Niagara Mohawk Power Corp.; Notice of Application

September 11, 1984.
The filing Company submits the following:

Take notice that on August 31, 1984, Niagara Mohawk Power Corporation (NMPC) tendered for filing an application pursuant to Section 203 of the Federal Power Act, seeking authority to acquire up to $250,000,000 of bonds and a note to be issued by Long Island Lighting Company (LILCO).

It is asserted that NMPC would acquire at a closing intended to occur on or before October 1, 1984 (the “Closing”) approximately $60,000,000 aggregate principal amount of LILCO’s General and Refunding Bonds ¾% Series due August 1, 1983 (Bonds) and LILCO’s unsecured note (Note) bearing interest at the rate of 19% per annum. The Bonds and the Note are to be acquired by NMPC under a Settlement Agreement dated August 30, 1984 between NMPC and LILCO (“Settlement Agreement”) relating to payment of construction costs of the Nine Mile Point Nuclear Station Unit No. 2 (“Unit”). At the Closing, LILCO will pledge to a pledgee acting on behalf of NMPC Bonds having an aggregate principal amount equal to $250 million less the principal amount of Bonds delivered to NMPC at the Closing. The pledged Bonds will be acquired by NMPC from time to time as NMPC makes further construction advances for the Unit on LILCO’s behalf.

In addition to interest payable on the Bonds at the rate of ¾% annually, LILCO has an unsecured obligation to make quarterly supplemental payments ("Supplemental Payments") to NMPC in amounts equal to 18.5% per annum on the principal amount of Bonds held by NMPC. This obligation is to be evidenced by the Note. Until the date of commercial operation of the Unit or certain other dates provided in the Settlement Agreement, LILCO may elect to defer the Supplemental Payments, and in such event NMPC may add the deferred amount as additional principal under the Note.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before October 5, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.
Kenneth F. Plumb,
Secretary.

[FR Doc. 84-24323 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. ER84-38-002]
Otter Tail Power Co.; Notice of Compliance Refund Report

September 11, 1984.

Take notice that on August 20, 1984, Otter Tail Power Company (Otter Tail) submitted for filing a compliance refund report pursuant to § 35.32(a) of the Commission’s Rules of Practice and Procedure.

Otter Tail states that the reduced rate levels were placed into effect on bills rendered for the period May 20-June 20, 1984; therefore, no amounts in the "excess billed" column of the report beginning June 1984 were reported.

Otter Tail also states that the interest was calculated at the average quarterly prime rate and was compounded quarterly. Otter Tail further states that a copy of the refund detail has been submitted to each customer and a copy of the complete refund report is being submitted to each state commission on the service list.

Any person desiring to be heard or to protest this filing should file commenters with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before September 29, 1984. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.
Kenneth F. Plumb,
Secretary.

[FR Doc. 84-24324 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. CP84-661-000]
Panhandle Eastern Pipe Line Co.; Notice of Request Under Blanket Authorization

September 11, 1984.

Take notice that on August 24, 1984, Panhandle Eastern Pipe Line Company (PEPL), P.O. Box 1942, Houston, Texas 77001, filed in Docket No. CP84-661-000 a request pursuant to Section 157.205 of the Commission’s Regulations under the Natural Gas Act (18 CFR 157.205) that PEPL proposes to transport natural gas on behalf of a qualified end-user under the authorization issued in Docket No. CP83-83-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

PEPL states that the proposed transportation service would be performed pursuant to a transportation agreement dated July 10, 1984 (Agreement) among PEPL, Central Illinois Light Company (CILCO) and Caterpillar Tractor Company (Caterpillar). It is explained that the Agreement provides for the transportation of up to 11,000 Mcf (Mcf) of natural gas per day on behalf of Caterpillar for use in boiler, unit heaters, heat treatment equipment, core ovens, and miscellaneous process equipment.

PEPL states that the Agreement provides for PEPL to receive a transportation quantity of up to 11,000 Mcf on an interruptible basis, at an existing point of interconnection between PEPL and the tailgate of Union Texas Products Corporation plant in Major County, Oklahoma. It is explained that PEPL would then transport and redeliver such gas, less four percent reduction for fuel, to CILCO at PEPL’s Peoria sales station in Tazewell County, Illinois, which in turn would make ultimate delivery to Caterpillar for its end-use at its facilities in Peoria, Illinois.

It is stated that CILCO is an existing jurisdictional customer of PEPL and Caterpillar is an existing end-user customer of CILCO.

It is stated that no new facilities are required for this transportation. The transportation charge is based on PEPL’s currently effective OST Tariff, and there is no Added Incentive Charge applicable to this transportation service. It is so stated.

Any person or the Commission’s staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission’s Procedural Rules (18 CFR
Take notice that on August 27, 1984, Southwestern Electric Power Company (SWEPCO) tendered for filing a Letter Agreement dated June 14, 1984 between SWEPCO and North Texas Electric Cooperative, Inc. (NTEC) amending a Power Supply Agreement dated April 8, 1982 between SWEPCO and NTEC (FERC Rate Schedule No. 84).

SWEPCO states that the sole purpose of the Letter Agreement is to correct a minor typographical error in the Power Supply Agreement. Correction of the typographical error has no substantive effect on the contractual arrangements between SWEPCO and NTEC.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 24, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb, Secretary.

[FR Doc. 84-34420 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. ER84-632-000]

Southwestern Electric Power Co.; Notice of Filing

September 11, 1984.

The filing Company submits the following:

Take notice that on August 27, 1984, Southwestern Electric Power Company (SWEPCO) tendered for filing a Letter Agreement dated June 14, 1984 between SWEPCO and North Texas Electric Cooperative, Inc. (NTEC) amending a Power Supply Agreement dated April 8, 1982 between SWEPCO and NTEC (FERC Rate Schedule No. 84).

SWEPCO states that the sole purpose of the Letter Agreement is to correct a minor typographical error in the Power Supply Agreement. Correction of the typographical error has no substantive effect on the contractual arrangements between SWEPCO and NTEC.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 24, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb, Secretary.

[FR Doc. 84-34420 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M
Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission’s Rules of Practice and Procedure (18 CFR 385.214 or 385.211) 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 motion to intervene in accordance with the Commission’s Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 motion 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 motion 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. 84-24329 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. CP82-487-002]

Williston Basin Interstate Pipeline Co. and Montana-Dakota Utilities Co.; Notice of Petition for Declaratory Order

September 11, 1984.

Take notice that on August 16, 1984, Williston Basin Interstate Pipeline Company (Williston) and Montana-Dakota Utilities Co. (MDU), 400 North Fourth Street, Bismarck, North Dakota 58501, filed a petition in Docket No. CP82-487-002 a petition pursuant to rule 207 (18 CFR 384.207) for the issuance of a declaratory order addressing the jurisdiction of certain producer gas that MDU has placed in storage, but has not paid for, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Specifically, MDU states it is suffering from a decline in demand for its gas and has projected purchases from its producer suppliers at approximately 35 percent of contractual levels. As a result it states it is unable to purchase and store all of the available gas; therefore, it alleges it has embarked on a program in which it receives and stores, as part of its system supply, its full contractual levels of casinghead and residue gas, but does not pay for this gas. MDU believes that this policy would avoid the possible flaring of casinghead and residue gas and/or the shutting-in of oil production and the related gas production. MDU contends that, ultimately, any of this gas it accepts into its system would be purchased by MDU and would become system supply, a Commission authorized act.

Alternatively, MDU submits that if this gas is later stored and transported on behalf of a producer to an off-system market, subject to an executed Rate Schedule S-2 service agreement, MDU is authorized to do so by virtue of its certificate in Docket No. CP83-234-000.

Therefore, Williston and MDU request that the Commission make a determination, in connection with its consideration of the settlement in Docket Nos. CP82-487-000, et al., that no additional authorizations are necessary to store volumes received from producer suppliers, but not paid for, and not subject to a Rate Schedule S-2 agreement.

Any person desiring to be heard or to make any protest with reference to said petition should on or before October 2, 1984, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission’s Rules of Practice and Procedure (18 CFR 385.214 or 385.211). 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 motion to intervene in accordance with the Commission’s Rules.

Kenneth F. Plumb, Secretary.

[FR Doc. 84-24329 Filed 9-13-84; 8:45 am]
BILLING CODE 6717-01-M

Southwestern Power Administration

Extension of Integrated System Power Rates; Order Confirming and Approving Extension of Integrated System Power Rates on an Interim Basis

AGENCY: Southwestern Power Administration.

ACTION: Notice of power rate order.

SUMMARY: The Deputy Secretary of Energy has confirmed and approved, on an interim basis, an extension of the existing Southwestern Power Administration System rates. This action is authorized under Delegation Order No. 0204-108, 48 FR 55694 (Dec. 14, 1983) and provides a continuation through September 30, 1986, of the System rates that were confirmed and approved on a final basis by the Federal Energy Regulatory Commission (FERC) for the period August 1, 1983, through July 31, 1984. The following System rates were extended through September 30, 1984, on an interim basis by Rate Order No. SWPA-15 and are authorized by Rate Order No. SWPA-16 to remain in effect on an interim basis through September 30, 1986, or until confirmed and approved on a final basis by the FERC:

- Rate Schedule F-4, Peaking Power
- Rate Schedule F-4A, Firm Power
- Rate Schedule F-4B, Firm Power through Oklahoma Utility Companies
- Rate Schedule IC-2 (Revised), Excess Energy
- Rate Schedule IC-2 (Revised), Interruptible Capacity

EFFECTIVE DATES: Rate Order No. SWPA-16 specifies October 1, 1984, as the effective date for the extension of the existing System rates.

FOR FURTHER INFORMATION CONTACT: Walter M. Bowars, Director, Power Marketing, Southwestern Power Administration, Department of Energy, P.O. Box 1619, Tulsa, Oklahoma 74101, (918) 581-7529

Fred A. Sheap, Office of Power Marketing Coordination, Department of Energy, CE-91, Forrestal Building, Room 0B-104, 1000 Independence Avenue SW., Washington, D.C. 20585.

SUPPLEMENTARY INFORMATION: The present System rates were approved by the FERC for the period August 1, 1983, through July 31, 1984, under Docket No. EF83-4011-000 and were extended by the Deputy Secretary of Energy through September 30, 1984, under Rate Order No. SWPA-15. The Administrator has prepared the 1983 Power Repayment Study and has determined that the existing System rates are consistent with the provisions of Section 5 of the
Flood Control Act of 1944 and Department of Energy Order No. RA 6120.2. In this regard, the Administrator has determined that the rates are the lowest possible rates to the customers consistent with sound business principles. Based on the 1983 Power Repayment Study, the Deputy Secretary of Energy has extended the effective period of the System rates on an interim basis through September 30, 1986, or until confirmed and approved on a final basis by the FERC.

Danny J. Boggs, Deputy Secretary.

DEPARTMENT OF ENERGY
Deputy Secretary of Energy

[Rate Order No. SWPA-16]

Order Confirming and Approving Extension of System Rates on an Interim Basis

August 28, 1984.

In the matter of: Southwestern Power Administration—System Rates.

Pursuant to Sections 302(a) and 301(b) of the Department of Energy Organization Act, Pub. L. 95-91, the functions of the Secretary of the Interior and the Federal Power Commission under Section 5 of the Flood Control Act of 1944, 16 U.S.C. 825s, for the Southwestern Power Administration were transferred to and vested in the Secretary of Energy. By Delegation Order No. 0204–33, effective January 1, 1979, 43 FR 60626 (December 28, 1978), the Secretary of Energy delegated to the Assistant Secretary for Resource Applications the authority to develop power and transmission rates, acting by and through the Administrator, and to confirm, approve and place into effect such rates on an interim basis, and delegated to the Federal Energy Regulatory Commission the authority to confirm and approve on a final basis or to disapprove power and transmission rates. This rate order is issued pursuant to the delegation to the Deputy Secretary of Energy.

Background

On May 17, 1984, the Southwestern Power Administration (SWPA) published notice in the Federal Register (49 FR 20905) that the 1983 Current Power Repayment Study for the integrated system projects indicates that the existing power rates satisfy cost recovery criteria specified in Department of Energy Order No. RA 6120.2 and Section 5 of the Flood Control Act of 1944. The Federal Register Notice was issued in accordance with Title 10, Part 903, Subpart A, of the Code of Federal Regulations entitled, "Procedures for Public Participation in Power and Transmission Rate Adjustments." The Federal Register Notice apprised the public that the Administrator proposes to request an extension of the effective period of the System rates through September 30, 1986, the date requested in the original rate filing. The rates have been in effect since confirmed and approved on a final basis by the Federal Energy Regulatory Commission (FERC) in Docket No. EP83-4011–000 for the period August 1, 1983, through July 31, 1984. An interim extension subject to final confirmation and approval by the FERC was granted for the period August 1, 1984, through September 30, 1984, by the Deputy Secretary of Energy on August 3, 1984. On May 17, 1984, the date of publication of the Federal Register Notice inviting public participation, SWPA mailed a copy of the Federal Register Notice and supporting 1983 Repayment Study to the customers for information. Based on the date of publication, written comments from customers and interested parties were due by June 18, 1984. However, the Administrator granted a request from the Southwestern Power Resources Association dated May 30, 1984, to extend the public comment period through June 30, 1984. Notice of the extended comment period was mailed to each customer June 7, 1984, and was published in the Federal Register June 18, 1984 (49 FR 24939). Written comments on the proposal are contained along with SWPA's responses in the Comments and Responses Section of this rate order. The existing System rates schedules are shown below:

Rate Schedule P-4, Peaking Power
Rate Schedule P-4A, Firm 1983 Repayment Rate Schedule F-4B, Firm Power through Oklahoma Utility Companies

Rate Schedule EE-2 (Revised), Excess Energy
Rate Schedule IC-2 (Revised), Interruptible Capacity

Rate Schedule F-4 applies to wholesale customers purchasing hydro and/or seasonal peaking power and peaking energy from the integrated system. This rate schedule is designed for peaking customer whose energy usage is 1200 kilowatt hours per kilowatt per year and for two peaking customers who are presently supplied 1000 kilowatt hours per kilowatt per year (Cajun Electric Cooperative, Inc., and Northeast Texas Electric Cooperative, Inc.). The two 1600 hour customers will be converted to 1200 hours usage beginning in FY 1986.

Rate Schedule F-4A applies to firm power sales from the integrated system and Rate Schedule F-4B applies to the Oklahoma Companies arrangements which provide for reimbursement to Public Service Company of Oklahoma (PSO) and Oklahoma Gas and Electric Company (OG&E) for thermal generation. The Oklahoma Companies arrangements provide for borderline power and energy sales to a number of municipalities in the service areas of PSO and OG&E. SWPA has separately-stated charges for transformation to load center delivery which SWPA also must pay. All the customers served by the companies under these arrangements receive load center service; the customers pay SWPA the load center firm rate (Rate Schedule F-4B), and SWPA pays the transmission costs, part of which is borne by the customers through the application of the rate for load center service. SWPA is reimbursed for the cost of power purchased under the contracts by the customers through a thermal energy charge which is passed through directly to the customers served under Rate Schedule F-4B.

Rate Schedule EE-2 (Revised) applies to sales of Excess Energy and Rate Schedule IC-2 (Revised) applies to sales of Interruptible Capacity.

Discussion

The 1983 Current Power Repayment Study indicates that the existing System rates will repay the integrated system investment with interest and all operating costs as required by Department of Energy Order No. RA 6120.2. This study is an update of the 1982 Repayment Study and tests the adequacy of the existing rates based on a new cost evaluation period of FY 1983 through FY 1986. The 1982 Repayment Study utilized a cost evaluation period of FY 1982 through FY 1986. The main difference in the two studies results...
from extending the cost evaluation period the additional year and updating costs to current levels.

In FERC's "Order Confirming and Approving Rates" for the Integrated System Projects, issued August 1, 1983, the Commission reiterated its concern over what it considers to be SWPA's arrearage in meeting scheduled repayment and suggested that "prompt correction of SWPA's amortization practices can ameliorate prior deficits in repayment obligations". While SWPA takes issue with the implication that scheduled amortization payments are required by law, or are even possible in a wholly hydroelectric system, SWPA does share the Commission's concern for timely repayment of all annual costs and the Federal investment. DOE Order No. RA 6120.2 prescribes the Secretary of Energy's policies and procedures for accomplishing timely repayment. SWPA is obliged to follow such policies.

As recognized by the FERC in Order No. EF83-4011-000, SWPA has taken action to improve its financial position in several ways. SWPA is continuing the policy of allowing all firm (load factor) power sales contracts to expire and replacing them with peaking power contracts which obligates SWPA to supply only 1200 kilowatt-hours per kilowatt per year. This limits the need for SWPA to purchase power from other utilities in low water years to fulfill contract obligations. Also, in designing the present System rate schedules, SWPA increased the capacity component of the rates relative to the energy component to ensure consistent recovery of costs, especially in low water years. In addition, the present rates include a purchased power adjustment charge to recover the cost of purchased power in average water years. SWPA established deferred accounts to reflect the balances of revenue from the purchased power adjustment and expenses from the cost of purchased power. In Order EF83-4011-000, the FERC directed SWPA to provide the monthly balances of its deferred credit and cost accounts together with a statement describing the effects of the purchased power cost adjustment on SWPA and the customers. SWPA has provided, in a separate attachment, the monthly balances of the deferred credit and cost accounts for FERC information. SWPA is assuming that any deferred credit or cost carried on its balance sheet will ultimately be "flowed back" to the customers in the form of periodic adjustments to the purchased power cost adjustment and will, over a period of time, even out and have no effect on System Power Repayment Study results. SWPA believes the purchased power adjustment has provided satisfactory results while in effect during this limited period and will include the results in the rate determination procedure at the time of the next rate filing after additional results are monitored and FY 1983 and subsequent actual financial data are included.

SWPA has taken additional steps to improve its financial position. SWPA has reviewed cost and revenue estimating procedures to assure the accuracy of those projections. Such accuracy is evidenced both by the comparison of the estimates for FY 1982 used in the 1982 Repayment Studies with actual costs experienced and SWPA's continuing analysis of alternative cost estimating methods. Further, SWPA is committed to annual power repayment and subsequent timely rate adjustments and has made a comparison, similar to the one the Commission staff has made regarding the actual repayment progress versus expected progress under various amortization methods, including the power repayment study method amortization "schedule". SWPA found that under the present rate level it will "catch-up" to accumulated amortization expected under the present repayment study method by FY 1990. The same study indicated that amortization through FY 1982 under this method should have been some $74 million, reaching $86 million by FY 1984 and about $135 million by FY 1990. It is expected that actual repayment status at the end of FY 1984 will approach $60 million.

SWPA's plan is to maintain amortization at the level necessary to repay investment and annual costs as required by legislation and resultant policy. SWPA believes that, given its commitment to annual power repayment studies and timely, unrestricted rate adjustments implemented as needed, any perceived deficiency should be readily corrected. SWPA believes that persistent monitoring of the annual repayment studies and decisive action to correct any mis-estimates of revenues and expenses will eliminate any potential "bow wave" effect on amortization. SWPA previously recognized the need for additional revenue and increased System rates approximately 33 percent effective April 1, 1979. Thus, two rate adjustments within little more than four years have increased average annual revenues approximately 70 percent. This cannot be ignored as a significant accomplishment toward repayment of the Federal investment and an indication of SWPA's intent to maintain revenues at adequate levels. SWPA has also updated its computer capabilities which facilitates analyses of revenues, expenses and other repayment study data not possible on the previous system. The new computer system will enable SWPA to test the effects of input variations on the repayment studies in very short time frames that previously required manual preparation. SWPA has also been successful in winning litigation directed toward eliminating the implementation of power rates on an interim basis. Interim rates will continue to facilitate cost recovery when rates are pending final review by the FERC.

In its August 1, 1983, Order on the System rates, the FERC specified that "* * * annual interest on additions should be computed using the current interest rate applicable in each year, as required by DOE Order No. RA 6120.2 (September 29, 1979), rather than the project interest rates which are reflected in SWPA's current repayment study". SWPA has made the necessary computer program changes using the current interest rates on plant additions rather than the original project interest rates. This change actually amounted to only a technical adjustment and had little, if any, effect on future interest expense. The change is reflected in the revenue distribution section of the 1983 Power Repayment Study.

SWPA also recognizes that the historic period used in this study ends more than 18 months before the filing date although the study was completed within the 18-month period. However, the limited approval period provided by FERC made completion of the 1983 FRS, which would include FY 1983 actual data, impossible prior to this filing time. Actual audited financial data are not available until approximately February following the end of a fiscal year making completion of a timely power repayment study difficult at best. Further, the public participation process required, and the preparation of both the Sam Rayburn Dam rate extension and the Tex-La Contract Rate increase at the same time virtually guaranteed that the criteria could not be met without preparing another study with the 1983 data to be filed at a later date. In addition, the data needed for filing a rate action require considerable additional time to prepare and this time simply would not have been available after waiting for FY 1983 financial data. Therefore, SWPA used actual FY 1982 financial data as the basis for the 1983 Power Repayment Study.
Comments and Responses

The Southwestern Power Administration received written comments from three organizations concerning the proposed extension of the System rates through September 30, 1986. The Southwestern Power Resources Association provided comments by letter dated June 26, 1984, the National Wildlife Federation by letter dated June 28, 1984, and the Department of the Army by letter also dated June 28, 1984. A summary of the two major comments and responses to these comments prepared by the SWPA staff follow:

Amortization Policy

Comment: The National Wildlife Federation (NWF) and Department of the Army (DOA) comments relate to repayment policy, and oppose priority of revenue distribution to the highest interest-bearing investment. The NWF further recommends straight-line amortization of the Federal investment to determine revenue requirements. Southwestern Power Resources Association, however, supports the present method of amortization as required under current Department of Energy policies in Order No. RA 6120.2.

Response: SWPA's repayment policy is set forth in Department Of Energy Order No. RA 6120.2. Section 8.c.(3) of that Order states: "To the extent possible, while still complying with the repayment periods established for each increment of investment and unless otherwise indicated by legislation, amortization of the investment will be accomplished by application to the highest interest-bearing investment first." The policy is based on Section 5 of the Flood Control Act of 1944 (Flood Control Act) which requires that power and energy from Federal projects be marketed, "...at the lowest possible rates to consumers consistent with sound business principles. ..." Priority of revenue distribution to the highest interest-bearing investment and the actual amortization methodology are separate issues. The policy of paying the highest interest-bearing investment first, results in reduced interest expense and is consistent with the least cost approach directed by the Flood Control Act. Amortization of the capital investment is required by the Flood Control Act to be accomplished, "...over a reasonable period of years. ..." This period has been determined by Order No. RA 6120.2 to be within 50 years from the date of commercial service for the hydroelectric projects and to be shorter periods for transmission and replacement investments based on their service lives. Repayment of investment within the established periods takes priority over distribution of revenue to the highest interest-bearing investment. Priority distribution of revenue to the highest interest-bearing investment is made only after payment of current and any deferred annual expense and is a sound business principle which results in the lowest rates to the consumer of power and energy to the customers. Proper business management requires priority retirement of the most expensive debt to reduce the cost of borrowing. Also, the benefits of Federal multipurpose hydroelectric projects are available not only to electric customers but to those who benefit from the other project purposes such as flood control, water supply, navigation, and recreation. Therefore, the opportunity supersedes the duty of the taxpayer to participate in the benefits of the hydroelectric projects financed by Congressional Appropriations. It should be noted that hydroelectric power does, in fact, reap actual monetary benefits to the taxpayer and not just hypothetical, indirect, and less specific benefits. The appropriations are tied to rates of interest determined by the cost of borrowing to the Government when the appropriations are made. The interest earned by the taxpayer on appropriations must be paid to the Treasury by the Power Marketing Administrations (PMAs) along with funds to repay the appropriations. Priority of revenue distribution is assigned to payment of imputed annual interest ahead of investment. For PMAs, Congressional Appropriations are the surrogate "debt instrument" which must be repaid within a term not to exceed 50 years. The logic that there are no debt instruments repayable to the Treasury could lead to the erroneous conclusion that no interest should be imputed at all. However, the PMAs (including SWPA) have carefully created a system which endeavors to impute interest costs and interest income that would be identical to the methods used in the private sector. This system includes the management of cash receipts and cash disbursements in such a way as to minimize expenses and maximize proceeds.

SWPA also believes that "Congress intended that sound business principles be applied to protect the Federal investment, not to artificially reduce the repayment obligations of the power purchasers." As reflected previously, Section 5 of the Flood Control Act presents a dual statutory standard regarding rates to be charged for the sale of power and energy. It requires that rates be both (1) the lowest possible to consumers and (2) consistent with sound business principles. The requirement to charge the lowest possible rates could result in rates that are too low to repay the Government's investment and related costs, if not governed by the requirements that the rates are to be consistent with sound business principles and recover costs over a reasonable period of years. Conversely, rates that are too high to pay annual costs and amortize investment could be determined to be excessive. Therefore, one must consider both requirements when developing power rates. Power Repayment Studies, which are prepared annually, demonstrate whether rates satisfy both requirements. Frequent monitoring of the Power Repayment Studies ensures that appropriate action is taken to repay the Federal investment as stipulated by legislation and resultant policy. The Congress decided in the original, and reiterated in subsequent, Power Marketing legislation that it wishes to recover all of the capital which it has invested in the power features of multiple-purpose water projects, including the cost of land, with interest, over a set period of years which bears no necessary relationship to the useful life of the project. Just as in a home mortgage, the recovery of the capital including capital invested in land, is set for a fixed period. Also, just like a home mortgage, current annual costs (such as taxes for a mortgage or operations and maintenance costs for the PMAs) must also be recovered. The mortgage payment is calculated so that equal payments will be made each year on a combination of interest and return of capital over the set period of years. In the early years, interest payments are large and capital payments are small. In the later years, the reverse applies. The rate of interest, as in a mortgage, is set at the beginning of the loan period and continues throughout the life of the loan.

Had the Congress conceived of its investment in power differently, some other method of determining the repayment obligation might well have been appropriate. For example, had the Congress wished to view its investment in power as a permanent investment of public funds which it expected the managers to protect and preserve, it would then have expected that depreciation would have been included in cost recovery. Straight Line or some other accepted form of depreciation on the constructed property, but not on the land, over the useful life of the property—not any arbitrary set period
Corps O&M Estimates

Comment: The Southwestern Power Resource Association (SPRA), while supporting the extension, expressed its opinion that Corps' Operation and Maintenance Expense Estimates are excessive by $5.2 million annually and indicated that their previously proposed alternatives for calculating Corps O&M expenses "are as valid today as they were when we originally submitted them to SWPA, DOE and the FERC.

Response: In a continuing effort to develop both accurate and understandable procedures for forecasting costs in our power repayment studies, as encouraged by the FERC in its rate orders directed to SWPA, we have reviewed the methodology used to estimate Corps O&M. Since considerable customer confusion was evidenced in the previous rate filing as to the practice by the Corps, which included not only inflation but other cost increase factors as well, the Corps was requested to provide SWPA its future O&M estimates based on FY 1983 cost levels. The Corps applied escalation factors based on project age to its FY 1983 projections to account for "increased O&M requirements that inevitably occur at older projects." Subsequently, SWPA adjusted the Corps' estimates by compounded rates of inflation based on Cross National Product Deflators. Such a method removes the inconsistency in approach between Corps O&M estimates and SWPA O&M and purchased power costs, as well as eliminating the Corps' rate of change percentages which had been confused with inflation and which were applied to typically deficient base year costs (also confusing). SWPA is of the opinion that the new Corps estimates of future O&M expense are based on reasonable and accurate assumptions and that the new methodology warrants serious consideration, even though the result is a reduction in total estimated Corps O&M expense of approximately $2.6 million annually beginning in the fifth year of the cost evaluation period.

Further, the new methodology was previously recommended by SPRA* (formerly Committee on Power for the Southwest) and the customers as an alternative to the method used to calculate Corps O&M expense in the 1982 Power Repayment Study (PRS). It should be noted, however, that the other projected increases in system costs caused the PRS to show the continuing inadequacy of current rates. SWPA will continue to monitor Corps O&M expense, and all other expenses to
ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-2669-3]

Availability of Environmental Impact Statements Filed September 4, 1984 Through September 7, 1984 Pursuant to 40 CFR 1506.9

EIS No. 840399, Final, FHW, OR, Albany-Junction City Highway/OR-60E Improvement, Queen Avenue to Tangent Drive, Linn County, Due: October 15, 1984, Contact: Dale Wilken, (503) 399-5749.
EIS No. 840400, DS/Suppl, COE, MN, Chaska Flood Control Plan, Minnesota River, Carver County, Due: October 29, 1984, Contact: Robbin Blackman, (612) 725-7746.
EIS No. 840402, DS/Suppl, COE, KY, Yatesville Lake Multipurpose/Local Protection Project, Blaine Creek, Lawrence County, Due: October 29, 1984, Contact: John Justice, Jr., (304) 529-5034.
EIS No. 840403, Draft, COE, WA, Quillayute River Navigation Project, Operations and Maintenance, Clallam County, Due: October 29, 1984, Contact: W. Burton Hamner, (206) 764-3624.
EIS No. 840405, Draft, COE, AK, Auke Bay Breakwater and Maina Developments, Permit, Juneau, Due: October 29, 1984, Contact: Gene Augustine, (907) 552-4942.
EIS No. 840406, Final, FHWA, CA, Roseville Bypass/CA-65 Construction, I-60 to CA-65, Placer Co., Due: October 15, 1984, Contact: Mike Cook, (916) 440-3541.
Amended Notice
EIS No. 840398, DS/Suppl, HUD, WA, Gem Heights Planned Development, Mortgage Insurance, Pierce County, Published FR 9-7-84. Correction—This document was inadvertently filed with the Environmental Protection Agency (EPA) as a Federal Environmental Impact Statement. Its correct status is a State Environmental Impact Statement and is therefore being officially retracted.
Allan Hirsch, Director, Office of Federal Activities.
[FR Doc. 84-24380 Filed 9-13-84; 8:45 am]
BILLING CODE 6560-50-M

[OPTS-51538; FRL-2670-2]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of the final rule published in the Federal Register of May 13, 1983 (46 FR 21722). This notice announces receipt of seventeen PMNs and provides a summary of each.

PMN 84-1139, 84-1140, 84-1141, 84-1142, 84-1143, 84-1144, 84-1145 and 84-1146—December 3, 1984.
Written comments by: PMN 84-1132, 84-1133, 84-1134, 84-1135, 84-1136 and 84-1137—October 29, 1984.
PMN 84-1138—November 2, 1984.

ADDRESS: Written comments, identified by the document control number "[OPTS-51538]" and the specific PMN number should be sent to: Document Control Officer (TS-793), Chemical Information Branch, Information Management Division, Office of Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M Street SW., Washington, DC 20460, (202-382-3532).

FOR FURTHER INFORMATION CONTACT: Wendy Cleland-Hammert, Premanufacture Notice Management
SUPPLEMENTARY INFORMATION: The following notices contain information extracted from the non-confidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete non-confidential document is available in the Public Reading Room E-107 at the above address.

PMN 84-1132

**Importers:** Confidential. **Chemical:** (G) Heterocyclic substituted copper phthalocyanine. **Use/Production:** (G) Site-limited dye intermediate. Import range: Confidential. **Toxicity Data:** No data submitted. Exposure: Processing a total of 6 workers, up to 3 hrs/day, up to 48 da/yr. Environmental Release/Disposal. Release to water. Disposal by publicly owned treatment works (POTW).

PMN 84-1133

**Manufacturer:** Confidential. **Chemical:** (G) Hydroxy acrylic resin. **Use/Production:** (G) Resin will be made into paint by our customer. Prod. range: Confidential. **Toxicity Data:** No data submitted. Exposure: Confidential. Environmental Release/Disposal. Confidential.

PMN 84-1134

**Importers:** Confidential. **Chemical:** (G) Hydroxy acrylic resin. **Use/Production:** (G) Paint is imported and sold. Import range: Confidential. **Toxicity Data:** No data submitted. Exposure: Confidential. Environmental Release/Disposal. Confidential.

PMN 84-1135

**Manufacturer:** Confidential. **Chemical:** (G) Vinyl urethane. **Use/Production:** (G) Resin. Prod. range: Confidential. **Toxicity Data:** No data submitted. Exposure: Confidential. Environmental Release/Disposal. Confidential. Disposal by POTW.

PMN 84-1136

**Importers:** UNIROYAL INC. **Chemical:** (G) Substituted aromatic amide. **Use/Import:** (S) Industrial modifier for amine-cured epoxy systems. Import range: Confidential. **Toxicity Data:** Acute oral: > 5,000 mg/kg; irritation: Skin—Very mild, Eye—Non-irritant; Ames Test: Positive. Finished product: Negative.

**Exposure.** Manufacture and use: dermal and inhalation, a total of 4-10 workers/tower, 2 workers/line and 2-5 workers/curing unit, 1 hr/batch. **Environmental Release/Disposal.** Less than 1 to 10 kg/yr released to air.

PMN 84-1137

**Manufacturer:** UNIROYAL INC. **Chemical:** (G) Cycloaliphatic epoxide. **Use/Production:** (S) Industrial modifier for amine-cured epoxy systems. Prod. range: Confidential. **Toxicity Data.** Acute oral: Between 4,250 and 5,000 mg/kg; irritation: Skin—Mild, Eye—Mild-irritant; Ames Test: Positive. Exposure: Use: dermal and inhalation, a total of 4-10 workers/tower, 2 workers/line, 2-5 worker/curing unit and 2 workers/filament winder/hr/batch. Environmental Release/Disposal. Less than 1 to 10 kg/yr released to air.

PMN 84-1138

**Manufacturer:** Confidential. **Chemical:** (G) Sulfonated vinyl homopolymer salt. **Use/Production:** (G) Oil recovery additive. Prod. range: Confidential. **Toxicity Data:** No data submitted. Exposure. Confidential. Environmental Release/Disposal. Confidential. Disposal by POTW.

PMN 84-1139

**Manufacturer:** Confidential. **Chemical:** (G) Cellulosic ether. **Use/Production:** (G) Rheological modifier for fluids used in recovery of subterranean oil and gas. Prod. range: Confidential. **Toxicity Data:** No data submitted. Exposure. Manufacture: dermal, a total of 10 workers, up to 4 hrs/day, up to 35 da/yr. **Environmental Release/Disposal.** Confidential. Disposal by industrial wastewater treatment facility.

PMN 84-1140

**Manufacturer:** Confidential. **Chemical:** (G) Monobasic acid—modified alkyd resin. **Use/Production:** (G) Site-limited polymer intermediate. Prod. range: Confidential. **Toxicity Data:** No data submitted. Exposure: Manufacture: dermal, a total of 6 workers. **Environmental Release/Disposal.** Confidential.

PMN 84-1141

**Importers:** Confidential. **Chemical:** (G) Phenylene bis(benzothiazoyloxyalkylamide) [methylimidazole] derivative mixed salts. **Use/Import:** (S) Industrial colorant for paper. Prod. range: Confidential. **Toxicity Data.** Acute oral: > 5 g/kg; Irritation: Skin—Irritant, Eye—Severe; Ames Test: Mutagenic. Exposure: Processing a total of 3 workers per plant. **Environmental Release/Disposal.** Release to water.

PMN 84-1142

**Manufacturer:** The C.P. Hall Company. **Chemical:** (G) Aliphatic polyester. **Use/Production:** (S) Industrial plasticizer. Prod. range: Confidential. **Toxicity Data.** No data submitted. Exposure. Confidential. **Environmental Release/Disposal.** Confidential.

PMN 84-1143

**Manufacturer:** Confidential. **Chemical:** (G) 2,4,6-trisubstituted phenol. **Use/Production:** (G) Chemical intermediate—destructive use. Prod. range: Confidential. **Toxicity Data.** No data submitted. Exposure. Confidential. **Environmental Release/Disposal.** Confidential.

PMN 84-1144

**Manufacturer:** Confidential. **Chemical:** (G) Isoalkyleneoxy alkanoate. **Use/Production:** (G) Solvent. Prod. range: Confidential. **Toxicity Data.** Acute oral: > 2,000 mg/kg; Acute dermal: > 2,000 mg/kg; Irritation: Skin—Essentially no irritation; Eye—Slight; LC50: 48 hr (Daphnia magna): 370 mg/L; LC50: 96 hr (Fathead minnow): 71 mg/L; BOD (Industrial) Day 5: 1% Thod, Day 10: 8% Thod, Day 20: 20% Thod; BOD (Municipal) Day 5: 5% Thod, Day 10: 15% Thod, Day 20: 20% Thod. Exposure: Manufacture: dermal, a total of 3 workers. **Environmental Release/Disposal.** Release to air, Disposal by incineration.

PMN 84-1145

**Manufacturer:** SCM Specialty Chemicals. **Chemical:** (G) Alkyltrialkoxysilane. **Use/Production:** (G) Surface modifier. Prod. range: Confidential. **Toxicity Data.** No data submitted. Exposure. Confidential. **Environmental Release/Disposal.** Confidential.
PMN 84-1146

**Manufacturer:** Confidential.  
**Chemical:** (G) Substituted polyethylene glycol succinate.  
**Use/Production:** (G) Papermaking additive.  
**Prod. range:** Confidential.  
**Toxicity Data:** Acute oral: >5 g/kg; Acute dermal: >5 g/kg; Irritation: Skin—Mild, Eye—Moderate; Ames Test: Negative.  
**Exposure:** Manufacture: dermal, a total of 90 workers, up to 6 hrs/day, up to 240 da/yr.  
**Environmental Release/Disposal:** 0.05 to 7 kg/day released. Disposal by incineration.

By mail:

**DATE:** September 10, 1984.

**Automated Sciences Group, Inc.:** Transfer of Data to Contractor

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA plans to transfer information submitted under sections 3, 6, and 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to Kendrick & Company, Suite 500, 800 18th Street NW, Washington, D.C. 20006, under Contract No. 68-02-3983. This contractor shall perform various services for the Office of Pesticide Programs (OPP) of EPA. Some of the information that will be made available to this contractor has been claimed to be confidential business information (CBI). Information will be transferred to the contractor consistent with requirements of 40 CFR 2.301(h). This action will enable the contractor to fulfill the obligations of the contract, and this notice serves to notify affected persons.

**DATE:** September 9, 1984.

**FOR FURTHER INFORMATION CONTACT:**

By mail:

Office location and telephone number: Rm. 222, CM#2, 1921 Jefferson Davis Highway, Arlington, Virginia, (703–557–2613).

**SUPPLEMENTARY INFORMATION:** Under this contract, Automated Sciences Group, Inc., shall index, code, and enter technical data into the Pesticide Data Management System (PDMS) from which retrievals are run and bibliographies produced to support the registration, tolerance, and special review programs, and other data-dependent activities of the pesticide registration program. Section 10(e) of FIFRA provides that information that is considered by the submitter to be trade secret or commercial or financial as described by FIFRA section 10(d) may be disclosed to an authorized contractor when such disclosure is necessary for the performance of the contract. EPA routinely receives such CBI as part of the data that are submitted by pesticide registrants and others as provided for in FIFRA sections 3, 6 and 7.

Contractors are authorized to receive such data if the EPA program office managing the contract makes the determinations specified in 40 CFR 2.301(h)(2) as referenced in § 2.307. Such determinations have been made concerning the contract with Automated Sciences Group, Inc.

FIFRA section 10(f) provides a criminal penalty for wrongful disclosure of confidential information, whether such disclosure is made by an EPA employee or an EPA contractor.

The contract with Automated Sciences Group, Inc., specifically prohibits disclosure of confidential business information to any third party in any form without written authorization from EPA, and personnel of this contractor will be required to sign a nondisclosure agreement before they are permitted access to such information.
Section 10(e) of FIFRA provides that information that is considered by the submitter to be trade secret, commercial or financial as described by FIFRA section 10(d) may be disclosed to an authorized contractor when such disclosure is necessary for the performance of the contract. EPA routinely receives such CBI as part of the data that are submitted by pesticide registrants and others as provided for in FIFRA section 3, 6, and 7. Contractors are authorized to receive such data if the EPA program office managing the contract makes the determinations specified in 40 CFR 2.301(h)(2) as referenced in § 2.307. Such determinations have been made concerning the contract with Kendrick & Company.

FIFRA section 10(f) provides a criminal penalty for wrongful disclosure of confidential information, whether such disclosure is made by an EPA employee or an EPA contractor. The contract with Kendrick & Company specifically prohibits disclosure of confidential business information to any third party in any form without written authorization from EPA, and personnel of this contractor will be required to sign a nondisclosure agreement before they are permitted access to such information.

Dated: September 6, 1964.

Steven Schatzow,
Director, Office of Pesticide Programs.

[FED Register Doc. 84-26373 Filed 8-13-84; 8:45 am]
BILLING CODE 6560-50-M

[OW-FRL–2670–5]

Nebraska Pretreatment Program Approval

AGENCY: Environmental Protection Agency.

ACTION: Notice of approval of the national pollutant discharge elimination system pretreatment program of the State of Nebraska.

SUMMARY: On September 7, 1964, the Environmental Protection Agency approved the State of Nebraska’s National Pollutant Discharge Elimination System State Pretreatment Program. This action authorizes the State of Nebraska to administer the National Pretreatment Program as it applies to municipalities and industries within the State.


SUPPLEMENTARY INFORMATION:

Background

The Pretreatment Program, required by the Clean Water Act of 1977, governs the control of industrial wastes introduced into Publicly Owned Treatment Works (POTWs). The objectives of the Pretreatment Program are:

1. To prevent introduction of pollutants into POTWs which will interfere with the operation of a POTW, including interference with its use or disposal of municipal sludge; (2) prevent the introduction of pollutants into POTWs; (3) improve opportunities to recycle and reclaim municipal and industrial wastewaters and sludge. Local pretreatment programs will be the primary vehicle for administering, applying and enforcing pretreatment standards for industrial users of POTWs. To receive pretreatment program approval, a State must submit to the EPA a modification to its NPDES program pursuant to the requirements and procedures of the General Pretreatment Regulation (40 CFR Part 403).

In support of its application for pretreatment program approval, the State of Nebraska has submitted to EPA copies of the relevant statutes and regulations, and the program description and forms but also is providing the public with an up-to-date summary of the State’s program. The following table will provide the public with an up-to-date list and a description of the resources to be dedicated to the program. The sample forms indicate the information to be collected from industrial users of POTWs, including industrial waste surveys and permit applications; permits; and monitoring and noncompliance reports. Based upon this information, EPA has concluded that the State will have the necessary procedures and resources, including the procedures and resources listed in 40 CFR 403.10(f) (2) and (3), to administer the pretreatment program. This conclusion is supported not only by a review of the State’s program description and forms but also by the State’s experience in administering its approved NPDES program.

Federal Register Notice of Approval of State NPDES Programs or Modifications

EPA will provide Federal Register notice of any action by the Agency approving or modifying a State NPDES program. The following table will provide the public with an up-to-date list of the status of NPDES permitting authority throughout the country.

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<thead>
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<th>State</th>
<th>Approved NPDES permit program</th>
<th>Approved to regulate Federal facilities</th>
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* Date of administration signature.

Review Under Executive Order 12291 and the Regulatory Flexibility Act

The Office of Management and Budget has exempted this action from OMB review requirements of Executive Order
Pursuant to section 605(d) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), I certify that this State Pretreatment Program Approval will not have a significant impact on a substantial number of small entities.

Approval of the Nebraska NPDES State Pretreatment Program establishes new substantive requirements, but merely transfers responsibility for administration of the program from EPA to the State.


William D. Ruckelshaus, Administrator.

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

(FCC 84-320; Report No. DS-305)

Radiodetermination Satellite Service; Applications Acceptable for Filing


The Commission has found, upon initial review, that the following applications filed by Geostar Corporation (GEOSTAR) on March 31, 1983, for authority to construct, launch and operate radiodetermination satellites are acceptable for filing. The Commission reserves the right to return these applications, however, if, upon further examination, it is determined that they are defective or not in conformance with the Commission's rules, regulations and policies.

Geostar Corporation

2191-DSS-P/LA-84
2192-DSS-P/LA-84
2193-DSS-P/LA-84
2194-DSS-P/LA-84

Application for authority to construct, launch and operate four space stations in the radiodetermination satellite service. Each of the proposed satellites will receive transmissions from a central earth station facility within the 18.5 MHz band between 6525-6541.5 MHz and retransmit these signals throughout the United States in the band 2483.5-2500 MHz at a nominal e.i.r.p. of 34 dBW. Transceivers receiving these signals will, at random intervals, transmit signals back to the satellite in the band 1610.0-1625.5 MHz at a nominal e.i.r.p. of 25.7 and 30 dBW. These signals will be received by the satellite and will be retransmitted to the central station within the band 5117-5163 MHz at a nominal e.i.r.p. of 34 dBW. Telemetry, tracking and telecommand will be conducted in the 5 GHz band. The requested orbital locations are 70° W.L., 100° W.L. and 130° W.L. with a fourth satellite colocated at one of these locations as an in-orbit spare. The proposed system would provide radiodetermination and associated message transfer services. This would allow subscribers to determine latitude, longitude and altitude and to exchange brief encoded messages using inexpensive transceivers. Services are proposed to be offered on a noncommon carrier basis.

Simultaneously with the submission of its applications GEOSTAR petitioned the Commission to begin a rulemaking to reallocate spectrum to accommodate this system. (RM-4426) On July 12, the FCC adopted a Notice of Proposed Rulemaking to allocate frequencies at 16.0-16.5 MHz, 17.5-18.0 MHz, and 5177-5183 MHz for this service, as well as to address regulatory and licensing issues concurrently. See Notice of Proposed Rulemaking, FCC 84-319, Docket Nos. 84-688 and 84-690. Comments concerning the reallocation of spectrum and licensing policies and procedures should be filed in accordance with that notice. For reference purposes, GEOSTAR's applications have been assigned the file numbers listed above. Comments or petitions on GEOSTAR's applications may be filed within thirty (30) days of the date of this notice. The time for filing subsequent pleadings is specified in Section 1.45 of the Rules. 47 CFR 1.45.

No extensions of time will be granted because of the need to expedite initiation of this new service to the public.

Interested parties wishing to file radiodetermination satellite service applications to be considered concurrently with GEOSTAR's application must do so within forty-five days of the date of this Notice. See, e.g., Direct Broadcast Satellite Service, 46 FR 42339 (September 6, 1981); Domestic Fixed Satellite Service, 46 FR 40233.

We require each applicant to file a concrete, comprehensive proposal for its proposed radiodetermination satellite system and services, describing in detail all pertinent technical and operational aspects of the system and its ability in fact to proceed expeditiously with actual construction and launch. In particular, this information shall include that specified in Appendix B of Space Station Application Filing Procedures, 46 FR 40256 (September 6, 1981), as appropriate. However, in response to item II.F, applicants should address issues relating to compatibility with the proposed Geostar system as required by paragraph 34 of the Notice of Proposed Rulemaking, rather than 24 orbital spacing. Applicants should also describe, as a central part of the application, "the position, velocity and/ or other characteristics of an object or the obtaining of information relating to these parameters, by means of the propagation properties of radio waves," 47 CFR 2.1, as well as any other ancillary services to be provided. Applications that fail to comport with these requirements, or that fail to address meaningfully the other matters raised in the Notice of Proposed Rulemaking, supra, concerning licensing policies and procedures, as of the cut-off date will be dismissed as unacceptable for filing.

Action by the Commission July 12, 1984. Commissioners Fowler (Chairman), Quello and Patrick with Commissioner Dawson dissenting in part and issuing a statement.

For further information contact: Fern Jarmulnek at (202) 634-1822.

William J. Tricarico,
Secretary, Federal Communications Commission.

BILLING CODE 6712-01-M

[MM Docket Nos. 84-650 et al.; File Nos.
BP-810202AH]

Central Bucks Broadcasting Co., et al., Applications for Construction Permits; Hearing Designation Order

In the matter of applications of Central Bucks Broadcasting Co., WBUX(AM), Doylestown, Pennsylvania, Has: 1570 kHz, 5 kW, DA-D; Req: 1160 kHz, 1 kW, DA-2, U (MM Docket No. 84-650, File No. BP-810202AH); Windjammer Communications Corp., WQMR(AM), Skowhegan, Maine, Has: 1150 kHz, 1 kW, D, Req: 1160 kHz, 1 kW, DA-2, U (MM Docket No. 84-651, File No. BP-810560AH); Valley Broadcasting Co., WNYN(AM), Lehighton, Pennsylvania, Has: 1350 kHz, 1 kW, DA-D; Req: 1160 kHz, 1 kW, 5 kW-LS, DA-2, U (MM Docket No. 84-654, File No. 811111AA); Housatonic Valley Broadcasting Corp., WQMR(AM), Skowhegan, Maine, Has: 1150 kHz, 1 kW, D, Req: 1160 kHz, 1 kW, 5 kW-LS, DA-2, U (MM Docket No. 84-654, File No. 811111AA); Housatonic Valley Broadcasting Corp., WINQ(AM), Brookfield, Connecticut, Has: 940 kHz, 1 kW, D, Req: 1160 kHz, 1 kW, 2.5 kHz-LS, DA-2, U, Berkshire Broadcasting Corp. (MM Docket No. 84-654, File No. BP-811116AA); Somerset Valley Broadcasting Co. Inc., WBRW(AM), Mechanicsville, New York, Has: 1170 kHz, 250 W, D, Req: 1160 kHz, 1 kW, 5 kW-LS, DA-2, U (MM Docket No. 84-653, File No. BP-810631AW); Raymark Broadcasting Co. Inc., WRID(AM), Homestead, Pennsylvania, Has: 1350 kHz, 1 kW, DA-D; Req: 1160 kHz, 1 kW, 5 kW-LS, DA-2, U (MM Docket No. 84-654, File No. 811111AA); Housatonic Valley Broadcasting Co., WINE(AM), Berkshire, Massachusetts, Has: 940 kHz, 1 kW, D, Req: 1160 kHz, 1 kW, 2.5 kHz-LS, DA-2, U, Berkshire Broadcasting Corp. (MM Docket No. 84-654, File No. BP-811116AA); Somerset Valley Broadcasting Co. Inc., WBRW(AM),
By the Chief, Mass Media Bureau. *

1. The Commission, by the Chief, Mass Media Bureau, acting pursuant to its discretion, has before it for consideration a number of petitions to deny, which are linked to each other either directly or indirectly through the presence of intervening interlocking proposals.1 Also before the Commission are petitions to deny filed by various applicants2 and outside parties, and pleadings responsive thereto.

2. Mechanicville Broadcasting Company (Mechanicville). Mechanicville notes that 1,638 persons would reside within the proposed daytime 1 W/m contour, a figure greater than 1 percent of the 95,651 persons located within the 25 mV/m contour. Hence, the proposal does not comply with § 73.37(a)(2) of the Commission's Rules. Mechanicville states, however, that it will satisfy all reasonable complaints of nighttime interference within the 1 W/m contour; consequently, an appropriate condition will be specified.

3. Houseaton Valley Broadcasting Company (Housatonic). A petition to deny has been filed by Housatonic alleging overlap between the 0.5 mV/m contour of Houseaton and the 0.5 mV/m contour of adjacent channel station WCRR. Cornwall-on-Hudson, New York, prohibited by § 73.37(a)(2) of our Rules. In addition, Mechanicville claims that Housatonic's proposed nighttime operation fails to meet the coverage requirements of § 73.24(j) of our Rules.

4. Review of all measurement data submitted by the applicants here persuades us that no overlap exists between the 0.5 mV/m contours of WCRR and the Housatonic proposal. As for Housatonic's coverage of its community of license, Brookfield Town according to the applicant is a combination of urban and rural areas typical of New England civil divisions. We note that Houseaton's proposed nighttime interference-free contour would not intersect a substantial area within the actual city limits of Brookfield Town; this coverage however does include the major population centers of Brookfield and Brookfield Center which represent the areas of highest population density within the Census Division. Consequently, we conclude that a waiver of § 73.24(j) (the coverage requirement of our Rules) is warranted.

5. Further, the Commission has not yet received Federal Aviation Administration clearance for the antenna tower proposed by Housatonic.

6. Berkshire Broadcasting Corporation (Berkshire). A petition to deny has been filed by Mechanicville. The petition alleges that Berkshire has failed to comply with § 73.24(j) (the nighttime interference requirement of our Rules) which limits nighttime power of new or expanded Class A and B stations to 1 kilowatt. Consequently, an appropriate condition will be specified.

7. With respect first to our acceptance criteria, only two commercial broadcast stations are licensed to Danbury, Connecticut, WLAD and the co-owned WDAQ(FM), and no FM channel is available for use in that community. Consequently, the proposed WLAD operation would provide a second nighttime aural transmission service to Danbury, and is therefore acceptable for filing under § 73.37(e)(2) of our Rules. In addition, Berkshire has requested a waiver of § 73.24(j) (the coverage requirement of our Rules). We have, however, adopted a strict standard for waiving requests of this nature. Waivers will be granted only upon a showing that the higher power proposed is necessary to provide principal city coverage and will not impede our allocation objectives. While Berkshire argues that operation at 5 kW is necessary to provide substantial compliance with the nighttime coverage requirement of § 73.24(j) of the Commission's Rules, it appears that operation at 1 kW might cover a sufficient percentage of the residential areas of Danbury either to achieve substantial compliance with the coverage requirements or to satisfy coverage requirements in the manner discussed above in paragraph 4 with respect to New England civil divisions. Hence, Berkshire has not submitted the required preclusion study. Consequently, an appropriate issue will be specified.

9. Somerset Valley Broadcasting Company, Inc. (Somerset). Mechanicville has filed a "request" that the Commission return the Somerset application because of overlap of its proposed 0.5 mV/m contour with the 0.5 mV/m contour of WCNX(AM), Middletown, Connecticut, in contravention of Section 73.37(a)(2) of our Rules. Based on our engineering studies, we conclude that no prohibited overlap will occur, especially in light of the latest amendment, filed March 12, 1984, to reduce daytime power and redesign the directional antenna. Consequently, the petition filed by Mechanicville will be denied.

10. In addition, New Jersey Bell has submitted a letter dated February 1, 1982 stating that its equipment within Somerset's proposed 1 V/m contour is susceptible to AM RFI and could cause interference to the telephone company's operation. Consequently, an appropriate condition will be specified.

11. Minority Broadcasting Company of the Midwest, Inc. (Midwest). Somerset has filed a petition to deny alleging that the Midwest proposal fails to provide the nighttime interference-free coverage of the community of license required by § 73.24(j) of our Rules. In addition, a petition for return of this application as unacceptable for filing has been filed by Central Bucks Broadcasting Company. In its petition, Central Bucks complains that Midwest has photocopied the entire technical showing prepared for Central Bucks here by E. Harold Munn, Jr. (with only a substitute page 1, Section V-A of Form 310) without the knowledge or consent of Mr. Munn.

12. Midwest has submitted an amendment dated March 12, 1984 proposing a new antenna site 3.8 miles south of the original antenna site. The amendment includes a complete engineering study, prepared on behalf of Midwest, demonstrating that the
proposed 10 mV/m nighttime interference-free contour would cover the entire community of Warrington. Consequently, the petition of Somerset County, Rama, and the City of New Brunswick, Mechanicsville, cited in Section VI, Form 301, as required in Section VI, Form 301, of the presiding Administrative Law Judge within 30 days of the release of this Order. The presiding Administrative Law Judge will then evaluate the coverage map submitted and specify any additional issues as appropriate. Perry has also failed to provide data on Section V–G, Form 301 (i.e., missing information on one of the proposed towers). Consequently, a clarifying engineering amendment is required.

19. In addition, the Commission has not yet received Federal Aviation Administration clearance for the antenna tower proposed by Perry. An appropriate issue will be specified.

20. Rama Communications Group, Inc. (Rama). New Jersey Bell has submitted a letter dated March 2, 1984 stating that its T-1 carrier facility located within Rama's 1 V/m contour may be subject to blanketing interference. Consequently, an appropriate condition will be specified.

21. Local notice certification issues. Applicants for new broadcast stations or major modifications of existing stations are required to give local notice of the filing of their applications in accordance with § 73.3560 of the Commission's Rules. They must then file proof of such notice or certify that they have or will comply with the public notice requirement. We have no evidence, however, that Perry, Raymark, and Midwest have done either. If they have not already done so, Perry, Raymark, and Midwest will be required to give local public notice and to file a statement that they have complied with the local public notice requirement with the presiding Administrative Law Judge within 30 days of the release of this Order.

22. Environmental narrative issues. Since the Mechanicville and Perry proposals constitute major environmental actions as defined by § 1.1303(a) of the Commission's Rules, the applicants are required to submit the environmental narrative information described in § 1.1311 of our Rules. The Mechanicville and Perry proposals fail to include information concerning access roads and power lines to their respective sites and their zoning classifications (if any).

23. Consequently, Mechanicville and Perry will be required to file within 30 days of the release of this Order amended environmental narrative statements with the presiding Administrative Law judge. In addition, copies shall be filed with the Chief, Audio Services Division, who will then proceed regarding this matter in accordance with the provisions of § 1.1313(b). Accordingly, § 1.1317 of the Rules is waived to the extent that the comparative phase of the case will be allowed to begin before the environmental phase is completed. See Golden State Broadcasting Corp., 71 FCC 2d 229 (1972), recon. denied sub nom. Old Pueblo Broadcasting Corp., 83 FCC 2d 337 (1980).

24. Except as indicated by the issues specified below, all applicants are qualified to construct and operate as proposed. However, since the

4 Mechanicville also raises allegations of a violation by Perry of our regional concentration of control provision; such contentions have been mooted by our Repeal of the "Regional Concentration of Control" Provisions of the Commission's Multiple Ownership Rules, 84 FCC 2d 156, released May 1, 1984. In addition, the license of Perry's WCFPRAM), Webster, Massachusetts, has been assigned to OKun Broadcasting Corporation (BAL-840104EQ, consummated March 23, 1984), and an assignment of the license of Perry's WRTT(AM), Vernon, Connecticut, has been granted to Radio-Television-Tele-Communications, Inc. (BAL-840142EP, consummation still pending), thus eliminating any potential multiple ownership problem.
proposals are mutually exclusive, they must be designated for hearing in a consolidated proceeding. As the proposals are for different communities, we will specify an issue to determine pursuant to section 307(b) of the Communications Act of 1934, as amended, which proposal (or combination of proposals) would best provide a fair, efficient, and equitable distribution of radio service. We will also specify a contingent comparative issue, should such an evaluation of the proposals prove warranted.

25. Accordingly, it is ordered, that pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding to be held before an Administrative Law Judge at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine whether there is a reasonable possibility that a hazard to air navigation would occur as a result of the tower heights and locations proposed by Housatonic Valley Broadcasting Company and Edward F. Perry, Jr.

2. If a final environmental impact statement is issued with respect to Edward F. Perry, Jr. and Mechanicville Broadcasting Company which concludes that the proposed facilities are likely to have an adverse effect on the quality of the environment, to determine:
   (a) Whether the proposals are consistent with the National Environmental Policy Act, as implemented by § 1.1301–1319 of the Commission's Rules.
   (b) Whether, in light of the evidence adduced pursuant to (a) above, the applicants are qualified to construct and operate as proposed.

3. To determine with respect to the proposal of Berkshire Broadcasting Corporation whether circumstances exist which warrant waiver of § 73.21(a)(2)(ii)(C) of the Commission's Rules.

4. To determine with respect to the application of Minority Broadcasting Company of the Midwest, Inc.:
   (a) Whether the applicant has available sufficient funds to construct and operate as proposed; and
   (b) Whether, in light of the evidence adduced pursuant to (a) above, the applicant is financially qualified.

5. To determine with respect to the application of Edward F. Perry, Jr.:
   (a) Whether the applicant has available sufficient funds to construct and operate as proposed; and
   (b) Whether, in light of the evidence adduced pursuant to (a) above, the applicant is financially qualified.

6. To determine: (a) The areas and populations which would receive primary aural service from the proposals and the availability of other primary service to such areas and populations, and (b) in light thereof and pursuant to section 307(b) of the Communications Act of 1934, as amended, which of the proposals (or combination of proposals) would best provide a fair, efficient and equitable distribution of radio service.

7. To determine, in the event it is concluded that choice among the applicants should not be based solely on considerations relating to section 307(b), which of the proposals would, on a comparative basis, best serve the public interest.

8. To determine, in light of the evidence adduced pursuant to the foregoing issues, which of the applications should be granted.

26. It is further ordered, That the Federal Aviation Administration is made a party to the proceeding.

27. It is further ordered, That § 1.1317 of the Commission's Rules is waived to the extent indicated herein. Within 30 days of the release of this Order, Edward F. Perry, Jr. and Mechanicville Broadcasting Company shall submit the amended environmental narrative statement required by § 1.1311 of the Rules to the presiding Administrative Law Judge with a copy to the Chief, Audio Services Division.

28. It is further ordered, That Edward F. Perry, Jr., Raymark Broadcasting Company, Inc., and Minority Broadcasting Company of the Midwest, Inc. shall comply with the local notice provisions of § 73.3300 of the Commission's Rules, as discussed above, and advise the presiding Administrative Law Judge as to compliance within 30 days of the release of this Order.

29. It is further ordered, That in the event the application of Mechanicville Broadcasting Company is granted, the construction permit shall contain the following condition:

   The applicant, pursuant to § 73.88 of the Commission's Rules, shall satisfy all reasonable complaints of blanketing interference within its 1 V/m contour.

30. It is further ordered, That the petition to deny filed by Mechanicville Broadcasting Corporation against the proposed operation of Minority Broadcasting Company of the Midwest, Inc., are dismissed as moot.

31. It is further ordered, That Minority Broadcasting of the Midwest shall submit the EEO information required in Section VI, Form 301, to the presiding Administrative Law Judge within 30 days of the release of this Order.

32. It is further ordered, That Edward F. Perry, Jr., shall submit an amendment specifying all amendment and Commission proceedings to which he is a party, and describing all issues being litigated in each, to the presiding Administrative Law Judge within 30 days of the release of this Order.

33. It is further ordered, That Edward F. Perry, Jr. shall submit an amendment detailing the nighttime interference-free coverage of his proposal, an amended Section V–G, Form 301, and appropriate radiation scales to the daytime and nighttime horizontal antenna plots to the presiding Administrative Law Judge within 30 days of the release of this Order.

34. It is further ordered, That the statement of notice filed by Mechanicville Broadcasting Company against the proposed operation of Edward F. Perry, Jr., is granted to the extent indicated herein, and is denied in all other respects.
The Commission, by the Chief, Mass Media Bureau, acting pursuant to delegate authority, has under consideration the mutually exclusive applications of D.R.O., Inc. (D.R.O.), Radcomm, Inc. (Radcomm) and Minority Broadcasting Company of the Midwest, Inc. (MBC).

2. Radcomm. WWHK is presently operating under a special temporary authority to remain silent pending financial reorganization of Radcomm. In addition, a lawsuit is currently pending in a local Michigan court among the shareholders of Radcomm over the funding of the radio station and the financial responsibilities of each of the owners. Under these circumstances, a question is raised as to whether Radcomm possesses sufficient funds to construct and operate its proposed facilities for three months without revenue; consequently, an appropriate financial issue will be specified.

3. MBC. D.R.O. has filed a motion to dismiss and a supplement thereto claiming that MBC, in support of its application, submitted an incomplete engineering exhibit. Under Commission policy, however, the fact that the MBC application as initially submitted contained copied engineering material did not render the application incomplete and therefore unacceptable at the time of filing. See, e.g., Roanoke Christian Broadcasting, Inc., FCC 84-68, released March 20, 1984. Further, MBC submitted its own complete engineering exhibit prior to the effective date of an injunction issued by the United States District Court (filed in the Northern District of Illinois, Eastern Division pursuant to a civil suit filed by D.R.O.). Therefore, the court's language in its injunction barring the use of the copied engineering "for any purpose" never effectively rendered the application incomplete at any point during its pendency. Accordingly, the petitions will be denied on this basis.

4. We note that MBC in its exhibit has calculated its nighttime interference-free coverage on the basis of 10 mV/m. Commission engineering studies, however, indicate that the nighttime interference-free contour will be considerably greater than 10 mV/m. MBC has not provided a contour map indicating nighttime interference-free city coverage with the higher value. Consequently, the applicant must submit an amendment to the presiding Administrative Law Judge within 30 days of the release of this Order. The Administrative Law Judge will then evaluate the amended proposal and, if the coverage is deemed to be inadequate, specify any additional issues or grant a waiver of § 73.244(j) (the coverage requirement of our Rules) as appropriate.

5. MBC has also failed to provide the EEO information required in Section VI, Form 301. Consequently, MBC will be required to file the EEO program found in Section VI, Form 301, with the presiding Administrative Law Judge within 30 days of the release of this Order.

7. Except as indicated by the issues specified below, all applicants are qualified to construct and operate as proposed. However, since the proposals are mutually exclusive, they must be designated for hearing in a consolidated proceeding. As the proposals are for different communities, we will specify an issue to determine pursuant to section 307(b) of the Communications Act of 1934, as amended, which proposal (or combination of proposals) would best provide a fair, efficient, and equitable distribution of radio service. We will also specify a contingent comparative issue, should such an evaluation of the proposals prove warranted.

Accordingly, it is ordered, That pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding to be held before an Administrative Law Judge at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine with respect to the application of Radcomm, Inc.: (a) Whether the applicant has available sufficient funds to construct and operate as proposed; and (b) Whether, in light of the evidence adduced pursuant to (a) above, the applicant is financially qualified.

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1 Operation with the facilities specified herein is subject to modification, suspension or termination without right to hearing, if found by the Commission to be necessary in order to conform to the Final Acts of the ITU Administrative Conference on Medium Frequency Broadcasting in Region 2, Rio de Janeiro 1981, and to bilateral and other multilateral agreements between the United States and other countries.
2. To determine with respect to the application of Minority Broadcasting Company of the Midwest, Inc.: (a) Whether the applicant has available sufficient funds to construct and operate as proposed; and (b) Whether in light of the evidence adduced pursuant to (a) above, the applicant is financially qualified.

3. To determine: (a) The areas and populations which would receive primary aural service from the proposals and the availability of other primary service to such areas and populations, and (b) in fight thereof and pursuant to section 307(b) of the Communications Act of 1934, as amended, which of the proposals (or combination of proposals) would best provide a fair, efficient and equitable distribution of radio service.

4. To determine, in the event it is concluded that a choice among the applicants should not be based solely on considerations relating to section 307(b), which of the proposals would, on a comparative basis, best serve the public interest.

5. To determine, in light of the evidence adduced pursuant to the foregoing issues, which of the applications should be granted.

9. It is further ordered, That the petition to dismiss and supplement thereto filed by D.R.O., Inc., are denied.

11. It is further ordered, That Minority Broadcasting Company of the Midwest, Inc. shall submit an amendment specifying the coverage to Fenton, Michigan provided by the actual nighttime interference-free contour to the presiding Administrative Law Judge within 30 days of the release of this Order.

13. It is further ordered, That in addition to the copy served on the Chief, Hearing Branch, a copy of each amendment filed in this proceeding subsequent to the date of adoption of this Order shall be served on the Chief, Data Management Staff, Audio Services Division, Mass Media Bureau, Room 350, 1919 M Street, N.W., Washington, D.C. 20554.

14. It is further ordered, That the applicants herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 73.3535(g) of the Commission's Rules, give notice of the hearing within the time and in the manner prescribed in such Rule, and shall advise the Commission of the publication of such notice as required by § 73.3535(g) of the Rules.

Federal Communications Commission.

W. Jan Gay,

Assistant Chief, Audio Services Division,
Mass Media Bureau.

[FR Doc. 84-2235 Filed 9-13-84; 8:45 am]

BILLING CODE 6712-01-M


WABB, Inc.; et al.; Application for Construction Permit; Hearing Designation Order

In the matter of, WABB, Inc., WABB (AM), Prichard, Alabama, HAS: 1480 kHz, 5 kW, DA-N, U, Req: 1160 kHz, 1 kW, 10 kW-LS, DA-N, U (MM Docket No. 84-846 File No. BP-810220 AG); Minority Broadcasting Co. of Alabama, Inc., Prichard, Alabama, Req: 1160 kHz, 1 kW, 10 kW-LS, DA-N, U (MM Docket No. 84-847 File No. BP-810394 AB); United Broadcasting Co., Inc., Mobile, Alabama, Req: 1160 kHz, 1 kW, 10 kW-LS, DA-N, U (MM Docket No. 84-848, File No. BP-810432 AB); Alabama Native American Broadcasting Co., WASG (AM), Atmore, Alabama, HAS: 1140 kHz, 10 kW, U, Req: 1160 kHz, 2.5 kW, 10 kW-LS, DA-2, U (MM Docket No. 84-849, File No. BP-810724 AH), for construction permit.


By the Chief, Mass Media Bureau.

1. The Commission, by the Chief, Mass Media Bureau, acting pursuant to delegated authority, has under consideration the mutually exclusive applications of WABB, Inc. (WABB), Minority Broadcasting Company of Alabama (Minority), United Broadcasting Company, Inc. (United), and Alabama Native American Broadcasting Company (Alabama Native).

2. WABB. A petition to deny has been filed against the proposed operation of WABB by National Public Radio (NPR). NPR has alleged that the WABB proposal, although specifying Prichard as the community of license, would continue to maintain its primary coverage in the metropolitan Mobile area.

3. To the extent that this contention relates to divining the service intentions of WABB, our abolition of the suburban community policy (Report and Order, 93 FCC 2d 436 (1983)), obviates any need for us to consider this allegation. We note however, as does NPR, that WABB proposes to retain its main studio in Mobile without the good cause showing required by §73.1125 of our Rules. Consequently, an appropriate issue will be specified.

4. We further note, as does NPR, that WABB has offered its present facilities on 1480 kHz to Spring Hill College of Mobile, Alabama, contingent upon the grant of WABB's 1160 kHz application. Should the WABB proposal on 1160 kHz be granted, however, WABB would no longer have an interest in the facility at 1480 kHz to assign, as it plans, and the frequency of 1480 kHz would revert to the public domain. See Southern Keswick, Inc., 34 FCC 2d 624 (1972).

5. WABB states in its application that the nighttime limit to its proposal is 3.2 mV/m. We have determined, however, that the nighttime interference-free contour would be slightly greater than the normally protected 10 mV/m contour, and WABB has not submitted any showing of its actual nighttime-interference-free coverage contour to support its proposal.

Consequently, WABB will be required to submit an amendment detailing the nighttime interference-free coverage of its actual contour to the presiding Administrative Law Judge within 30 days of the release of this Order. It is clear, however, that WABB is attempting to serve the city of Prichard from a deep null in its radiation pattern. Consequently, the normally protected 10 mV/m nighttime-interference-free contour and the slightly greater actual contour provide service to only an isolated portion of Prichard. Therefore, WABB has failed to satisfy the coverage requirement of §73.24(j). Although WABB has failed to request a waiver of this rule, we will permit the presiding Administrative Law Judge to evaluate the coverage map submitted and determine whether circumstances exist which warrant a waiver of § 73.24(j) of our rules.

6. Applicants for new broadcast stations or major modification of existing facilities are required to give local notice of the filing of their applications in accordance with § 73.3520 of the Commission's Rules. They must then file proof of such notice or certify that they have or will comply with the public notice requirement. WABB has filed a local public notice incorrectly listing Mobile, Alabama as the proposed community of license. Consequently, WABB will be required to submit an amended local public notice and to file a statement that it has complied with the local public notice requirement with the...
presiding Administrative Law Judge within 30 days of the release of this Order.

7. Minority. A petition to dismiss and a motion to dismiss and return application have been filed by WABB and United, respectively, against the proposed operation of Minority. Both petitioners maintain that Minority has submitted the entire WABB engineering proposal except for page 1 of Section V (Form 301) in support of its proposal. The Commission, however, has previously determined that "an applicant whose engineering data is used by another without authorization can adequately protect its property rights, if any, in court. . . ." Roanoke Christian Broadcasting, Inc., FCC 84-98, released March 20, 1984. Consequently, we will specify no issues in this regard.

8. The petitioners also allege, correctly, that Minority actually specified three potential antenna sites in its application; in response, Minority has filed an amendment dated December 23, 1981 identifying the transmitter site as "7355 Telegraph Road; 1/4 block north of intersection of Telegraph Road and Bay Bridge Road." Both petitioners, in their replies, claim that the address of 7355 Telegraph Road at the corresponding coordinates provided by Minority is non-existent. We must conclude under these circumstances that Minority has failed to specify a definite and viable transmitter site and has failed, as a consequence, to establish its technical qualifications to construct and operate as proposed. Consequently, an appropriate issue will be specified. Such a technical, rather than legal, issue will be designated for hearing in a subsequent proceeding to be held before an Administrative Law Judge at a time and place to be specified in a consolidated proceeding. As the proposals are for different communities, we will specify an issue to determine pursuant to section 307(b) of the Communications Act of 1934, as amended, whether construction of the proposed facilities are likely to have an adverse effect on the environment, to determine whether the proposal complies with the coverage requirement of § 73.24(j) of the Commission's Rules and, if not, specify a waiver issue as appropriate.

12. Alabama Native. Alabama Native has requested a nighttime operating power of 2.5 kW in contravention of § 73.21(a)(2)(ii)(C) which limits nighttime power of Class II-B stations on the clear channel frequencies to 1 kW. It has been determined, however, that using the proposed pattern at the permitted power of 1 kW, coverage of Atmore will be achieved. Consequently, Alabama Native will be required to file an amendment to reduce its nighttime power to 1 kW with the presiding Administrative Law Judge within 30 days of the release of this Order.

13. Environmental narrative issues. Since the WABB and United proposals constitute major environmental actions as defined by § 1.1305(a) of the Commission's Rules, the applicants are required to submit the environmental impact information described in § 1.1311 of our Rules. WABB's environmental narrative statement fails to state whether construction of the proposed facility has been a source of local controversy in the community; United's environmental narrative statement fails to include information concerning power lines to the site and whether construction has been a source of local controversy.

14. Consequently, WABB and United will be required to file amended environmental narrative statements with the presiding Administrative Law Judge within 30 days of the release of this Order. In addition, copies shall be filed with the Chief, Audio Services Division, who will then proceed regarding this matter in accordance with the provision of § 1.1313(b). Accordingly, § 1.1317 of the Rules is waived to the extent that the comparative phase of the case will be allowed to begin before the environmental phase is completed. See Golden State Broadcasting Corp., 71 FCC 2d 229 (1979), recon. denied sub nom. Old Pueblo Broadcasting Corp., 83 FCC 2d 337 (1980).

15. Except as indicated by the issues specified below, all applicants are qualified to construct and operate as proposed. Since the proposals are mutually exclusive, however, they must be designated for hearing in a consolidated proceeding. As the proposals are for different communities, we will specify an issue to determine pursuant to section 307(b) of the Communications Act of 1934, as amended, which proposal (or combination of proposals) would best provide a fair, efficient, and equitable distribution of radio service. We will also specify a contingent comparative issue, should such an evaluation of the proposals prove warranted.

16. Accordingly, it is ordered, That pursuant to section 306(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding to be held before an Administrative Law Judge at a time and place to be specified in a subsequent Order, upon the following issues:

1. If a final environmental impact statement is issued with respect to WABB, Inc. and United Broadcasting Company, Inc. which concludes that the proposed facilities are likely to have an adverse effect on the quality of the environment, to determine:

(a) Whether the proposals are consistent with the National Environmental Policy Act, as implemented by §§ 1.1301-1319 of the Commission's Rules; and

(b) Unless the Commission finds that the proposal is the best practical and feasible alternative having regard to its technical and economic implications, the proposal shall be disapproved.

Minority has, in any event, failed to obtain FAA clearance for its proposed antenna operation; an appropriate issue will therefore be specified.

2 Operation with the facilities specified herein is subject to modification, suspension or termination without right to hearing if found by the Commission to be necessary in order to conform to the Final Acts of the ITU Administrative Conference on Medium Frequency Broadcasting in Region 2, Rio de Janeiro, 1961, and to bilateral and other multilateral agreements between the United States and other countries.
(b) Whether, in light of the evidence adduced pursuant to (a) above, the applicants are qualified to construct and operate as proposed.

2. To determine whether the proposal of WABB, Inc. complies with the main studio location requirements of § 73.1125 of the Commission's Rules.

3. To determine, with respect to the proposal of WABB, Inc., whether circumstances exist which warrant a waiver of § 73.24(j) of the Commission's Rules.

4. To determine whether Minority Broadcasting Company of Alabama, Inc. has available a definite antenna site and is technically qualified to construct and operate as proposed.

5. To determine with respect to the application of Minority Broadcasting Company of Alabama, Inc.: (a) Whether the applicant has available sufficient funds to construct and operate as proposed, and (b) Whether, in light of the evidence adduced pursuant to (a), the applicant is financially qualified.

6. To determine whether there is a reasonable possibility that a hazard to air navigation would occur as a result of the tower height and location proposed by Minority Broadcasting Company of Alabama, Inc.

7. To determine: (a) The areas and populations which would receive primary aural service from the proposals and the availability of other primary service to such areas and populations, and (b) in light thereof and pursuant to section 307(b) of the Communications Act of 1934, as amended, which of the proposals (or combination of proposals) would best provide a fair, efficient and equitable distribution of radio service.

8. To determine, in the event it is concluded that choice among the applicants should not be based solely on considerations relating to section 307(b), of which the proposals would, on a comparative basis, best serve the public interest.

9. To determine, in light of the evidence adduced pursuant to the foregoing issues, which of the applications should be granted.

10. It is further ordered, That the Federal Aviation Administration is made a party to the proceeding.

11. It is further ordered, That § 1.1317 of the Commission's Rules is waived to the extent indicated herein. Within 30 days of the release of this Order, WABB, Inc. and United Broadcasting Company, Inc. shall submit the amended environmental narrative statement required by § 1.1311 of the Rules to the presiding Administrative Law Judge with a copy to the Chief, Audio Services Division.

12. It is further ordered, That WABB, Inc. shall submit an amendment detailing the actual nighttime interference-free coverage of its proposal to the presiding Administrative Law Judge within 30 days of the release of this Order.

13. It is further ordered, That WABB, Inc. shall submit an amended local notice certification pursuant to § 732.3580 of the Commission's Rules, as discussed above, to the presiding Administrative Law Judge within 30 days of the release of this Order.

14. It is further ordered, That the petition to deny filed by National Public Radio, is granted to the extent indicated herein and is denied in all other respects.

15. It is further ordered, That the petition to dismiss filed by WABB, Inc. and the motion to dismiss and return application filed by United Broadcasting Company, Inc., are granted to the extent indicated herein and are denied in all other respects.

16. It is further ordered, That Minority Broadcasting Company of Alabama, Inc. shall submit a revised Section II, Form 301 detailing the ownership of the applicant's stock, to the presiding Administrative Law Judge within 30 days of the release of this Order.

17. It is further ordered, That United Broadcasting Company, Inc. shall submit an amendment detailing the actual nighttime interference-free coverage of its proposal to the presiding Administrative Law Judge within 30 days of the release of this Order.

18. It is further ordered, That Minority Broadcasting Company of Alabama, Inc. shall submit an amended local notice certification pursuant to § 732.3580 of the Commission's Rules, as discussed above, to the presiding Administrative Law Judge within 30 days of the release of this Order.

19. It is further ordered, That Minority Broadcasting Company of Alabama, Inc. shall submit a revised Section II, Form 301 detailing the ownership of the applicant's stock, to the presiding Administrative Law Judge within 30 days of the release of this Order.

20. It is further ordered, That Alabama Native American Broadcasting Company shall submit an amendment to reduce its nighttime power to 1 kW to the presiding Administrative Law Judge within 30 days of the release of this Order.

21. It is further ordered, That National Emergency Training Center, Emmitsburg, Maryland, shall submit an amended local notice certification pursuant to § 732.3580 of the Commission's Rules, as discussed above, to the presiding Administrative Law Judge within 30 days of the release of this Order.

22. It is further ordered, That in addition to the copy served on the Chief, Hearing Branch, a copy of each amendment filed in this proceeding subsequent to the date of adoption of this Order shall be served on the Chief, Data Management Staff, Audio Services Division, Mass Media Bureau, Room 350, 1919 M Street, N.W., Washington, D.C. 20554.

23. It is further ordered, That in the event it is concluded that choice among the applicants should not be based solely on considerations relating to section 307(b), of which the proposals would, on a comparative basis, best serve the public interest.

24. It is further ordered, That the application of Minority Broadcasting Company of Alabama, Inc. and United Broadcasting Company, Inc., are granted to the extent indicated herein and are denied in all other respects.

25. It is further ordered, That Alabama Native American Broadcasting Company shall submit an amendment to reduce its nighttime power to 1 kW to the presiding Administrative Law Judge within 30 days of the release of this Order.

26. It is further ordered, That in addition to the copy served on the Chief, Hearing Branch, a copy of each amendment filed in this proceeding subsequent to the date of adoption of this Order shall be served on the Chief, Data Management Staff, Audio Services Division, Mass Media Bureau, Room 350, 1919 M Street, N.W., Washington, D.C. 20554.

27. It is further ordered, That in the event it is concluded that choice among the applicants should not be based solely on considerations relating to section 307(b), of which the proposals would, on a comparative basis, best serve the public interest.

28. It is further ordered, That the petition to dismiss filed by WABB, Inc. and the motion to dismiss and return application filed by United Broadcasting Company, Inc., are granted to the extent indicated herein and are denied in all other respects.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 89-545), announcement is made of the following committee meeting:

Name: Board of Visitors (BOV) for the National Fire Academy (NFA).


Place: National Emergency Training Center, Emmitsburg, Maryland.

Time: 8:30 a.m.—5:00 p.m.

Proposed Agenda: October 15-16: Approval of Minutes; Old Business; BOV Visitation to NFA Classes and Facilities; New Business.

The meeting will be open to the public with approximately 10 seats available on a first-come, first-serve basis. Members of the general public who plan to attend the meeting should contact Mr. Joseph Donovan, Superintendent, National Fire Academy, National Emergency Training Center, 16825 South Seton Avenue, Emmitsburg, MD 21727 (telephone number 301-447-4671) on or before October 8, 1984.

Minutes of the meeting will be prepared by the Board and will be available for public viewing in the Associate Director's Office, Building N, National Emergency Training Center, Emmitsburg, MD 21727. Copies of the minutes will be available upon request 30 days after the meeting.


Joseph L. Donovan,
Superintendent, National Fire Academy.

[FR Doc. 84-24335 Filed 9-13-84; 8:45 am]

BILLING CODE 6712-01-M
[FEMA-723-DR]

Major Disaster and Related Determinations; Nevada

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Nevada (FEMA-723-DR), dated September 6, 1984, and related determinations.

DATED: September 6, 1984.


Notice

Notice is hereby given that, in a letter of September 6, 1984, the President declared a major disaster under the authority of the Disaster Relief Act of 1974, as amended, (42 U.S.C. 5121 et seq., Pub. L. 93-288) as follows:

I have determined that the damage in certain areas of the State of Nevada, resulting from severe storms and flooding, beginning or about July 22, 1984, is of sufficient severity and magnitude to warrant a major-disaster declaration under Pub. L. 93-288. I therefore declare that such a major disaster exists in the State of Nevada.

In order to provide Federal assistance, you are hereby authorized to allocate, from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under Pub. L. 93-288 for Public Assistance will be limited to 75 percent of total eligible costs in the designated area.

The time period prescribed for the implementation of Section 313(a), priority to certain applications for public facility and public housing assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, and redelegated to me, I hereby appoint Mr. Tommie C. Hamner of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following area of the State of Nevada to have been affected adversely by this declared major disaster:

Clark county for Public Assistance only.

(FCatalog of Federal Domestic Assistance No. 83.516, Disaster Assistance. Billing Code 6718-02)

Samuel W. Speck,
Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.

[FR Doc. 84-24333 Filed 9-13-84; 8:45 am]
BILLING CODE 6715-01-M

[FEMA-722-DR]

Major Disaster and Related Determinations; New Mexico

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of New Mexico (FEMA-722-DR), dated September 6, 1984, and related determinations.

DATED: September 6, 1984.


Notice

Notice is hereby given that, in a letter of September 6, 1984, the President declared a major disaster under the authority of the Disaster Relief Act of 1974, as amended, (42 U.S.C. 5121 et seq., Pub. L. 93-288) as follows:

I have determined that the damage in certain areas of the State of New Mexico, resulting from severe storms and flooding, beginning on or about August 8, 1984, is of sufficient severity and magnitude to warrant a major-disaster declaration under Pub. L. 93-288. I therefore declare that such a major disaster exists in the State of New Mexico.

In order to provide Federal assistance, you are hereby authorized to allocate, from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under Pub. L. 93-288 for Public Assistance will be limited to 75 percent of total eligible costs in the designated area.

The time period prescribed for the implementation of Section 313(a), priority to certain applications for public facility and public housing assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, and redelegated to me, I hereby appoint Mr. Lonnie R. Chant of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of New Mexico to have been affected adversely by this declared major disaster:

Eddy, Lincoln and Otero Counties for Public Assistance only.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance. Billing Code 6718-02)

Samuel W. Speck,
Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.

[FR Doc. 84-24334 Filed 9-13-84; 8:45 am]
BILLING CODE 6715-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984. Interested parties may inspect and obtain a copy of each agreement at the Washington, D.C. Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 15 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-000161-042.
Title: Gulf United Kingdom Freight Conference.

Parties:
Atlantic Cargo Services, AB
Compagnie Generale Maritime
Hapag Lloyd AG
Intercontinental Transport (ICT) BV
Lykes Bros. Steamship Co., Inc.
Sea-Land Service, Inc.
Trans Freight Lines, Inc.

Synopsis: The proposed amendment provides for through ratemaking authority, incorporates previously adopted model agreement provisions prescribed by the Commission’s interim rules and restates and reorganizes the agreement.

Agreement No.: 207-010640.
Title: Armada/GLTL East Africa Service.

Parties:
Armada Great Lakes/East Africa
Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, D.C. Office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-008090-024.
Title: Mediterranean North Pacific Coast Freight Conference.
Parties: d'Amico Societa' Di Navigazione Per Azioni "Italia" Societa' Per Azioni Di Navigazione Zim Israel Navigation Co., Limited United Yugoslav Lines
Synopsis: The proposed amendment would substitute a new article concerning independent action for the Commission's interim mandatory rule and would add a new article authorizing conference action with respect to service contracts.

Agreement No.: 221-010641.
Title: San Francisco Marine Terminal Agreement.
Parties: San Francisco Port Commission (Port) Columbus Line (CL)
Synopsis: The agreement provides that CL will have the non-exclusive use of the Port's Piers 94 and 96, to be used as a container terminal for a period of three years with two one-year extension options. CL will use the facilities for its regularly scheduled Northern California port of call. The Port will reduce its revenues from wharfage, dockage, demurrage and storage on CL's vessels by 40 percent. The parties have requested a 14 day review period.

By Order of the Federal Maritime Commission.
Francis C. Humey, Secretary.

FEDERAL RESERVE SYSTEM

Federal Reserve Bank of Dallas

First Bancorp, Inc.; Formation of; Acquisition by; or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.24) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act 12 U.S.C. 1842(c).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received not later than October 5, 1984.

A. Federal Reserve Bank of Dallas
(Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:
1. First Bancorp, Inc., Denton, Texas; to become a bank holding company by acquiring 80 percent of the voting shares of First State Bank of Denton, Denton, Texas.
Corporation, East Hampton, New York, in providing through direct acquisition (purchase) various types of equipment to be leased, for specific periods of time to lessees (end users). As lessor, Leasehampton Corp. will be providing various businesses with the equipment they require without their having to make an outright purchase. At the end of the lease term, a purchase option may be exercised by the lessee to purchase the equipment from Leasehampton Corp. Leasehampton Corp. is benefited by rental income inclusive of an appropriate financing charge, investment tax credit benefits, tax deferral from the application of accelerated depreciation, as well as the residual cash value of the equipment at the expiration (maturity) of the lease. Leasehampton Corp. will be arranging the financing of lease transactions that have been generated by various third party lessors (lease brokers) in which an assignment is provided to convey and transfer all rights, title and interest in and to the equipment so described on the lease contract. Funding of all such lease transactions will be fully amortizing and the exercising of purchase options will be the responsibility of the lessor and lessee.

B. Federal Reserve Bank of Cleveland

[Leasehampton Corp. will be providing through direct acquisition (purchase) various types of equipment to be leased, for specific periods of time to lessees (end users). As lessor, Leasehampton Corp. will be providing various businesses with the equipment they require without their having to make an outright purchase. At the end of the lease term, a purchase option may be exercised by the lessee to purchase the equipment from Leasehampton Corp. Leasehampton Corp. is benefited by rental income inclusive of an appropriate financing charge, investment tax credit benefits, tax deferral from the application of accelerated depreciation, as well as the residual cash value of the equipment at the expiration (maturity) of the lease. Leasehampton Corp. will be arranging the financing of lease transactions that have been generated by various third party lessors (lease brokers) in which an assignment is provided to convey and transfer all rights, title and interest in and to the equipment so described on the lease contract. Funding of all such lease transactions will be fully amortizing and the exercising of purchase options will be the responsibility of the lessor and lessee.]

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 5, 1984.

A. Federal Reserve Bank of New York

(1) Norstar Bancorp Inc., Albany, New York; to acquire Chapdelaine & Co. Government Securities, Inc., New York, New York, thereby acting as a broker to primary dealers of U.S. government securities and securities issued by U.S. government agencies; acting as an underwriter, broker and dealer in obligations of the United States, and bank obligations, including certificates of deposit and bankers' acceptances, that state member banks of the Federal Reserve System may be authorized to underwrite and deal in; and acting as an "inadvertent principal" in the event of the mistaken purchase of securities not authorized by customers when such customers refuse to accept the securities.
Respondents: Individuals who wish to have their Black Lung Student's Benefits Continued
Subject: Recapitulation of State's Report of Wages Paid (0960-0042)—Extension No Change
Respondents: State Agencies
Subject: Statement of Living Arrangements, Support and Maintenance (0960-0174)—Revision
Respondents: Individuals who apply for SSI Benefits
OMB Desk Officer: Robert J. Fishman

Health Care Financing Administration
Subject: Statement of Living
OMB Desk Officer: Robert J. Fishman

Home Health Agency Cost Report—Extension (0938-0022)
Respondents: Providers of Services
Schedule of Net Hours Available—Existing Collection
Respondents: Medicare Contractors
OMB Desk Officer: Fay S. Iudicello

Forged Checks—Revision (0936-0205)
Respondents: Medicare Contractors
OMB Desk Officer: Fay S. Iudicello

Copies of the above information collection clearance packages can be obtained by calling HHS Reports Clearance Officer on 202-245-6511.

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, D.C. 20503. ATTN: [name of OMB Desk Officer].

Wallace O. Keene,
Acting Deputy Assistant Secretary for Management Analysis and Systems.

BILLING CODE 4150-04-M

Food and Drug Administration
[Docket No. 75N-0164; DESI 597]

Certain Anticholinergics in Combination With a Sedative; Drug Efficacy Study Implementation, Denial of Hearing, and Withdrawal of Approval of New Drug Applications

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs is denying a hearing and withdrawing approval of the new drug applications of three anticholinergic/sedative combination products because they lack substantial evidence of effectiveness. The products are offered as adjunctive therapy in the treatment of peptic ulcer and the irritable bowel syndrome.
A. Proof of Effectiveness

The manufacturers here could have taken advantage of this time to demonstrate the effectiveness of their products. Furthermore, the agency has never implied that it would treat all anticholinergic/sedative combinations as a class. The June 20, 1978 notice specifically stated that the data on one product would be applicable to another only if the two products contained the same ingredients and the same recommended dosage (43 FR 26491).

The Commissioner has reviewed the studies submitted to demonstrate the effectiveness of the products covered by the present notice. The Commissioner finds that the studies do not constitute substantial evidence of such effectiveness. The Commissioner also finds that the manufacturers have not raised any genuine and substantial issue of fact justifying a hearing. In addition, the Commissioner finds the legal arguments presented unpersuasive. Accordingly, the Commissioner is denying the hearing requests and withdrawing approval of the new drug applications. A full discussion follows:

I. The Drugs

1. Pro-Banthine with Phenobarbital Tablets contains 15 mg propantheline bromide and 15 mg phenobarbital.
2. Valpin with Phenobarbital Tablets and Valpin 50 with Phenobarbital Tablets contain 15 mg anisotropine methylbromide and 15 mg phenobarbital, and 50 mg anisotropine methylbromide and 15 mg phenobarbital, respectively.

II. Recommended Uses

The drugs are labeled as possibly effective as adjunctive therapy in the treatment of peptic ulcer and in the treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis, acute enterocolitis, and functional gastrointestinal disorders).

III. Data Submitted To Support Claims of Effectiveness and Legal Arguments

A. Proof of Effectiveness

The Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 301 et seq.) requires that all drugs be shown to be effective for their labeled indications. Section 505(e) of the act (21 U.S.C. 355(e)) directs FDA to withdraw approval of a new drug application if the manufacturer fails to carry the burden of showing that there is substantial evidence respecting the efficacy of the approved drug. The general contours of substantial evidence are defined by section 505(d) of the act to include "evidence consisting of adequate and well-controlled investigations * * *. To explain the basis upon which FDA determines the effectiveness of a drug and to enunciate the requirements for and characteristics of an adequate and well-controlled clinical investigation, FDA published regulations outlining principles developed over a period of many years by investigators actively engaged in the evaluation of the effectiveness of drugs (21 CFR 314.111). In the case of a drug that contains a fixed combination of drugs, FDA has also published regulations that require that, for there to be substantial evidence of effectiveness, each ingredient designated as active must contribute to the claimed effect (21 CFR 300.50(a)) (the combination policy).

B. Pro-Banthine With Phenobarbital Tablets

Searle submitted the results of a study comparing the effectiveness of Pro-Banthine with Phenobarbital Tablets (Pro-Banthine PB), Pro-Banthine Tablets (propantheline bromide alone), phenobarbital alone, and placebo in the irritable bowel syndrome. The design of the study meets the requirements of the combination policy but, as noted in the January 16, 1981 notice of opportunity for hearing (NOOH), the study does not demonstrate the effectiveness of Pro-Banthine. Upon submission of the study, Searle acknowledged that there were no statistically significant differences among treatment groups. Furthermore, Searle made no specific response to the Director's evaluation of the study in the NOOH, nor did it submit additional data. Also, Searle has failed to provide any data or information to counter the agency's conclusion in the January 16, 1981 notice that substantial evidence of effectiveness has not been submitted.

Instead, Searle argues in its request for hearing that Pro-Banthine PB should remain on the market pending the agency's evaluation of effectiveness in treatment of the irritable bowel syndrome of all other identical, similar, or related anticholinergic/sedative combinations. According to Searle, the components of the anticholinergic/sedative combinations are closely related in pharmacological and clinical action. Thus, the firm asserts that if one anticholinergic/sedative product is shown to be effective because of a different protocol design, a larger patient population, or the use of a new methodology, all other related products would show similar results if studied under the same conditions.

Searle notes that the agency found a compelling medical need for anticholinergic/sedative combinations when it exempted the products from the schedule established for completion of the DESI review. Searle states that this medical need still exists.

Finally, Searle argues that because these products have always been treated as a class and subject to the same time limits for conducting studies, manufacturers have had to compete for the same medical investigators and patients. The firm states that the manufacturers were unable to enroll sufficient patients in the studies to demonstrate effectiveness, and that had it known that the agency would not act against the products on a class basis, it would have continued to attempt to enroll and study additional patients.

The Commissioner is taking action at this time against those anticholinergic/sedative combination products for which the supporting data are seriously incomplete. The Commissioner is not required to "choose between attacking every aspect of a problem or not attacking the problem at all." Dandridge v. Williams, 397 U.S. 471,487 (1970). The agency is currently reviewing the data submitted on other anticholinergic/sedative combinations and will take appropriate regulatory action on those products when the review is complete.

If, as Searle suggests, a number of anticholinergic/sedative combinations were found to be effective, it might be possible to generalize the observations and concluded that, as a class, products of this type, appropriately formulated, are useful for some conditions. That conclusion, however, would not be helpful in determining whether a particular combination product was effective. Other than simply asserting that Pro-Banthine PB is related to anticholinergic/sedative combinations, Searle has presented no evidence demonstrating the effectiveness of other products or showing that such evidence would be applicable to its product as formulated. In the absence of such evidence, only studies of the particular combination can be considered pertinent to that combination. There are no other propantheline bromide with phenobarbital tablets under review for effectiveness.

In 1975, the agency found a medical need for anticholinergic/sedative combinations to remain on the market pending an evaluation of their effectiveness. This finding was based on the perceived importance of the drugs to patient convenience and selection of proper dosage. There is no medical need, however, for a product that has not been shown to be effective after numerous years of study.
The Commissioner acknowledges that all manufacturers of anticholinergic/sedative combinations had to compete for patients and investigators and that the studies were difficult to conduct. It must be noted, however, that a number of manufacturers were able to complete studies. In addition, the difficulties of conducting a study have no bearing on the evaluation of the effectiveness of the drug studied and do not excuse as company from proving that its product is effective. *Cooper Laboratories, Inc. v. Commissioner*, 501 F.2d 772, 779 (D.C. Cir. 1974). For all the foregoing reasons, Searle’s hearing request is denied.

**C. Valpin With Phenobarbital Tablets**

Du Pont conducted a study comparing the effectiveness of Valpin 50 PB Tablets, Valpin 50 Tablets (anisotropine methylbromide alone), phenobarbital alone, and placebo in treating irritable bowel syndrome. The design of this study meets the requirements of the combination policy. The study, however, does not provide substantial evidence of effectiveness of either of the Valpin products. Du Pont has submitted reports on only 22 of a possible 120 patients. Only 19 of the 22 patients completed the scheduled treatment. The statistical summary of these preliminary results, submitted by Du Pont, concludes: “Data are not extensive enough for statistical analysis to test for differences in treatment responses among medication groups.” FDA noted this acknowledgment by Du Pont in the January 18, 1981 NOOH (46 FR 3079). Du Pont did not in its request for hearing suggest that the study provides substantial evidence of effectiveness.

Du Pont instead contends that the NOOH is deficient for failing to refer specifically to data Du Pont had submitted, making it impossible for Du Pont to respond to the Director’s evaluation. As just noted, the NOOH specifically stated that Du Pont conceded that its data were inadequate to draw any conclusions about the effectiveness of Valpin PB and Valpin 50 PB because only 19 patients were enrolled in the study. Du Pont’s argument overlooks this reference to its products and the data submitted in support of them.

Du Pont also asserts that the NOOH covers the entire category of anticholinergic/sedative combinations, and that Du Pont is entitled to benefit from all pertinent data submitted by any manufacturer, but that the NOOH failed to cite studies conducted by other manufacturers, or to note where such studies are located. Thus, Du Pont argues that it cannot comment on these studies even though they may affect the determination of effectiveness of its own products. Du Pont incorporates by reference any data submitted by other manufacturers of products identical, similar, or related to Valpin PB and Valpin 50 PB and asserts that if a hearing is held on any of such products, it is entitled to participate in the hearing.

This argument suggests that effectiveness conclusions about anticholinergic/sedative combinations must be made on a class basis. As shown above, the Commissioner is not required to proceed in this manner. Moreover, and more importantly, there are no other anisotropine methylbromide-phenobarbital combinations under review for effectiveness. Other than simply asserting that Valpin PB and Valpin 50 are related to the Valpin methylbromide/sedative combinations, Du Pont has failed to submit any evidence that data demonstrating the effectiveness of other such combinations are applicable to its products. In the absence of such evidence, only studies of the particular combination under review can be considered pertinent to that combination (21 CFR 314.111(a)(5)(ii)(b); see 43 FR 20491).

In addition, it is important to note Du Pont’s responsibility to incorporate in his evaluation pertinent data not submitted by the sponsor of which he is aware. Accordingly, the Commissioner considered two literature references submitted by another firm to support its request seeking a different drug on the effectiveness of anisotropine methylbromide combined with phenobarbital. The first reference (King, J.C., “Anisotropine Methylbromide for the Treatment of Gastrointestinal Syndrome,” *Current Therapeutic Research*, 8(11):535–541, 1966) reported on a double-blind, crossover study comparing three antispasmodic drugs—anisotropine methylbromide, anisotropine methylbromide combined with phenobarbital, and belladonna alkaloids combined with phenobarbital. The drugs were administered to 140 patients with gastrointestinal spasm due to a variety of gastrointestinal disorders including pylorospasm, spastic colon, duodenitis, diverticulitis, functional gastrointestinal spasm, irritable colon, gastroenteritis, cholelithiasis, gastritis, acute cholecystitis, internal hemorrhage, carcinoma of the cecum, cardiomyopathy, heartburn, diaphragmatic hernia, hiatus hernia, and postgastrectomy dumping syndrome.

For the comparison relevant here (anisotropine methylbromide versus anisotropine methylbromide/phenobarbital), the author stated that among the crossover patients, greater relief of gastrointestinal spasm was obtained with anisotropine methylbromide/phenobarbital than with anisotropine methylbromide alone. In 58 patients, 89 percent obtained good to excellent results with anisotropine methylbromide/phenobarbital compared with 86 percent for anisotropine methylbromide alone.

This study does not provide substantial evidence of the effectiveness of Valpin PB in irritable bowel syndrome. The design of the study does not meet the criteria of the combination policy, as there was no phenobarbital group. It is impossible, therefore, to determine the contribution of anisotropine methylbromide to the effectiveness of the combination as a whole (21 CFR 300.50(a)). Only three patients were diagnosed as having irritable bowel syndrome, and neither patient assignments nor results were tabulated by diagnosis. Accordingly, even if three patients were an adequate patient population, it is impossible to compare quantitatively the results of the different medications in the treatment of irritable bowel syndrome (21 CFR 314.111(a)(5)(ii)(c)(4)).

The second reference (Battman, R.C., C.J. Movratoff, and J.E. Kaufman, “Anisotropine Methylbromide—A New Antispasmodic for Gastrointestinal Disorders,” *Current Therapeutic Research*, 5(5):213–218, 1965) was a report of a single-blind study comparing anisotropine methylbromide alone (administered in both 10-mg and 15-mg doses) and anisotropine methylbromide combined with phenobarbital. The drugs were administered to 67 patients with a variety of gastrointestinal disorders characterized as peptic ulcer, diverticulitis, functional gastrointestinal disturbance (when the symptomology appeared to be associated with anxiety unrelated to any specific condition), constipation, and gastroenteritis. The authors state that overall effectiveness, regardless of diagnosis, was 77.3 percent for anisotropine methylbromide alone (10 mg). 75 percent for the anisotropine
methylbromide alone (15 mg), and 85 percent for the anisotropine methylbromide combined with phenobarbital.

The study fails to provide substantial evidence of the effectiveness of Valpin PB in irritable bowel syndrome or in peptic ulcer, another appropriate indication for investigation. The design of the study does not meet the criteria of the combination policy, as there was no phenobarbital group. It is impossible, therefore, to determine the contribution of anisotropine methylbromide to the effectiveness of the combination as a whole (21 CFR 300.50(a)). The number of patients diagnosed as having irritable bowel syndrome (i.e., lower functional gastrointestinal disease as opposed to upper functional gastrointestinal disease) was not specified either in the protocol or in the report of the results of the study, thereby making it impossible to compare quantitatively the effectiveness of the different medications in the treatment of irritable bowel syndrome (21 CFR 314.111(a)(5)(ii)(a)(2)(iii) and (a)(4)).

Du Pont also argues that FDA imposed a protocol design that was virtually impossible to follow and that this accounted for the low rate of accession into Du Pont's study. Du Pont contends, therefore, that action against Valpin PB and Valpin 50 PB (as well as any other anticholinergic/sedative combination) should be stayed until reasonable guidelines for conducting studies can be developed and firms are given a reasonable opportunity to complete studies. Du Pont states that it is prepared to work with the agency in establishing practical and valid clinical study methods.

Du Pont's assertion that the "FDA sanctioned protocol" for conducting studies of anticholinergic/sedative combinations is virtually impossible to follow is without merit. FDA has not established any specific protocol for testing of anticholinergic/sedative combination drugs. It has, however, drafted guidelines for studying such products. These guidelines do not constitute legal requirements, but rather reflect an approach to testing efficacy of such drugs which is acceptable to FDA (21 CFR 10.90(b)). If the protocol outlined in the guidelines is too difficult or is otherwise impractical, there has never been any impediment to Du Pont's planning and conducting studies of another design, which it claims is willing to do. Furthermore, the difficulty of conducting a clinical trial does not excuse a company from proving that its product is effective. Cooper Laboratories, Inc. v. Commissioner.
purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

However, pursuant to the foregoing finding, approval of those parts of NDA 12-575 pertaining to Actifed-C Expectorant, and all the amendments and supplements for that product, are withdrawn effective October 15, 1984. Shipment in interstate commerce of the product above, or any identical, related, or similar product that is not the subject of an approved new drug application, will then be unlawful.


Harry M. Meyer, Jr.,
Director, Center for Drugs and Biologics.

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Public Health Service

Advisory Committee; 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 months of October and November 1984:

Name: Health Services Research Review Subcommittee.

Date and Time: October 4-5, 1985, 8:00 a.m.
Place: Linden Hill Hotel, Pinehurst Room, 5400 Poole Hill Road, Bethesda, Maryland 20814.

Open October 4, 8:00 to 12:00 noon. Closed for remainder of meeting.

Purpose: The Subcommittee is charged with the initial review of grant applications for Federal assistance in the program areas administered by the National Center for Health Services Research (NCHSR).

The agenda is in accordance with the provisions set forth in section 552(b)(6), Title 5, U.S. Code, and the Determination by the Assistant Secretary for Health, pursuant to Pub. L. 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should contact Dr. Alan E. Myers, National Center for Health Services Research (NCHSR).

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Livestock Grazing; Proposed Deviation From Scheduled Preparation of Environmental Impact Statements

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed deviation from scheduled preparation of environmental impact statements on livestock grazing.


ADDRESS: Comments and suggestions should be sent to: Director (220), Bureau of Land Management, 1800 C Street, N.W., Washington, D.C. 20240.


Proposed Deviation From Scheduled Preparation of Environmental Impact Statements on Livestock Grazing

The amended final judgment in this case requires Federal defendants, specifically the Bureau of Land Management (BLM), to prepare a series of environmental impact statements (EIS's) on their program for managing livestock grazing on public lands. The judgment contemplates material deviations from the judgment upon notice to this court. Specifically, paragraph 9 of the amended final judgment provides:

If the federal defendants believe, in good faith, that circumstances dictate that any material deviations must be made, then in any event, the federal defendants shall give
Delays in completing the San Juan, Colorado, Resource Area RMP/EIS; the Lahontan, Nevada, Resource Area RMP/EIS; and the Book Cliffs, Utah, Resource Area RMP/EIS flow from concerns about the land use plans rather than the accompanying site-specific EIS’s on managing livestock grazing. Public comments on the draft plan for the San Juan, Colorado, Resource Area required the BLM to reconsider its analysis on oil and gas leasing and wilderness designation. The BLM’s response to these comments, including revisions to the draft plan, has added 2 months to the document’s scheduled completion. Similarly, in developing its draft plan for Lahontan, Nevada, Resource Area, public comments required the BLM to issue a supplement to the plan, which discussed areas of critical environmental concern and rights-of-way corridors. Preparing and circulating the plan’s supplement, including the consistency review of the State of Nevada’s Governor, placed the BLM 6 weeks behind its original schedule. And, again, public comments on the draft plan for the Book Cliffs, Utah, Resource Area required the BLM to reconsider its analysis of tar sand development in the area. The BLM’s response to these comments, including revisions to the draft plan, has added 2 months to the document’s scheduled completion. Because the BLM treats an EIS on its livestock grazing program as interrelated with an RMP, the delays in completing the above three land use plans have necessarily resulted in concomitant delays for completing the site-specific EIS’s on managing livestock grazing in the respective resource areas.

The Cedar, Utah Resource Area RMP/EIS has been delayed due to an extended public comment period. The BLM thought the additional 30 days of comment could be compressed into the original schedule. Recent experience has proven this not to be the case. The Cedar, Utah, Resource Area RMP/EIS scheduled completion has been delayed by 2 weeks.

Completion of the John Day, Oregon, Resource Area RMP/EIS has been delayed by management problems. First, a new word processing system proved incompatible with the existing system, delaying issuance of the draft RMP/EIS. Second, subsequent delays occurred because the available staff also was required to work simultaneously on a statewide EIS discussing proposed wilderness designations. These delays have set back publication of the John Day, Oregon, Resource Area RMP/EIS by 6 weeks.

Robert F. Burford, Director.

[FR Doc. 84-26576 Filed 9-13-84; 8:45 am]
BILLING CODE 4310-OG-4

INTERSTATE COMMERCE COMMISSION

Agricultural Cooperatives; Intent To Perform Interstate Transportation for Certain Nonmembers


The following Notices were filed in accordance with section 10526(a)(5) of the Interstate Commerce Act. These rules provide that agricultural cooperatives intending to perform...
nonmember, nonexempt, interstate transportation must file the Notice. Form BOP 102, with the Commission within 30 days of its annual meetings each year. Any subsequent change concerning officers, directors, and location of transportation records shall require the filing of a supplemental Notice within 30 days of such change.

The name and address of the agricultural cooperative (1) and (2), the location of the records (3), and the name and address of the person to whom inquiries and correspondence should be addressed (4), are published here for interested persons. Submission of information which could have bearing upon the propriety of a filing should be directed to the Commission's Office of Compliance and Consumer Assistance, Washington, D.C. 20423. The Notices are in a central file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C.

Intent To Engage in Compensated Intercorporate Hauling Operations

This is to provide notice, as required by 49 U.S.C. 11524(b)(1), that the named corporations intend to provide or use compensated intercorporate hauling operations as authorized in 49 U.S.C. 10524(b).

1. Parent corporation and address of principal office: Art Metal-U.S.A., Inc., 300 Passaic Street, Newark, NJ 07104.
2. Wholly-owned subsidiaries which will participate in the operations and state(s) of incorporation:
   (a) Steel Sales, Inc., A New Jersey corporation.
   (b) Art Plating, Inc., A New Jersey corporation.
      1. Parent corporation and address of principal office: Century Resources, Inc., 3060 Valley View Drive, Columbus, Ohio 43204.
      1. Parent corporation and address of principal office: Gamble-Skogmo, Inc., 3340 Ocean Park Boulevard, Santa Monica, CA 90405.
      2. Wholly-owned subsidiaries which will participate in the operations, and state(s) of incorporation:
         (i) Howard Brothers Discount Stores, Inc., A Louisiana corporation;
         (ii) Leath and Company, An Indian corporation;
         (iii) Leath Furniture Company, A Michigan corporation;
         (iv) Leath Furniture Company, An Illinois corporation;
         (v) Red Owl Stores, Inc., A Delaware corporation;
         (vi) Snyder's Drug Stores, Inc., A Minnesota corporation;
         (vii) Southland Wholesale Distributors, Inc., A Louisiana corporation; and
      2. Wholly-owned subsidiaries which will participate in the operations, and state(s) of incorporation:
         (i) Henkel Corporation—Delaware.
         (ii) Bonewitz Chemical Services, Inc.—Iowa.
      1. Parent corporation and address of principal office: M&L Unlimited, Inc., 1630 Summit Street, P.O. Box 302, New Haven, IN 46774.
      2. Wholly-owned subsidiaries which will participate in the operation:
         1. Parent corporation and address of principal office: The Wickes Corporation, 3340 Ocean Park Boulevard, Santa Monica, CA 90405.
         2. Wholly-owned subsidiaries which will participate in the operations, and state(s) of incorporation:
            (i) Lee L. Woodard Sons, Inc.;
            (ii) Paragon Wood Products, Inc.;
            (iii) Wickes Europe, Inc.; and
            (iv) Yorktowne, Inc.; all of which are Delaware corporations.

James H. Bayne,
Secretary.

Bill Chaplin, P.O. Box 3080, Lake Oswego, OR 97034.

June M. Fahmey, P.O. Box 275, Broadway, VA 22815.

Durham, OR 97042.

James H. Bayne,
Secretary.

[FR Doc. 84-24414 Filed 9-13-84; 8:45 am]
BILLING CODE 7035-01-M


AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts from the requirement of prior approval under 49 U.S.C. 11343 the acquisition by Missouri Pacific Railroad Company of trackage rights over rail lines of The Alton & Southern Railway Company between St. Louis, MO, and Lenox (Mitchell), IL, and between Granite City and East St. Louis, IL, subject to labor protection.

DATES: This exemption is effective on October 15, 1984. Petitions for reconsideration must be filed by October 4, 1984. Petitions for stay must be filed by September 24, 1984.

ADDRESSES: Send pleadings referring to Finance Docket No. 30537 to:
(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423 and
(2) James H. Durkin, Esq., Missouri Pacific Railroad Company, 210 North 13th Street, St. Louis, MO 63103.

FOR FURTHER INFORMATION CONTACT: Louis E. Gitomer (202) 275-7245.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission’s decision. To purchase a copy of the full decision, write to T.S. InfoSystems, Inc., Interstate Commerce Commission, Room 2227, Washington, DC 20423, or call toll-free (800) 424-5403, or 289-4357 (DC Metropolitan area).


By the Commission, Chairman Andre, Vice Chairman Taylor, Vice Chairman Terrell, Commissioner Starrett and Gradison.

James H. Bayne,
Secretary.

[FR Doc. 84-24427 Filed 9-13-84; 8:45 am]
BILLING CODE 7035-01-M

Norfolk Southern Lines, Inc., a agency summary schedule. 

opposition evidence must be filed no more than October 15, 1984. Preliminary comments by intervening public parties must be filed by October 30, 1984. Responsive applications and opposition evidence must be filed no later than November 13, 1984. Additional scheduling information is included in the Commission’s decision.

FOR FURTHER INFORMATION CONTACT: Louis E. Gitomer (202) 275-7245.

ADDRESS: An original and 20 copies of all pleadings, referring to Finance Docket No. 30500, should be sent to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

Applicants’ Representative: Eugene T. Liipfert, Fritz R. Kahn, Suite 1000, 1660 L Street, NW., Washington, DC 20036

R. Allan Wimbish, Norfolk Southern Corporation, 204 South Jefferson Street, Roanoke, Virginia 24042

Martin A. Weissert, North American Van Lines, Inc., P.O. Box 988, Fort Wayne, Indiana 46801

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission’s decision. To purchase a copy of the full decision, write to T.S. InforSystems, Inc., Room 2227, Interstate Commerce Commission, Washington, DC 20423, or call 289-4357 (DC Metropolitan area) or toll free (800) 424-4803.


By the Commission, Chairman Taylor, Vice Chairman Andre, Commissioners Sterrett and Gradison.

James H. Bayne, Secretary.

[FR Doc. 84-4429 Filed 9-15-84; 8:45 am]

BILLING CODE 7035-01-M

[Ex Parte No. 456]

The Staggers Rail Act of 1980—Conference of Interested Parties

AGENCY: Interstate Commerce Commission.

ACTION: Institution of Proceeding.

SUMMARY: The Commission is instituting a proceeding to (1) gather information from carriers and shippers regarding the problems and benefits arising from the implementation of recent legislation, particularly the Staggers Rail Act of 1980, and (2) provide a forum for direct discussion among these affected parties.

It is hoped that this conference will lead to a more complete understanding of the changes that have occurred in rail transportation as a result of such legislation, and its implementation, and that it will assist the parties in resolving any problems that may exist.

DATES: Notice of Intent to Participate should be filed by October 1, 1984. A docket management conference is scheduled for October 3, 1984.

ADDRESS: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

Comments should refer to Ex Parte No. 456.

FOR FURTHER INFORMATION CONTACT: David H. Allard, Chief Administrative Law Judge, (202) 275-7502.

SUPPLEMENTARY INFORMATION: Pursuant to 49 U.S.C. 10321 and 10311, the Commission is instituting this proceeding. Our purpose is twofold: to gather and analyze, with the assistance of shippers and carriers, information relating to the effect of the reforms stemming from recent rail legislation and to offer a forum for full and frank discussion of problems by those directly affected. This proceeding may lead to a greater consensus among all parties as to the proper role of regulation in today’s rail transportation markets and will offer opportunities for resolving commercial disputes without recourse to agency, court or legislative intervention.

While the Commission may, as a result of information developed in this proceeding, reexamine existing policies and procedures, it is not our purpose here to determine the rights or obligations of parties, or otherwise relitigate matters at issue before the Commission or resolved in other regulatory proceedings.

A docket management conference is set for 9:30 a.m., October 3, 1984, Offices, Interstate Commerce Commission, Washington, D.C. before the Commission’s Chief Administrative Law Judge. The agenda for that conference will include (1) organization, management and structure of the information gathering process; and (2) appropriate time tables for the completion of all aspects of the proceeding. Common interest conference groups may be formed, under the Chief Administrative Law Judge’s supervision, around areas such as contracting, reciprocal switching, revenue adequacy, market rate criteria, maximum reasonable rate guidelines, joint rate and joint route cancellations, etc. In advance of the conference, parties should meet, where practical, and discuss agenda suggestions and submit these ideas to the Chief Administrative Law Judge no later than October 1, 1984.

An agenda for the October 3 conference will be available from the Commission’s Public Information Office at noon, October 2, 1984.

Parties should be prepared at the conference to discuss means of submitting relevant information and views. They also should be prepared to participate in conference groups and exchange ideas with a view towards: (1) Resolving, to the greatest practical extent through commercially viable processes, areas where disputes may exist among the parties; and (2) identifying the benefits of deregulation that should be preserved or enhanced.

The record and results of the conference groups shall be certified by the Chief Administrative Law Judge to the Commission.

This decision will not significantly affect the quality of the human environment or conservation of energy resources and will not have an adverse impact on small business.

Authority: 49 U.S.C. 10321 and 10311.

It is ordered:

1. A proceeding is instituted upon the Commission’s own motion to investigate the effect of recent rail legislation, particularly the Staggers Rail Act of 1980, on the users and providers of rail services.

2. A docket management conference on this subject before the Commission’s Chief Administrative Law Judge will be held at 9:30 a.m., October 3, 1984, Offices of Interstate Commerce Commission, Washington, DC 20423.

3. After the initial docket management conference, a service list shall be established to permit notice to all interested parties and copies of all materials served on the Commission prior to or subsequent to the Conference to be served on all parties on that list.

4. This notice will be published in the Federal Register.

By the Commission, Chairman Taylor, Vice Chairman Andre, Commissioners Sterrett and Gradison.

James H. Bayne, Secretary.

[FR Doc. 84-24820 Filed 9-13-84; 8:45 am]
BILLING CODE 7035-01-M

[Docket No. AB-6 (Sub-202)]

Burlington Northern Railroad Company—Abandonment—in Latah and Nez Perce Counties, ID; Findings

The Commission has found that the public convenience and necessity permit the Burlington Northern Railroad Company to abandon its 37.73-mile rail line between Moscow, ID [milepost 88.80] and Arrow, [milepost 123.50] in Latah and Nez Perce Counties, ID. A certificate will be issued authorizing this abandonment unless within 15 days after this publication the Commission also finds that: (1) A financially responsible person has offered assistance (through subsidy or purchase) to enable the rail service to be continued; and (2) it is likely that the assistance would fully compensate the railroad.

Any financial assistance offer must be filed with the Commission and the applicant no later than 10 days from publication of this Notice. The following notation shall be typed in bold face on the lower left-hand corner of the envelope containing the offer: "Rail Section, AB-OFA." Any offer previously made must be remade within this 10-day period.

Information and procedures regarding financial assistance for continued rail service are contained in 49 U.S.C. 10905 and 49 CFR 1152.27.

James H. Bayne, Secretary.

[FR Doc. 84-24818 Filed 9-13-84; 11:44 am]
BILLING CODE 7035-01-M

[Ex Parte No. 347 (Sub-1)]

Coal Rate Guidelines—Nationwide

AGENCY: Interstate Commerce Commission.

ACTION: Postponement of Oral Argument.

SUMMARY: The oral argument in this proceeding, previously scheduled for 10:00 a.m., September 18, 1984, (49 FR 33381, 8-22-84), has been postponed.

DATES: Oral argument in Ex Parte No. 347 (Sub-No. 1) is now scheduled for 10:00 a.m., October 4, 1984. By September 27, 1984, the coordinators should provide the Office of the Secretary with any changes in the list of participants or time allocations previously furnished. The Commission will issue a schedule of appearances.

ADDRESS: The oral argument will be heard in Hearing Room A at the Interstate Commerce Commission Building, 12th Street and Constitution Avenue, NW., Washington, D.C.

This notice is issued under the authority of 49 U.S.C. 10321 and 5 U.S.C. 553.


By the Commission, Acting Chairman Frederic N. Andre.

James H. Bayne, Secretary.

[FR Doc. 84-24815 Filed 9-13-84; 11:44 am]
BILLING CODE 7035-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

Federal-State Unemployment Compensation Program: Unemployment Insurance Program Letter No. 30–84

Unemployment Insurance Program Letter No. 30–84 establishes September 28, 1984 as the due date for the payment of interest due on interest-bearing Title XII advances at the end of FY 84. It also provides guidelines relating to interest due on interest-bearing Title XII advances at the end of FY 84.

Procedure.

To expedite the interest calculation and billing process at Treasury and to provide SESAs with more time at the end to transmit interest amounts due, the following procedure is being initiated:

a. Treasury Calculation and Billing of Interest Due. September 21, 1984, has been designated as the cut-off date for the calculation of interest due. Interest will be calculated by Treasury on the outstanding balance of interest-bearing Title XII advances as of the close of business on that day and projected through September 30, 1984. This amount will be billed to the States as the amount of interest due and payable on or before September 28, 1984.

b. The Department of Labor and the Trust/Funds Branch in the U.S. Treasury have determined and agreed that since the last day of Fiscal Year 1984 falls on a Sunday, any interest due and payable prior to October 1 must be paid on or before September 28, 1984. The rate of interest to be charged on Title XII advances during Calendar Year 1984 is 8.78 percent; the rate of interest for Calendar Year 1985 is 10.00 percent.

c. The due date for interest due on May through September advances must be made before the first day of the next fiscal year. The due date for deferred interest on May through September loans remains unchanged (before December 31 of the following year) as does the date for interest due on interest-bearing Federal-State Unemployment Tax Act on this subject.

2. Background. Public Law 98–21 amended section 1202(b)(3)(A) of the Social Security Act to require that the payment of interest due on Title XII advances be made before the first day of the next fiscal year. The due date for deferred interest on May through September loans remains unchanged (before December 31 of the following year) as does the date for interest due on interest-bearing Title XII advances. The Social Security Act, section 1202(b)(9), and UIPL 31–83.


4. Conclusion. This notice is issued under the authority of 49 U.S.C. 10321 and 5 U.S.C. 553.


Frederic N. Andre, Deputy Assistant Secretary of Labor.
b. Increased Interest Due to Advances Received After September 21, 1984. The formula SESAs are to follow to calculate the daily interest accrual on Title XII advances received during the period September 24 through September 28, 1994, is as follows:

Interest Rate (9.78 percent) times 1 day divided by 366 times the amount advanced that day equals the amount of interest due for that day (rounded to the nearest cent). This procedure must be repeated for each day an advance is outstanding from the day of receipt until and including September 30, 1994. Since the amount advanced each day is a separate advance, the daily interest accrual must be calculated on each advance as explained above from the day of receipt until and including September 30, 1994.

The increased amount of interest due will be the sum of the daily interest accruals resulting from the above calculations and is to be added by the SESA to the amount billed by Treasury.

c. Reduction of Interest Amount Billed Due to Voluntary Repayments Made After September 21, 1984. To determine the amount of interest to be subtracted from the amount billed by Treasury in the event a repayment(s) is made subsequent to September 21, and on or before September 28, 1994, the following procedure should be used:

Perform the calculation as explained in (b) above to determine the daily interest accrual for each repayment from the date made until and including September 30, 1994 (rounded to the nearest cent). The amount to be subtracted from the amount billed by Treasury will be the sum of the daily interest accruals from each day’s repayment(s) as explained above.

Any adjustment to the amount billed by Treasury must be documented and substantiated in a letter to the Trust/Funds Branch which must follow the interest payment immediately. Treasury will verify the transactions and adjustments and advise the States if further action is required.

Accuracy in the calculation of adjustments by SESAs is essential. If a discrepancy occurs which results in a late payment, the sanctions provided in section 3304(a)(17) of the Federal Unemployment Tax Act and sections 303(c)(3) and 1202(b)(3) of the Social Security Act would apply.

d. The billing notice to the States will include the name and telephone number of a contact person in the Trust/Funds Branch in the U.S. Treasury. It will contain detailed instructions for SESAs to follow to pay the interest amount due and payable on or before September 28, 1994, will also be included in the billing letters prepared by Treasury.

e. Treasury Staff are available for consultation with SESAs at any time to verify loans, repayments, and interest charges. Correspondence to the Treasury should be mailed to: Mr. Melvin Vianick, Manager, Trust/Funds Branch, U.S. Treasury Department, Treasury Annex #1 Room 326, Washington, DC 20220.

6. Action Required. Agency Administrators should assure that the responsible individuals are advised of this directive; and assure that any interest due and payable on or before September 28, 1984, (or at any later time) is paid timely and in accordance with the instructions provided by the U.S. Treasury Department and federal law requirements.

7. Inquiries. Direct questions to the appropriate regional office.

[FR Doc. 84-24417 Filed 9-13-84; 8:45 am]
BILLING CODE 4510-30-M

Mine Safety and Health Administration

[Docket No. M-84-19-M]

Phelps Dodge Corp.; Petition for Modification of Application of Mandatory Safety Standard

Phelps Dodge Corporation, Tyrone, New Mexico 88365 has filed a petition to modify the application of 30 CFR 55.9-22 (berms or guards) to its Tyrone Branch (I.D. No. 29-00159) located in Grant County, New Mexico. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977. A summary of the petitioner’s statements follows:

1. The petition concerns the requirement that berms or guards be provided on the outer bank of elevated roadways.

2. There are elevated roadways on the outer banks of the tailings dams working level roads. The roads in question are not used for loading, hauling or dumping of the product being mined; they are service roads used primarily in the operational surface following rainfalls. Berms tend to retain the moisture and delay such maintenance.

3. The present practice, established pursuant to direction from the state of New Mexico, is that erosion of the faces of the dams be minimized for the safe operation of tailing dams. The state has required that a slight outward grade be maintained to promote immediate drainage of rainfall in a lateral fashion across the roads to prevent the collection of water into large rivulets which would erode the face of the dam. The dams are constructed with sand fraction underflow of hydrocyclones which are spaced evenly in the pipeline across the dam. The sands can be mobilized by even the smallest runoff from rains, the competency of the dam structure itself is directly related to the thickness of the sand shell, and deep erosion channels resulting from runoff reduces the depth of the sand shell, thereby reducing the integrity and safety of the dam and those persons working thereon.

4. Petitioner proposes to install berms only under the following conditions:

a. Along roadways where the outside slope is steeper than 3 to 1; and

b. Along sections of roadways narrower than 20 feet of clear width.

5. Petitioner states that construction of berms along all other roadways could reduce the integrity and safety of the dams because:

a. The berms could cause pooling of floodwaters, promoting absorption of water in the shell of the dam. The greater the excess water contained in the dam the lower its safety factor.

b. If there were breaks in the tailings pipeline on the dams, berms along roadways would tend to direct the entire flow into a single channel which could shortly cause dam failure or significant damage to the dam.

c. The erosion and soaking of roadways which would result by placing berms along the roadways across the dam could create a potential severe driving hazard during times of rainfall, causing water to collect. Maintenance of the roads requires ready access by road maintenance equipment to dress the operational surface following rainfalls. Berms tend to retain the moisture and delay such maintenance.

6. Petitioner states that guard facilities such as post and cables would also result in a diminution in safety to miners. In order to maintain the lateral drainage across the roadways, and protect the integrity of the dam and the safety of persons working thereon, it is necessary not to have any trace berm whatever along the crest of the dam. Posts and/or cables would interfere in sweeping the roadway clear of all materials to the crest of the dam, resulting in leaving a trace berm which would interfere with lateral drainage.

7. As an alternate method, petitioner proposes to classify and use the tailing dam roads as follows:

a. Operational: The most recently constructed road at each dam is the operational road at that dam, and will be used for normal access. Operational roads may be used by personnel who service and maintain cyclones, piping and roads, and by supervisors, tailing dam operators and other authorized
personnel who are knowledgeable about the road system and the rules;

b. Intermittently Used: Some roads at each dam are used intermittently by a small number of individuals, primarily engineering technicians who log piezometers. Access to these roads will be restricted to authorized personnel such as supervisory and engineering department personnel. Access will be physically restricted and signs setting forth the classification will be posted at each end;

c. Abandoned: Roads which are seldom used and are not required for normal operations will be classified as abandoned. Access to roads classified as abandoned will be physically restricted.

8. Petitioner further states that trucks normally assigned to tailing dam service have a maximum width of eight feet; other vehicles which normally travel the roads are narrower. The only wider vehicle is a road grader needed for periodic maintenance of the roadway and outer slope. Traffic control signs setting forth the speed limits will be posted at each end of each operational road. Signs showing curves will be installed on the inside of the roads as needed along its length.

9. All personnel assigned to work at tailings dams are and will be task-trained in the duties and hazards likely to be encountered. Vehicles routinely assigned to use at the dams are equipped with two-way radios. No vehicles without an operable radio will be assigned to an operator on any shift.

10. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before October 15, 1984. Copies of the petition are available for inspection at that address.


Patricia W. Silvey,
Director, Office of Standards, Regulations and Variances.

[FR Doc. 84-24418 Filed 9-13-84; 8:45 am]
BILLING CODE 4510-45-M

Office of Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 84–136; Exemption Application No. D-4066 et al.]

Grant of Individual Exemptions; Atalanta Sosnoff Segmentation Fund, et al.

AGENCY: Office of Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1984 (the Code).

The restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to the acquisition from Atalanta Sosnoff Capital Corporation (A/S) of interests in the Partnership by employee benefit plans (the Plans) for which A/S provides or will provide investment management services and therefore is or will be a fiduciary, provided that:

(a) They are in the interest of the plans and their participants and beneficiaries; and

(b) They are protective of the rights of the participants and beneficiaries of the plans.

Atalanta/Sosnoff Segmentation Fund, L.P. (the Partnership) Located in New York, New York

[Prohibited Transaction Exemption 84–136; Application No. D–4066]

Exemption

Section I. Transactions Involving Acquisition of a Partnership Interest

The restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to the acquisition from Atalanta Sosnoff Capital Corporation (A/S) of interests in the Partnership by employee benefit plans (the Plans) for which A/S provides or will provide investment management services and therefore is or will be a fiduciary, provided that:

(a) The restrictions of sections 406(a), 406(b)(2) and 407(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to the transactions described below if the applicable conditions set forth in Section IV are met:

1. Transactions Between Parties in Interest and the Partnership: General.

Any transaction between a party in interest with respect to a Plan and the Partnership, or any acquisition or holding by the Partnership of employer securities, if the party in interest is not A/S or one of its affiliates and it, at the time of the transaction, acquisition or holding, the interest of the Plan, together with the interests of any other plans maintained by the same employer or employee organization in the Partnership, does not exceed 5 percent of the total of all assets in the Partnership.

2. Special Transactions Not Meeting the Criteria of Section II(a)(1) Between Employers of Employees Covered by a Multiemployer Plan and the Partnership.
Any transaction between an employer (or an affiliate of an employer) of employees covered by a multiemployer plan (as defined in section 3(37)(A) of the Act and section 414[(1)] of the Code) that is a Plan, and the Partnership; or any acquisition or holding by the Partnership of employer securities, if at the time of the transaction, acquisition or holding—

(A) the interest of the multiemployer plan in the Partnership does not exceed 10 percent of the total assets in the Partnership; and the employer is not a substantial employer with respect to the plan, or

(B) the interest of the multiemployer plan in the Partnership exceeds 10 percent of the total assets in the Partnership; but the employer is not a substantial employer with respect to the plan and would not be a substantial employer if "5 percent" were substituted for "10 percent" in the definition of "substantial employer;"

(3) Acquisitions, Sales or Holdings of Employer Securities.

(A) Except as provided in subsection (B) of this section (3), any acquisition, sale or holding of employer securities by the Partnership which does not meet the requirements of paragraphs (a)(1) and (a)(2) of this Section II, if no commission is paid to A/S or to the employer, or any affiliate of A/S or the employer in connection with the acquisition or sale of employer securities; and

(aa) Neither A/S nor any of its affiliates is an affiliate of the issuer of the security; and

(bb) If the security is a debt obligation of the issuer, either:

1. The Partnership owns the obligation at the time the Partnership acquires an interest in the partnership, and interests in the Partnership are offered and redeemed in accordance with value procedures of the Partnership applied on a uniform or consistent basis, or

2. Immediately after acquisition of the obligation by the Partnership 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 at least 50 percent of the aggregate amount of obligations issued in the issue and outstanding at the time of acquisition is held by persons independent of the issuer, A/S, its affiliates and any collective investment fund maintained by A/S or its affiliates shall be considered to be persons independent of the issuer if A/S is not an affiliate of the issuer.

(B) In the case of a Plan that is not an eligible individual account plan (as defined in section 407(d)(3)(B) of the Act), the exemption provided in subparagraph (3)(A) of this paragraph (a) shall be available only if, immediately after the acquisition of the employer securities, the aggregate fair market value of employer securities with respect to which A/S or its affiliate has investment discretion does not exceed 10 percent of the fair market value of all the assets of the Plan with respect to which A/S or its affiliate has such investment discretion.

(C) For purposes of the exemption contained in subparagraph (3)(A) of this paragraph (a), the term "employer securities" shall include securities issued by a person who is a party in interest with respect to a Plan by reason of a relationship to the employer described in section 3(14) (E), (G), (H) or (I) of the Act.

(b) Transactions With Persons Who Are Parties In Interest With Respect to a Plan Solely by Virtue of Being Certain Service Providers or Certain Affiliates of Service Providers. The restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to any transaction between the Partnership and a person who is a party in interest with respect to a Plan that has an interest in the Partnership if—

(A) The person is a party in interest (including a fiduciary) solely by reason of providing services to the Plan, or solely by reason of a relationship to a service provider described in section 3(14) (F), (G), (H) or (I) of the Act, or both, and the person neither exercised nor has any discretionary authority, control, responsibility or influence with respect to the investment of the Plan's assets in, or held by, the Partnership;

(B) The person is not A/S or an affiliate thereof; and

(C) The person is a party in interest with respect to a Plan whose interest in the Partnership, aggregated with the Partnership interests held by any other Plan maintained by the same employer or employee organization, does not exceed 20 percent of the total limited partnership units of the Partnership.

Section III. Excess Holdings Exemption for Employee Benefit Plans

(a) The restrictions of sections 406(a) and 407(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to any acquisition or holding of employer securities (other than through the Partnership) by a Plan if (1) the acquisition or holding constitutes a prohibited transaction solely by reason of being aggregated with employer securities held by the Partnership; (2) the requirements paragraphs (a)(1), (a)(2) or (a)(3) of Section II of this exemption are met; and (3) the applicable conditions set forth in Section IV of this exemption are met.

Section IV—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 A/S or its affiliate, the terms of the transaction are not less favorable to the Partnership than the terms generally available in arm’s-length transactions between unrelated parties.

(b) A/S or its affiliate 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 IV to determine whether the conditions of this exemption have been met, except that (1) a prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of A/S or its affiliate, 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 that may be assessed under section 502(s) 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 section 2 of this paragraph (c) 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 IV are unconditionally available at their customary location for examination during normal business hours by:

(A) any duly authorized employee or representative of the Department or the Internal Revenue Service,

(B) any fiduciary of a Plan who has authority to acquire or dispose of the interests in the Partnership of the Plan or any duly authorized employee or representative of such fiduciary,

(C) any contributing employer to any Plan or any duly authorized employee or representative of such employer, and

(D) any participant or beneficiary of any Plan, or any duly authorized employee or representative of such participant or beneficiary.

(2) None of the persons described in subparagraphs (B) through (D) of this paragraph (c) shall be authorized to examine trade secrets of A/S or its affiliate, or commercial or financial information which is privileged or confidential.
Section V—Definitions and General Rules

For the purposes of this exemption, (a) 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, 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.

(b) The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(c) 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(a)(6) of the Code), or a brother, a sister, or a spouse of a brother or sister.

(d) The term "substantial employer" means for any plan year an employer (treating employers who are members of the same affiliated group, within the meaning of section 1563(a) of the Code, determined without regard to section 1563(a)(4) and (e)(3)(C) of the Code, as one employer) who has made contributions to or under a multiemployer plan for each of—
   (1) The two immediately preceding plan years, or
   (2) The second and third preceding plan years, equaling or exceeding 10 percent of all employer contributions paid to or under that plan for each such year.

(e) The time as of which any transaction, acquisition or holding occurs is the date upon which the transaction is entered into, the acquisition is made or the holding commences. In addition, in the case of a transaction that is continuing, the transaction shall be deemed to occur until it is terminated. If any transaction is entered into, or an acquisition is made, on or after the effective date of this exemption, or a renewal that requires the consent of the Partnership occurs on or after the effective date of this exemption, 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 property so acquired. Notwithstanding the foregoing, this exemption shall cease to apply to a transaction exempt by virtue of subsections II(a)(1) or II(b) at such time as the interest of the Plan exceeds the percentage interest limitations set forth in those subsections, unless no portion of such excess results from an increase in the assets allocated to the Partnership by the Plan. For this purpose, assets allocated do not include the reinvestment of Partnership earnings. Nothing in this paragraph (e) shall be construed as exempting a transaction entered into by the Partnership which becomes a transaction described in section 406 of the Act or section 4975 of the Code while the transaction is continuing, unless the conditions of the exemption were met either at the time the transaction was entered into or at the time the transaction would have become prohibited but for this exemption.

(f) Each Plan shall be considered to own the same proportionate undivided interest in each asset of the Partnership as its proportionate interest in the total assets of the Partnership as calculated on the most recent preceding valuation date of the Partnership.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on July 6, 1984 at 49 FR 29487.

Written Comments

The only comment received by the Department was submitted by the applicants who were seeking to correct errors of fact contained in their original exemption application. Both the original application and the notice of proposed exemption state that Mr. Martin T. Sosnoff owns 50% of the outstanding capital stock and is an executive officer of Atalanta Capital Corporation (Capital) and that Mr. Shepard D. Osherow is an executive officer of Emerald Capital (Capital) and that Mr. Shepard D. Osherow resigned his position with Capital and Mr. Sosnoff relinquished his equity interest in Capital. The Department has considered this information and has determined, on the basis of the entire record in this case, that the exemption should be granted as proposed.

For Further Information Contact: Mrs. Mary Jo Fite of the Department, telephone (202) 523-8671. (This is not a toll-free number.)

Emerald Packaging, Inc. Employees Profit Sharing Plan and Emerald Packaging, Inc. Pension Plan (the Plans) Located in Berkeley, California

[Prohibited Transaction Exemption 84-137; Exemption Application Nos. D-4992 and D-4993]

Exempted

The restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply, for a period of five years, to the proposed loans by the Plans of up to 25% of each Plan's assets to Emerald Packaging, Inc., provided that the terms of the transactions are not less favorable to the Plans than those obtainable in an arm's length transaction with an unrelated party at the time of consummation of each transaction.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on July 6, 1984 at 49 FR 27943.

Temporary Nature of Exemption

This exemption is temporary and will expire five years after the date of grant with respect to the making of any loan. Subsequent to the expiration of this exemption, the Plans may hold loans originated during this five year period until the loans are repaid. Should the applicant wish to continue entering into loans transactions beyond the five year period, the applicant may submit another application for exemption.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8971. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 406(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or 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 participants and beneficiaries of the plan and in a prudent fashion in accordance with
section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 404(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries; (2) These exemptions are, supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative exemption is not dispositive of whether the transaction is in fact a prohibited transaction; (3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, D.C., this 11th day of September 1984.

Eliot I. Daniel,
Acting Assistant Administrator for Fiduciary Standards, Office of Pension and Welfare Benefit Programs, Department of Labor.

[FR Doc. 84-24401 Filed 9-13-84; 8:45 am]
BILLING CODE 7537-01-M

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

Dance 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 Dance Advisory Panel (Overview Section) to the National Council on the Arts will be held on October 2, 1984, from 9:00 a.m.—6:00 p.m. and on October 3, 1984, from 9:00 a.m.—5:30 p.m. in room M-07 of the Nancy Hanks Center, 1100 Penn., Avenue, N.W., Washington, D.C. 20506.

A portion of this meeting will be open to the public on October 2, 1984, from 9:00 a.m.—3:00 p.m. to discuss policy and guidelines review.

The remaining sessions of this meeting on October 1, 1984, from 9:30 a.m.—3:00 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 of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and (9)(b) of section 552b 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) 682-5433.


John H. Clark,
Office of Council and Panel Operations, National Endowment for the Arts.

BILLING CODE 7537-01-M

Inter-Arts 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 Inter-Arts Advisory Panel (Dance/Inter-Arts/State Programs Presenting-Initiating Section) to the National Council on the Arts will be held on October 1, 1984, from 9:30 a.m.—6:00 p.m. in room 730 of the Nancy Hanks Center, 1100 Penn., Avenue, N.W., Washington, D.C. 20506.

A portion of the meeting will be open to the public on October 1, 1984, from 3:00—6:00 p.m. to discuss policy and guidelines review.

The remaining sessions of this meeting on October 1, 1984, from 9:30 a.m.—3:00 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 of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and (9)(b) of section 552b 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) 682-5433.


John H. Clark,
Director, Office of Council and Panel Operations, National Endowment for the Arts.

BILLING CODE 7537-01-M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Atmospheric Sciences; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Committee for Atmospheric Sciences (ACAS).

Date: October 3–5, 1984.

Time: 9:00 a.m.—5:00 p.m.

Place: Room 543, National Science Foundation, 1800 G Street, N.W., Washington, D.C. 20550.

Type of meeting: Open.

October 3 (9:00 a.m.—5:00 p.m.) and October 4 (9:00 a.m.—12:00 noon) are for the purpose of discussion, evaluation and recommendations and oversight concerning support for research and research-related activities in the atmospheric sciences area.

Agenda

October 3, 1984, Room 543—9:00 a.m. to 5:00 p.m. (Open)

—Opening Remarks by Chairman, ACAS and Division Director, ATM

—Approval of Minutes from ACAS Meeting April 25–27, 1984

—Science and Engineering Education

—Interactions

—Response to the Centers and Facilities Section (CFS) Review at April 25–27, 1984 Meeting

—Remarks by Acting Assistant Director, AEO

—Long Range Planning for FY 1997–91

—Criteria for Long Range Planning (LRP) for FY 1987–91

—Response of ACAS Chairman to LRP

Discussion

October 4, 1984, Room 543—9:00 a.m. to 12:00 noon (Open)

—Remarks by Director, NSF

—Conclusion of Long Range Planning for FY 1987–91

October 4, 1984, Rooms 628, 642, and 643—1:00 p.m. to 5:00 p.m. and October 5, 1984, 8:30 a.m. to 5:00 p.m. (Closed)

Committee review of the Atmospheric Chemistry, Climate Dynamics, and Experimental Meteorology Programs including examination of proposal jackets, reviewer comments and other privileged material.

Reason for Closing: The meeting will deal with a review of grants and declinations in which the Committee
Emist will review materials containing the names of applicant institutions and principal investigators and privileged information contained in declined proposals. This meeting will also include a review of peer review documentation pertaining to applicants. Any non-exempt materials that may be discussed at this meeting (proposals that have been awarded) will be inextricably intertwined with the discussion of exempt materials and no further separation is practical. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), the Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, on July 6, 1979.


M. Rebecca Winkler,
Committee Management Coordinator.

Permits issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.


SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice of permits issued.

FOR FURTHER INFORMATION CONTACT:
Charles E. Myers, Permit Office, Division of Polar Programs, National Science Foundation, Washington, D.C. 20550. Telephone (202) 357-7934.

SUPPLEMENTARY INFORMATION: On July 30, 1984, the National Science Foundation published a notice in the Federal Register of permit applications received. On September 7, 1984 permits were issued to:

Wayne Z. Trivelpiece
David F. Parmelee
Donald B. Siniff
Arthur L. DeVries
William M. Hamner
Charles E. Myers,
Permit Office, Division of Polar Programs.

NUCLEAR REGULATORY COMMISSION

Correction

In FR Doc. 84-22965 appearing on page 34317 in the issue of Wednesday, August 29, 1984, make the following correction to the table "NRC Import/Export Applications": The third entry in the column "Material in kilograms; Total element" reading "88,377" should have read "38,377".

BILLING CODE 7555-01-M
Environmental Impact Statement need not be prepared. These conclusions were based on the following:

(a) The excess reactivity available under the Technical Specifications is insufficient to support a reactor transient generating enough energy to cause overheating of the fuel or loss of integrity of the cladding;

(b) The expected consequences of a broad spectrum of postulated credible accidents have been considered, emphasizing those likely to cause loss of integrity of fuel-element cladding. The staff performed conservative analyses of the most serious credible accidents and determined that the calculated potential radiation doses in unrestricted areas are small fractions of 10 CFR Part 20 limits of 10 CFR Part 20 and are as low as is reasonably achievable (ALARA); and

(c) The systems provided for control of radiological effluents can be operated to ensure that releases of radioactive wastes from the facility are within the limits of 10 CFR Part 20 and are as low as is reasonably achievable (ALARA); and

(d) The licensee’s Technical Specifications, which provide limiting conditions for the operation of the facility, are such that there is a high degree of assurance that the facility will be operated safely and reliably.

For further details with respect to this proposed action, see the application for license renewal dated September 19, 1977, as supplemented, the Environmental Assessment, and the Safety Evaluation Report prepared by the staff (NUREG-1064).

These documents are available for public inspection at the Commission’s Public Document Room, 1717 H Street NW, Washington, D.C. 20555. Copies may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Director, Division of Licensing.

Copies of NUREG-1064 may be purchased by calling (301) 492-9630 or by writing to the Publication Services Section, Document Management Branch, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; or purchased from the National Technical Information Service, Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161.

Dated at Bethesda, Maryland, this September 5, 1984.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,
Director, Division of Licensing.

Dated at Bethesda, Maryland this 10th day of September 1984.

For the Nuclear Regulatory Commission.

James V. Zimmerman,
Assistant Director, Export/Import and International Safeguards, Office of International Programs.

Applications for Licenses To Export Nuclear Facilities or Materials; Mitsui & Co. (U.S.A.), Inc.

Pursuant to 10 CFR 110.70(b) “Public notice of receipt of an application” please take notice that the Nuclear Regulatory Commission has received the following applications for export licenses. Copies of the applications are on file in the Nuclear Regulatory Commission’s Public Document Room located at 1717 H Street, NW., Washington, D.C. 20555.

A request for hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the Federal Register. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the Secretary, U.S. Nuclear Regulatory Commission, and the Executive Secretary, U.S. Department of State, Washington, D.C. 20522.

In its review of applications for licenses to export production or utilization facilities, special nuclear materials or source material, noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recipient nation of the facility or material to be exported. The table below lists all new major applications.

Dated this 10th day of September 1984 at Bethesda, Maryland.

For the Nuclear Regulatory Commission.

Harold R. Denton,
Director, Office of Nuclear Reactor Regulation.

Dated at Bethesda, Maryland this 10th day of September, 1984.

For the Nuclear Regulatory Commission.

Harold R. Denton,
Director, Office of Nuclear Reactor Regulation.

BILUNG CODE 7590-01-M
October 30, 1984—Postal Service
Answering Brief [see 39 CFR
3001.115(c)].

November 14, 1984—(1) Petitioner's
Reply Brief should petitioner choose to
file one [see 39 CFR 3001.115(d)].

November 21, 1984—(2) Deadline for
motions by any party requesting oral
argument. The Commission will exercise
its discretion, as the interest of a prompt
and just decision may require, in
scheduling or dispensing with oral
argument [see 39 CFR 3001.116].

January 3, 1985—Expiration of 120-day
decisional schedule [see 39 U.S.C.
404(b)(5)].

BILLING CODE 7110-01-M

SECURITIES AND EXCHANGE
COMMISSION
[Release No. 14134-812-5109]
The Bank of New York; Proposal To
Amend an Existing Order of the
Commission Pursuant to Section 38(a)
of the Act

Notice is hereby given that the
Commission proposes to issue an order
pursuant to Section 38(a) of the
Investment Company Act of 1940
(“Act”) amending an existing order of
the Commission dated November 20,
1981 (Investment Company Act Release
No. 12053). The existing order exempts
The Bank of New York (“BONY”), 90
Washington Street, New York, New
York 10015, any subcustodian of BONY,
any custodian for which BONY acts as
subcustodian and any investment
company registered under the Act other
than an investment company registered
under Section 7(d) of the Act
(“company”) from the provisions of
Section 17(f) of the Act and Rule 17f-4
thereunder to the extent necessary to
permit BONY, as the custodian of the
securities and other assets of an
investment company (“securities”) or as
the subcustodian of such securities as to
which any other entity is acting as
custodian and such other entity for
which BONY so acts, to deposit or to
cause or permit the deposit of such
securities in foreign banks and foreign
securities depositories (as defined in the
order) under certain conditions.

As defined in the application as
amended, “securities” do not include
securities issued by the Government of
the United States or of any State or of
any political subdivision thereof or by any
agency thereof or any securities issued
by any entity organized under the laws
of the United States or of any State
thereof other than certificates of deposit,
evidence of indebtedness and other
securities, issued or guaranteed by an
entity so organized which have been
issued or sold outside the United States.
“Foreign bank” is defined to be a
banking institution supervised and
regulated by the banking authorities in
the location where such institution may
maintain physical custody of the
securities and “securities depository” is
defined to be any system for the central
handling of securities abroad where all
securities of any particular class or
series of any issuer deposited within the
system are treated as fungible and may
be transferred or pledged by
bookkeeping entry without physical
delivery of the securities.

The existing order provides, inter alia,
that the custody agreement between
BONY and the company, or the
subcustodial agreement between BONY
and the entity which acts as the
custodian for the assets of the company,
is subject to the approval of the
company and, under Rule 17f—4(d)(5),
the approval and review at least
annually by the board of directors of the
company.

Section 38(a) of the Act provides, in
part, that the Commission shall have the
authority from time to time to make,
issue, amend and rescind such orders as
are necessary or appropriate to the
exercise of the powers conferred upon
the Commission by the Act. Pursuant to
that section, the Commission proposes
to amend the existing exemptive order
to conform certain conditions of that
order to Rule 17f—5 [17 CFR 270.17f-5]
which was adopted by the Commission

As amended, the BONY order would
permit registered management
investment companies to maintain cash
and cash equivalents with eligible
foreign custodian only in amounts
reasonably necessary to effect the
company’s foreign securities
transactions.1 Investment companies
relying on the amended order would be
able to maintain their securities and
other assets only in the care of the
following eligible foreign custodians: (i)
a banking institution or trust company
incorporated or organized under the
laws of country other than the United
States that is regulated as such by that
country’s government or an agency
thereof and that has shareholders’
equity in excess of $200 million (U.S.$
or the equivalent of U.S.$); (ii) a

1 See paragraph (a) of Rule 17f—5.
2 Id. at paragraph (c)(2)(i).
majority-owned direct or indirect subsidiary of a qualified U.S. bank or bank-holding company that is incorporated or organized under the laws of a country other than the United States and that has shareholders' equity in excess of $100 million (U.S. $ or the equivalent of U.S. $); 3 (iii) a securities depository or clearing agency, incorporated or organized under the laws of a country other than the United States, which operates the central system for handling of securities or equivalent book-entries in that country; 4 or (iv) a securities depository or clearing agency, incorporated or organized under the laws of a country other than the United States, which operates a transnational system for the central handling of securities or equivalent book-entries. 5

The existing order would be further amended to provide that before a foreign custody arrangement is implemented, a majority of the board of directors of the company must approve the foreign custodian and the terms of the custody agreement with that custodian as consistent with the best interests of the company and its shareholders. 6 Further, the board of directors must establish a system to monitor all foreign custody arrangements made pursuant to the terms of the amended order7 and, at least annually, review and approve the continuance of such arrangements as consistent with the best interests of the company and its shareholders. 8 Any investment companies that have made foreign custody arrangements in reliance on the existing exemptive order will have until March 1, 1985 to conform those arrangements to the conditions of the order as amended.

Notice is further given that any interested person wishing to request a hearing may do so, not later than October 1, 1984, at 5:30 p.m., by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Acting Secretary, Securities and Exchange Commission, Washington, D.C. 20549. After said date, an order will be issued amending the existing order unless the Commission orders a hearing upon request or upon its own motion.

By the Commission.
Shirley E. Hollis,
Acting Secretary.

[Release No. 14133; 812-4475]
The Chase Manhattan Bank, N.A.; Proposal To Amend An Existing Order of the Commission


Notice is hereby given that the Commission proposes to issue an order pursuant to Section 38(a) of the Investment Company Act of 1940 ("Act") amending an existing order of the Commission dated November 20, 1981 (Investment Company Act Release No. 12053). The existing order exempts the Chase Manhattan Bank, N.A. ("Chase"); 1 Chase Manhattan Plaza, New York, New York 10012, any subcustodian of Chase, any custodian for which Chase acts as subcustodian and any investment company registered under the Act other than an investment company registered under section 7(d) of the Act ("company") from the provisions of section 17(f) of the Act and Rule 17f-4 thereunder to the extent necessary to permit Chase, as the custodian of the securities and other assets of an investment company ("securities") or as the subcustodian of such securities as to which any other entity is acting as custodian, and such other entity for which Chase so acts, to deposit or to cause or permit the deposit of such securities in foreign banks and foreign securities depositories (as defined in the order) under certain conditions.

As defined in the application as amended, "securities" do not include securities issued by the Government of the United States or of any state or by any political subdivision thereof or by any agency thereof or any securities issued by any entity organized under the laws of the United States or of any state thereof other than certificates of deposit, evidences of indebtedness and other securities, issued or guaranteed by an entity so organized which have been issued or sold outside the United States. "Foreign bank" is defined to be a banking institution supervised and regulated by the banking authorities in the location where such institution may maintain physical custody of the securities and "securities depository" is defined to be any system for the central handling of securities abroad where all securities of any particular class or series of any issuer deposited within the system are treated as fungible and may be transferred or pledged by bookkeeping entry without physical delivery of the securities.

The existing order provides, inter alia, that the custody agreement between Chase and the company, or the subcustodial agreement between Chase and the entity which acts as the custodian for the assets of the company, is subject to the approval of the company and, Rule 17f-4(d)(5), the approval and review at least annually of the board of directors of the company.

Section 38(a) of the Act provides, in part, that the Commission shall have the authority from time to time to make, issue, amend and rescind such orders as are necessary or appropriate to the exercise of the powers conferred upon the Commission by the Act. Pursuant to that section, the Commission proposes to amend the existing exemptive order to conform certain conditions of that order to Rule 17f-5 [17 CFR 270.17f-5] which was adopted by the Commission in Investment Company Act Release No. 14132, dated September 7, 1984.

As amended, the Chase order would permit registered management investment companies to maintain cash and cash equivalents with eligible foreign custodians only in amounts reasonably necessary to effect the company's foreign securities transactions. Investment companies relying on the amended order would be able to maintain their securities and other assets only in the care of the following eligible foreign custodians: (i) a banking institution or trust company incorporated or organized under the laws of a country other than the United States that is regulated as such by that country's government or an agency thereof and that has shareholders' equity in excess of $200 million (U.S. $ or the equivalent of U.S. $); 9 (ii) a majority-owned direct or indirect subsidiary of a qualified U.S. bank or bank-holding company that is incorporated or organized under the laws of a country other than the United States and that has shareholders' equity in excess of $100 million (U.S. $ or the equivalent of U.S. $); 9 (iii) a securities depository or clearing agency, incorporated or organized under the laws of a country other than the United States, which operates a transnational system for the central...
handling of securities or equivalent book-entries.\footnote{Id. at paragraph (c)(2)(i).}
The existing order would be further amended to provide that before a foreign custody arrangement is implemented, a majority of the board of directors of the company must approve the foreign custody arrangement and the terms of the custody agreement with that custodian as consistent with the best interests of the company and its shareholders.\footnote{Id. at paragraph (a)(1).} Further, the board of directors must establish a system to monitor all foreign custody arrangements made pursuant to the terms of the amended order\footnote{Id. at paragraph (c)(2)(ii).} and, at least annually, review and approve the continuance of such arrangements as consistent with the best interests of the company and its shareholders.\footnote{Id. at paragraph (a)(2).} Any investment companies that have made foreign custody arrangements in reliance on the existing exemptive order will have until March 1, 1985 to conform those arrangements to the conditions of the order as amended.

Notice is further given that any interested person wishing to request a hearing may do so, not later than October 1, 1984, at 5:30 p.m., by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Acting Secretary, Securities and Exchange Commission, Washington, D.C. 20549. After said date, an order will be issued amending the existing order unless the Commission orders a hearing upon request or upon its own motion.

By the Commission.

Shirley E. Hollis,  
Acting Secretary.

[FR Doc. 84-24535 Filed 9-13-84; 0:45 am]  
BILLING CODE 8010-01-M

[Release No. 34-21302; File No. SR-NASD-84-14]

Self-Regulatory Organizations; Proposed Rule Change by National Association of Securities Dealers, Inc.; Relating to Proposed New Text of the NASD By-Laws

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 14, 1984, the National Association of Securities Dealers, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Association is proposing to replace the NASD By-Laws in their entirety with a new text which was contained in NASD Notice to Members 83-55 (Oct. 20, 1983).

II. Self-Regulatory Organization's Statements Regarding the Proposed Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed amendment to the By-Laws is primarily designed to conform the By-Law language to certain statutory changes, codify existing Board interpretations, clarify the application of certain provisions and generally update and modernize the By-Laws. In addition to the technical and substantive changes made within the By-Laws, it is proposed that present Schedules A through D be restyled and transferred to new sections of the NASD Manual which will be divided according to subject matter, e.g., Fees and Charges, Automated Systems, Member Qualifications and Administrative Districts. It is also proposed that Schedules E and G will be recrafted as Rules of Fair Practice. These changes to the schedules will be the subject of subsequent filings pursuant to Rule 15B-4 and it is contemplated that those changes will be coordinated with the implementation of the revised By-Laws. Schedule F was previously rescinded.

A section by section analysis of the purposes of the By-Law amendments is contained in Notice to Members 83-55 in the explanations following each section of the By-Laws. These explanations are incorporated by reference herein.

The proposed revisions to the By-Laws are designed to aid the Association in more adequately fulfilling its responsibilities as defined under Section 15A of the Securities Exchange Act of 1934 (the "Act").

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed amendment will not result in any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The proposed amendment was approved by the Association's membership by a vote of 1019 For; 21 Against. Comments had previously been received in response to Notice to Members 83-8 (February 4, 1983). The Association received five written comments which were generally accepted by the Board of Governors and incorporated into the text filed with the Commission for approval. Copies and Notices to Members relevant to the proposed rule change and comments by members thereto are available at the Commission's Public Reference Section or the main office of the NASD.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or  
(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 5th Street NW., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that
may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 5th Street NW, Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

All submissions should refer to the file number in the caption above and should be submitted by October 5, 1984.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Shirley E. Hollis,
Acting Secretary.

[FR Doc. 84-24355 Filed 9-13-84; 8:45 am]
BILLING CODE 8010-01-M

[Release No. 21309 (SR-BSE-84-2)]

Self-Regulatory Organization; Boston Stock Exchange, Inc.; Order Approving Proposed Rule Change


The Boston Stock Exchange ("BSE"). One Boston Place, Boston, Massachusetts 02108, submitted on July 5, 1984 copies of a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act") and Rule 19b-4 thereunder, to expand the pilot program established for execution of standard odd-lot market orders to purchase or sell shares in American Telephone and Telegraph ("AT&T") and the equity issues created as a result of the AT&T divestiture to include all BSE issues. The BSE is implementing these procedures on a two-month pilot basis.

Under the procedures, standard odd-lot orders received prior to the opening will be executed at the consolidated opening price. In addition, the BSE's procedures provide that any customer or his representative may request and be provided an execution based upon the opening in the primary market. An odd-lot differential may be charged on these orders. Standard odd-lot market orders received after the opening in all BSE issues will receive an execution price based on the best consolidated quotation in the stock at the time such order is received by the specialist. No odd-lot differential will be charged on these orders.

Notice of the proposed rule change, together with the terms of substance of the proposed rule change, was given by the issuance of a Commission Release (Securities Exchange Act Release No. 21180, July 27, 1984) and by publication in the Federal Register (49 FR 51023, August 2, 1984). No comments were received with respect to the proposed rule change.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of section 6 and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

Shirley E. Hollis,
Acting Secretary.

[FR Doc. 84-24432 Filed 9-13-84; 8:45 am]
BILLING CODE 8010-01-M

[Release No. 21302 (File No. SR-NASD-84-14)]

Self Regulatory Organizations; Filing and Proposed Rule Change; National Association of Securities Dealers, Inc.


The National Association of Securities Dealers, Inc. ("NASD"), 1735 K Street, N.W., Washington, D.C. 20006, submitted on June 14, 1984, copies of a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, to codify and revise generally the NASD's By-Laws. The proposed rule change is part of the NASD's effort to review and revise its rules, By-Laws, and interpretations. The proposed amendments: (1) codify existing interpretations of the NASD's Board of Governors, (2) conform the By-Law language to changes in the Act engendered by the Securities Acts Amendments of 1975; and (3) eliminate or modify obsolete provisions of the By-Laws. The proposed rule includes numerous technical and substantive modifications to the By-Laws. As an example of a technical change, the proposal would renumber and move Article XVI on the establishment of NASDAQ and Article XVII on the use of registered clearing agencies to a modified Article VII, which discusses the powers and authorities of the Board of Governors.

The Commission is particularly interested in receiving comments on two sections of the proposed rule change concerning summary disciplinary powers of the NASD's Board of Governors. Under section 3(c) of the By-Laws as proposed to be amended, the Board of Governors upon notice would be able to (1) cancel the membership of a member if it becomes ineligible for continuance in membership; (2) suspend or bar a person from continuing to be associated with any member if such person is or becomes ineligible for association due to lack of qualifications or to a statutory disqualification; or (3) cancel the membership of any member who continues to be associated with any such ineligible person. In addition, the NASD would retain the provision that permits the Board of Governors, upon fifteen days written notice, to cancel or suspend any member or associated person for failure to produce any report, document, or other information required to be filed or requested by the NASD.

The NASD further contemplates that it will file with the Commission additional technical modifications of its rules, By-Laws, and provisions. For example, the NASD states that it will submit another proposed rule change to redefine Schedules A through E and G of the By-Laws and transfer them to a new section of the NASD Manual. In order to assist the Commission in determining whether to approve the proposed rule change or institute proceedings to determine whether the proposed rule change should be disapproved, interested persons are invited to submit written data, views and arguments concerning the submission within 21 days after the date of publication in the Federal Register.
Acting Secretary.

Approving Proposed Rule Change; Self-Regulatory Organizations; Order

With the Secretary of the Commission, U.S.C. 552, will be available for review comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission. 450 Fifth Street, NW, Washington, D.C. 20549. Reference should be made to File No. SR–NASD–82–24.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the NASD.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12).

Shirley E. Hollis,
Acting Secretary.

[FR Doc. 84–24422 Filed 8–13–84; 8:45 am]
BILLING CODE 8010–01–M

Self-Regulatory Organizations; Order Approving Proposed Rule Change; Pacific Securities Depository Trust Co.


I. Introduction

On June 22, 1984, the Pacific Securities Depository Trust Company ("PSDTC") filed with the Securities and Exchange Commission a proposed rule change under section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78s(b)(1). The proposed rule change would establish a dividend reinvestment program (the "Program") for participants with positions in eligible securities and would institute fees to reflect PSDTC's costs for providing this service. The proposed rule change was amended on July 18, 1984, when PSDTC filed its proposed dividend reinvestment procedures with the Commission. The Commission solicited comment on the proposed rule change in Securities Exchange Release No. 21183.4 No letters of comment were received. As discussed below, the Commission is approving the proposed rule change.

II. Description

Generally, the Program will allow PSDTC participants to reinvest cash dividends and retain the resulting securities on deposit with PSDTC. Securities that are or will be eligible for this Program must meet certain requirements. First, the securities must be PSDTC eligible. In addition, the administrator of each dividend reinvestment plan ("DRP") must agree to comply with PSDTC procedures. Finally, the terms of each DRP must be compatible with PSDTC's DRP processing. Currently, eight securities are eligible for this Program.

Under the Program, PSDTC will notify its participants when a dividend is declared and whether the Program includes dividends on those securities. Generally, participants will receive this notice, which includes the deadline for acceptance of participant DRP instructions, approximately five business days prior to the announced record date. If it so elects, a participant may specify the number of shares on deposit at PSDTC, the dividend on which the participant elects to reinvest, and the number with respect to which it elects to receive a cash dividend. PSDTC will accept provisional reinvestment instructions by telephone pending receipt of a DRP participant instruction form. If participant instruction forms are not timely received, however, PSDTC retains the right to cancel any telephone instructions. Participants that wish to cancel their DRP instructions would be required to contact PSDTC immediately. PSDTC then will contact the plan administrator and, if the administrator accepts them, the instructions will be cancelled.

PSDTC will aggregate participant DRP instructions and request dividend reinvestment plan administrators to reinvest the appropriate quantity of dividends due PSDTC for those participants. PSDTC will receive securities purchased pursuant to DRP instructions submitted to plan administrators approximately three weeks after the cash dividend payment date. Upon receipt of the additional securities, PSDTC will process a stock dividend adjustment for the amount of full shares due to each participant and a cash dividend adjustment for fractional shares at a rate determined by each plan administrator.

PSDTC proposes to charge $18.00 for each DRP instruction processed, plus $5.00 for each special request. These proposed fees would be in addition to other applicable dividend processing fees.

III. Discussion

PSDTC states in its filing that the proposed rule change is consistent with the Act in general and with sections 17A(b)(3)(D) and 17A(b)(3)(F) of the Act in particular. As discussed more fully below, the Commission agrees and is approving the proposed rule change.

The Program would allow PSDTC participants to more efficiently and effectively manage their security positions. Specifically, to the extent that participants lessen the number of entities and separate transactions involved in purchasing additional securities, greater efficiencies and economies. Currently, PSDTC participants desiring to reinvest dividend proceeds must execute separate trades to acquire those securities after they receive the cash dividend.

The Commission also believes that the Program enhances the safeguarding of funds and securities and contributes to the immobilization of securities certificates. By permitting participants to reinvest all or part of their dividends, the Program allows PSDTC participants to receive and retain stock dividends within a depository environment. As a result, securities certificates are immobilized and participants' funds and securities are more effectively safeguarded.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the Act and the rules and regulations thereunder, and, in particular, the requirements of section 17A of the Act.

Accordingly, it is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (SR–PSDTC–84–8) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Shirley E. Hollis,
Acting Secretary.

[FR Doc. 84–24421 Filed 9–13–84; 8:45 am]
BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

Grant Assurances and Agreement for Airport Improvement Program; Correction

AGENCY: Federal Aviation Administration (FAA), (DOT).

49 FR 31029 (August 2, 1984).
ACTION: Correction of Preamble for notice of grant assurances to be used in the Airport Improvement Program.

SUMMARY: This notice corrects the preamble for the Notice of Grant Assurances to be used in the Airport Improvement Program that was published in the Federal Register, Vol. 49, No. 174, pg. 35282 on September 6, 1984.

FOR ADDITIONAL INFORMATION CONTACT: Mr. Robert E. David, APP-3, Office of Airport Planning and Programming (Room 619), Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591, Telephone (202) 426-8248.

Background: On September 6, 1984, the Federal Aviation Administration published a notice in the Federal Register of new grant assurances and agreement which would be used beginning in Fiscal Year 1985. The background section of the notice contained several errors and is being reprinted here for clarification. The grant assurances and agreement which were included in the September 6, 1984, notice were correct as printed. The correct background paragraph is as follows:

Background: Under the provisions of the Airport and Airway Improvement Act of 1982, as a condition to approval of a grant application, the Secretary must receive certain assurances from the sponsor (applicant). These assurances are submitted as Part V of the application for Federal assistance. The FAA has reviewed the assurances currently being used and updated them to reflect the requirements of current law. The assurances have also been revised to reflect that under the Airport Improvement Program grants can be made for the improvement of privately owned airports and for noise program implementation.

Two sets of assurances are included in this notice. The first set (FAA Form 5100–100) contains assurances to be made by airport sponsors in their applications requesting funds for airport development, airport planning and noise program implementation and by planning agencies in their applications requesting funds for integrated airport system planning. The second set (FAA Form 5100–100.1) contains assurances to be made by sponsors in their application requesting funds for noise program implementation when the sponsor does not own or operate the airport.

The assurances, submitted with the application for assistance under the Airport Improvement Program, are incorporated into the grant agreement by reference. For this reason, the grant agreement (FAA Form 5100–37) is also included as part of this notice. As need dictates, the assurances published herein may be amended to reflect the individual contractual circumstances at particular airports, or to resolve problems arising in the grant program. These assurances will be used beginning in Fiscal Year 1985 (October 1, 1984). Similar assurances have been applied to sponsors prior to that date under the terms of the 1982 Act and related laws.

Issued in Washington, D.C., on September 11, 1984.

William F. Shea, Associate Administrator for Airports.

[FR Doc. 84-24532 Filed 9-13-84; 8:40 am]
BILLING CODE 4910–13–M

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported for Exhibition; Determination

Notice is hereby given of the following determination: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13599, Mar. 29, 1978), and the Delegation of Authority from the Director, USA (47 FR 57600, Dec. 27, 1982), I hereby determine that the objects in the exhibit “Venice: The American View, 1860–1920” (included in the list 1 file as a part of this Determination), imported from abroad for the temporary exhibition without profit within the United States, are of cultural significance. These objects are imported pursuant to a loan agreement between the Fine Arts Museums of San Francisco and foreign lenders. I also determine that the temporary exhibition or display of the listed exhibit objects at the Fine Arts Museums of San Francisco, California, Palace of the Legion of Honor, beginning on or about October 20, 1984, to on or about January 20, 1985, and the possible additional display of all or some of the listed exhibit objects at the Cleveland Museum of Art, Cleveland, Ohio, beginning on or about February 27, 1985, to on or about April 21, 1985, is in the national interest.

Public notice of this Determination is ordered to be published in the Federal Register.

1 An itemized list of imported objects included in the exhibit is filed as part of the original document.


Thomas E. Harvey, General Counsel and Congressional Liaison.

[FR Doc. 84-24530 Filed 9-13-84; 8:40 am]
BILLING CODE 8350–01–M

VETERANS ADMINISTRATION

Agency Forms Under OMB Review

AGENCY: Veterans Administration.

ACTION: Notice.

The Veterans Administration has submitted to OMB for review the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document contains extensions, a revision and a new collection and lists the following information: (1) The Department or Staff Office issuing the form; (2) The title of the form; (3) The agency form number, if applicable; (4) How often the form must be filled out; (5) Who will be required or asked to report; (6) An estimate of the number of responses; (7) An estimate of the total number of hours needed to fill out the form; and (8) An indication of whether section 3504(h) of Pub. L. 96–511 applies.

ADDRESSES: Copies of the forms and supporting documents may be obtained from Patricia Viers, Agency Clearance Officer (732), Veterans Administration, 810 Vermont Avenue NW., Washington, DC 20420, (202) 389–2146. Comments and questions about the item on this list should be directed to the VA’s OMB Desk Officer, Dick Eisinger, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503, (202) 395–7318.

DATES: Comments on the information collections should be directed to the OMB Desk Officer within 60 days of this notice.


By direction of the Administrator.

Dominick Onorato, Associate Deputy Administrator for Information Resources Management.

Revision

1. Department of Veterans Benefits
2. Loan Service Report
3. VA Form 26–6608
4. On occasion
5. Individuals or Households
6. 55,000 responses
7. 27,500 hours
8. Not applicable

Extensions

1. Department of Veterans Benefits
Privacy Act of 1974: Amendment of System Notice

Notice is hereby given that the Veterans Administration is revising certain paragraphs and is considering the addition of two new routine use statements in the system of records entitled: Veteran, Patient, Employee, and Volunteer Research and Development Project Records—VA (34VA11) as set forth on page 677 of the Federal Register publication, Privacy Act Issuances, 1980 Compilation, Volume V, and amended on page 43244 of the Federal Register of September 30, 1982. The paragraphs being revised are: System Location, Safeguards, and Retention and Disposal. These revisions are necessary to include contractors who operate systems of records subject to the Privacy Act when conducting research studies for the Veterans Administration. Routine use statements numbered 5 and 6 are being added to provide for the release of information to research facilities or Federal agencies and their contractors so that research studies can be conducted under Agency contract.

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposed system of records to the Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue NW., Washington, D.C. 21420. All written comments received will be available for public inspection at the above address only between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays) until Oct. 29, 1984. If no public comment is received during the 30-day review period allowed for public comment or unless otherwise published in the Federal Register by the Veterans Administration, the proposed routine use statement is effective October 15, 1984.

Everett Alvarez, Jr.,
Deputy Administrator.

Notice of System of Records

In the system identified as 34VA11, "Veteran, Patient, Employee, and Volunteer Research and Development Project Records—VA", appearing at page 677 of the "Privacy Act Issuances, 1980 Compilation, Volume V", and 47 FR 43244 is revised as follows:

SYSTEM NAME:
Veteran, Patient, Employee, and Volunteer Research and Development Project Records—VA.

SYSTEM LOCATION:
Records are maintained at each VA health care facility where the research project was conducted and at VA Central Office. Address locations are listed in VA Appendix 1 at the end of this document. In addition, records are maintained at contractor and field work sites as studies are developed, data collected and reports written. A list of locations where individually identifiable data are currently located is available from the System Manager.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:
Title 38, United States Code, Chapter 73, Section 4101(a).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

5. Disclosure of medical record data, excluding name and address (unless name and address is furnished by the requester) for research purposes determined to be necessary and proper, to epidemiological and other research facilities approved by the Chief Medical Director.

6. In order to conduct Federal research necessary to accomplish a statutory purpose of an agency, at the written request of the head of the agency, or designee of the head of that agency, the name(s) and address(es) of present or former personnel of the Armed Services and/or their dependents may be disclosed (a) to a Federal department or agency or (b) directly to a contractor of a Federal department or agency. When a disclosure of this information is to be made directly to the contractor, the VA may impose applicable conditions on the department, agency and/or contractor to insure the appropriateness of the disclosure to the contractor.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

SAFEGUARDS:
Physical Security: Access to VA working space and medical record storage areas is restricted to VA
employees on a "need to know" basis. Generally, VA file areas are locked after normal duty hours and protected from outside access by the Federal protective Service. Employee file records and file records of public figures or otherwise sensitive medical record files are stored in separate locked files. Strict control measures are enforced to ensure that disclosure is limited to a "need to know" basis. Access to a contractor's records and their system of computers used with the particular project are available to authorized personnel only. Records on investigators stored on automated storage media are accessible by authorized VACO personnel via terminals which are dedicated to this research and development information system.

RETENTION AND DISPOSAL:
The project records are held five (5) years after completion of the research project and/or publication of a final report unless they become part of the patient's individual medical history file in which case the record would remain 15 years after the last activity of care. At the end of a study, records maintained by a contractor are returned to the VA for appropriate disposition.

[FR Doc. 84-24376 Filed 9-13-84; 8:45 am] BILLING CODE 8320-01-M
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).

CONTENTS

Federal Maritime Commission

1

National Foundation on the Arts and the Humanities

2

1

FEDERAL MARITIME COMMISSION

TIME AND DATE: 9:00 a.m.—September 19, 1984.

PLACE: Hearing Room One—1100 L Street, NW., Washington, D.C. 20573.

STATUS: Closed.

MATTERS TO BE CONSIDERED:


2. Agreement No. 207-010137-008: Modification of the Barber Blue Sea Line Joint Service to enlarge its scope.


CONTACT PERSON FOR MORE INFORMATION:

Francis C. Hurney, Secretary, (202) 523-5725.

Francis C. Hurney, Secretary.

The proposed meetings 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. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (3) information the disclosure of which would significantly frustrate implementation of proposed agency action; 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 these meetings will be closed to the public to subsections (c) (4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information about these meetings can be obtained from Mr. Stephen J. McCleary, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, D.C. 20506, or call (202) 786-0322.

Stephen J. McCleary, Advisory Committee Management Officer.
Part II

Architectural and Transportation Barriers Compliance Board

Advisory Standards for Chairs Used Primarily for Enplaning and Deplaning Physically Handicapped Passengers: Invitation for Public Comment
ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Advisory Standards for Chairs Used Primarily for Enplaning and Deplaning Physically Handicapped Passengers

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Invitation for public comment on the development of advisory standards.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (ATBCB or the Board) invites public comment on a proposal to develop advisory standards for chairs (i.e., aircraft boarding chairs) to be used primarily for the safe enplaning and deplaning of physically handicapped passengers. The ATBCB has received a number of reports of accidents and near-accidents involving the use of these chairs. The purpose of this invitation is to (1) investigate the nature and extent of the problems with such chairs; (2) prepare plans and proposals for actions that could be used by various parties, including, for example, air carriers, insurance providers, airport managers, and Federal, State and local governments; and (3) develop standards and provide technical assistance to public or private entities. Section A of the Supplementary Information describes the principal statutes under which the Board is issuing this invitation; Section B describes the boarding chairs and some of the reported problems; Section C asks a series of questions to elicit information on boarding chairs in four categories: Part (1) Problem Identification, Part (2) Specifications, Part (3) Procedural Issues, Part (4) Demographics; and Section D seeks information on other barriers encountered by disabled air travelers and possible solutions.

DATE: To be assured of consideration, comments must be in writing and must be postmarked on or before November 13, 1984.

ADDRESS: Comments should be sent to: Docket Trans-184, 330 C Street, SW., Room 1010, Mail Stop 2101 Washington, D.C. 20202. Comments received will be available for public inspection, Monday through Friday, from 9:00 a.m. to 5:00 p.m., except legal holidays.

FOR FURTHER INFORMATION CONTACT: For information concerning technical issues concerning this proposal, contact Mr. Dennis Cannon, Office of Technical Services, (202) 472-2700 (voice or TDD). Information on legal questions should be addressed to Ms. Linda Potter, Office of the General Counsel (202) 245-1901 (voice or TDD). These are not toll free numbers.

For additional copies of the proposal, contact Ms. Michelle Henson, Office of Technical Services, Room 1010, Mail Stop 2101 330 C Street, SW., Washington, D.C. 20202: (202) 472-2700 (voice or TDD). Copies of the proposal are also available on tape for those with visual impairments. Tapes may be obtained at the above address or by contacting Ms. Henson.

SUPPLEMENTARY INFORMATION:

A. Background

Under section 502 of the Rehabilitation Act of 1973, as amended, the Architectural and Transportation Barriers Compliance Board (ATBCB) is vested with various statutory functions relating to transportation barriers confronting persons with disability (29 U.S.C. (792)). First, the Board is directed to investigate and examine alternative approaches to transportation barriers, particularly with respect to public transportation (including air, water, and surface transportation whether interstate, foreign, intrastate, or local), and to determine what measures are being taken by Federal, State, and local governments and public and private agencies to eliminate such barriers. (Id. at 792(b)(2) and (3)). The Board is also required to “prepare plans and proposals for . . . actions as may be necessary to the goals of adequate transportation . . . for handicapped individuals, including proposals for bringing together in cooperative effort, agencies, organizations, and groups working toward such goals or whose cooperation is essential to effective and comprehensive action” (id. at 792(c)(3)).

The Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95-502) amended section 502 to provide the ATBCB with new functions regarding transportation barriers. Under the Amendments, the Board is required to “insure that public conveyances, including rolling stock, are readily accessible to, and usable by physically handicapped persons. (29 U.S.C. at 792(b)(6)).

The Amendments also require the Board, in cooperation and consultation with other concerned agencies, to “develop standards and provide appropriate technical assistance to any public or private activity, person or entity affected by regulations prescribed pursuant to this title [Title V of the Rehabilitation Act] with respect to overcoming . . . transportation . . . barriers” (id. at 792(d)(3)).

Clearly, ensuring that transportation (including air transportation) for persons with disabilities is accessible is a prime duty of the Board. The Board has reason to believe that current practices and standards regarding the use of aircraft boarding chairs for enplaning and deplaning disabled passengers are inadequate and unsafe. In fact, the Board has received a number of reports of accidents or near-accidents involving the use of these chairs.

As a result, the Board is concerned with the lack of standards in current regulations—standards that would ensure adequate safety features, equipment and procedures necessary to secure the safe enplaning and deplaning of physically handicapped passengers by airport operators and airline carriers. To carry out its responsibilities under section 502 to investigate barriers to air travel encountered by disabled persons, the Board is issuing this invitation to comment to collect information on the nature and extent of problems in enplaning and deplaning. Some of the problems may be addressed by specific design features to be incorporated in future equipment, while other problems may be addressed by recommending non-structural procedural changes for other agencies to consider in their rulemaking. Specifications which may be developed as a result of this inquiry could be used by airlines to prepare bid specifications for purchases of chairs. They could also be used by insurance providers to determine liability coverage needed or to assist them in implementing regulations issued by Federal, State, or local agencies.

Information on non-structural procedural matters could be used to prepare reports on barriers to air travel for the President and Congress. In addition, information obtained by this inquiry may be used by other Federal agencies and by the Board's Transportation Committee to identify problems and potential solutions.

With respect to specific design features, the Board is considering developing non-binding standards in consultation and coordination with a number of concerned agencies. These standards would be used to provide technical assistance to public and private entities to ensure the safe enplaning and deplaning of disabled passengers. In addition, they could supplement existing binding regulations in this area. For instance, in enforcing the requirement that enplaning and deplaning assistance be provided using aircraft boarding chairs, if necessary [14}
CFR 382.15(a)(2), an agency could utilize the non-binding standard to show whether the chair used met the requirement of providing boarding assistance. The standard would also be offered to Federal, State or local governments to be adopted as requirements in their regulations or codes. It should be noted that these standards would be only advisory unless adopted as mandatory by other agencies. Also, they would be separate from the Board's “Minimum Guidelines and Requirements for Accessible Design” (39 CFR Part 1190) and the standards prescribed pursuant to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157).

B. Chairs Used Primarily for Enplaning and Deplaning

In many airports, aircraft boarding chairs (often called “aisle chairs” although this term is sometimes used to mean an on-board wheelchair) are used for passengers requiring assistance in enplaning and deplaning. The type of equipment most commonly used is a narrow, high-back seat without arm rests on a wheeled, tubular frame. Similar to a dolly, it usually has two wheels, located at the rear, which are about eight inches in diameter, on which the frame must be tilted back to move the chair and passenger. The wheels usually have no locks (i.e., devices to keep the wheels from turning, popularly but incorrectly referred to as brakes) and, in the upright position, the chair depends on the contact of the footplate with the floor to prevent movement. Lap belts, shoulder harnesses, or leg belts may be provided but are frequently missing or broken. The width of the chair is approximately 16 inches so as to be compatible with typical aircraft aisles. The tubular frame and the footplate are specifically designed to allow the chair with passenger to be carried up or down stairs by two people or be wheeled by an assistant down a narrow aisle. The boarding chairs are also used, at times, for transporting disabled passengers between gates at the airport when a transfer to another plane is necessary.

The Architectural and Transportation Barriers Compliance Board has received a number of reports of accidents and near accidents involving boarding chairs during the enplaning and deplaning of disabled passengers on commercial airlines. Passengers using this equipment complain of the chairs' instability resulting from its high narrow design, the absence or inadequacy of restraining belts, and the lack of personnel trained specifically to assist passengers with physical limitations. In addition to safety concerns, passengers required to use these chairs complain of physical discomfort and the indignity which results from the use of the most common chairs. Depending on the chair design, some airlines also use the same narrow chair for movement within the airport. When this is the case, complaints are also registered about the boarding chair because it does not permit independent mobility; that is, a specially trained person must always accompany a boarding chair user. This may preclude the use of airport restroom facilities since the assistant is not always the same sex as the passenger. While the ATBCB’s review of the equipment used for assisting passengers has shown that aircraft boarding chairs which have safety features are available on the market, it has not been able to identify any regulation which would require airport and airline operators to use such chairs. To assist the ATBCB in carrying out its review, the Board has established a working group composed of representatives from the Department of Transportation, including the Federal Aviation Administration, the Civil Aeronautics Board and other Federal agencies to assist the ATBCB in reviewing existing regulations and to develop recommendations to ensure the safety of passengers with disabilities. Preliminary information suggests that some of the problems will not be solved by equipment design changes alone and solutions for those problems would not be appropriately included in a specification. Therefore, in addition to the equipment issues which are the main focus of this inquiry, some of the information obtained from the public in response to this inquiry may be used by the ATBCB Transportation Committee and this working group in making recommendations to the Board or other agencies on appropriate means to improve such equipment and/or procedures.

Since responses to different parts of this inquiry may be forwarded to different agencies, there may be some duplication in questions.


By vote of the Board.

Mary Alice Ford,
Chairperson, Architectural and Transportation Barriers Compliance Board.
C. Questions.

The following questions are divided into four parts representing the distinct areas of inquiry covered by this Invitation to Comment. Respondents may answer only the part(s) which concern them since each part will be analyzed separately and may be forwarded to different agencies for implementation. In addition, it is possible that some of the information can be supplied only by air carriers, engineers, or airport operators.

Answers may be provided directly on the invitation to comment; however, if additional space is needed to answer a question, please do not hesitate to include additional sheets of paper. Please number your answers to correspond to the questions in each part.

Part 1. Problem Identification. While the ATBCB has received some reports of problems, including from our own Board members, and has reviewed complaints made to the CAB, we are by no means certain of the magnitude of the problem. The Board, therefore, seeks information to highlight additional problem areas not already identified by the Board. Questions in this part are intended to clarify problems encountered by disabled air travelers and to highlight important areas of concern. Answers will assist the Board in assessing the priority to be placed on various components of advisory standards which the Board may develop. This information may also be useful to other agencies for areas to be addressed in their own regulation.

Based on your own experience or direct knowledge, please answer the following questions.

1.1. With respect to boarding chairs, what problems have been experienced by disabled travelers? Which of these problems have you experienced?

1.2. How often do each of these problems arise? How often has particular problem happened to you? Please indicate the nature of the problem and the number of times that you have experienced a particular problem and/or the number of times that you have knowledge of a particular problem occurring.
1.3. With respect to each of the problems identified above, please describe the cause of the problem. For example, was it caused by chair design flaws? Airline or airport personnel? Combination? Other?

1.4. Could these problems be corrected by adequate personnel training? If so, who should be trained?

1.5. Were the problems a result of failure to properly maintain equipment? If so, please describe the type of problem.

Part 2. Specifications. Some of the problems encountered during enplaning and deplaning appear to be a result of the design of the most commonly used chairs. Questions in this part relate to actual design features that might be incorporated in an ideal chair. Answers from this part may be used by the ATBCB to develop a model specification which could be used by the airline industry in preparing specifications for bid, the insurance industry to determine insurance coverage, or by local, State or other Federal agencies as part of their own binding regulations.

2.1. Type of Specification. Specifications can generally be grouped into two categories: performance and prescriptive. Performance standards specify the functions a device must perform without specifying the manner. Prescriptive standards, on the other hand, specify a particular design feature or additional equipment to be added to the device.
performance standard for a boarding chair might be that it be designed to be capable of maintaining a 98th percentile quadraplegic in an upright seated position. A prescriptive specification might call for armrests, lap, and shoulder harnesses. To be useful, a performance specification may need to prescribe a test to be passed to determine whether a particular design meets the criterion. Such a test might be that a 98th percentile anthropomorphic dummy be retained when the chair is tipped sideways at a 30° angle (or some other appropriate angle). Alternatively, a combination of the two can be used, such as requiring lap and shoulder belts and/or that a dummy be retained at a prescribed angle (the "and/or" means that lap belts can be provided which also pass the test, or some other method which passes the test, but not merely providing lap belts).

2.1.1. Should the ATBCB develop advisory standards for boarding chairs?

2.1.2. If so, should the ATBCB develop performance standards or prescriptive (specific design) standards? Combination? Please describe.

2.1.3. If the standards should be performance, what specific requirements should be included?

2.1.4. What tests, if any, should be performed?

2.1.5. Who should perform the tests? Manufacturer? Air Carrier? Independent testing laboratory? Other (specify)?

2.2. Independent Mobility. The standard manual wheelchair has two large wheels with handrims for self-propulsion. To be usable, such wheels must come above the seat level and the seat must fit between the two wheels. In order for such a chair to fit down the narrow aisle (approximately 16 inches) of a typical airplane, the seat would be extremely narrow and probably unusable. To provide for the maximum boarding chair seat width, consistent with
the narrow aisle, chair designers have used only small wheels placed below the seat, thus sacrificing independent mobility. This is generally only a problem if the chair is used outside the aircraft or for maneuvering in the lavatory. Some recent designs of travel chairs have both standard large rear wheels and four small casters. The large wheels, which allow independent mobility outside the aircraft, can be quickly and easily removed to allow the chair to traverse narrow aisles. The disadvantage is that the separate wheels could be damaged or misplaced when not attached to the chair. In the narrow aisle configuration, the chair can be moved by many disabled people by grasping stationary objects, such as lavatory grab bars, and pulling or pushing oneself along. Even this procedure is not possible with the most common boarding chair since it has only two wheels and must be tipped back to roll.

2.2.1. Should a standard for an aircraft boarding chair allow a user to propel and maneuver the equipment without assistance?

If this same chair is used as a circulation chair for transporting passengers within the terminal, then is independent mobility needed?

On board the aircraft?

2.2.2. If so, can this be accomplished without large wheels with handrim?

2.2.3. If large wheels with handrim are used, how can the chair be made narrow enough to traverse the aisle?

2.2.4. If large wheels are to be removed, how can they be kept with the chair to avoid damage or misplacement?

2.2.5. Should boarding chairs be rollable without having to be tipped back?
2.3. Safety. In addition to complaints about inadequate seat belts and harnesses, some disabled individuals complain of the lack of armrests. This contributes to the feeling of insecurity associated with the narrow, highback design which makes the chair inherently unstable. Some experimental chairs have been designed with outriggers which provide stability but can be folded for aisle passage. Another complaint involves the absence of wheel locks (often incorrectly called "brakes") to help prevent the chair from rolling. While even the most efficient wheel locks cannot prevent the chair from moving, especially on a smooth floor, they can contribute significantly to steadying the chair while a disabled person transfers from his/her chair to the boarding chair.

2.3.1. Should a boarding chair be required to have lap, shoulder, and leg harnesses?

How should they be attached?

Should the user be able to operate them unassisted?

Would a performance specification be better? (If so, what should it be?)

2.3.2. Should a boarding chair be required to have armrests? Why?

2.3.3. Should wheel locks be prescribed? Why?

2.3.4. Should the chair be required to be as stable (from sideways tipping) as a standard wheelchair?

What should the standard be?

How should it be measured? How should it be accomplished?

2.4. Single Design. There are actually three classes of wheelchairs which may be used by a disabled person traveling by air: In addition to the chairs used for enplaning and
deplaning passengers (i.e., boarding chairs) described above, there are airport circulation chairs and an on-board wheelchairs. The airport circulation chair is frequently a "standard" adult size wheelchair. Because they are intended to accommodate the entire spectrum of disabled passengers they rarely fit any one individual and are often described as uncomfortable. They may also have been modified to prevent folding to make unauthorized removal from the airport more difficult. The on-board wheelchair has been specifically designed for circulation within the aircraft, especially to the restroom. Particular attention has been given to weight and foldability due to stowage requirements. Such requirements are not necessarily relevant to enplaning/deplaning chairs or airport circulation chairs. Most on-board wheelchairs could be used for enplaning and deplaning but there is a reluctance to take such chairs far from the aircraft where they are to be kept.

2.4.1. Can one chair design be used for all three functions?

2.4.2. If so, should a single design be used?

2.4.3. If so, how should the problem of independent mobility in the airport be addressed?

2.4.4. What design features should be incorporated to prevent unauthorized removal? Will these features compromise the utility of the chair?

2.4.5. Are there characteristics unique to one or more classes of chairs that makes a single design impractical?

2.5. Seating. For easy transfer, the seat of the chair used for enplaning/deplaning physically handicapped passengers should be compatible with airport circulation chairs, on-board wheelchairs, aircraft seating, and personal wheelchair seats.

2.5.1. What should the seat height be?
2.5.2. Should the seat be padded?

With a specific thickness? (How thick?) Is specific padding needed only if this same chair is used as an airport circulation chair?

2.5.3. Should the chairs be provided with folding armrests for easy transfer?

Sliding seat panels to create a "bridge" between boarding chair and wheelchair or aircraft seat for easy transfer?

2.6. Scope. The Board is aware that some of the problems result from the apparent failure to have a sufficient number of boarding chairs or to provide the equipment in a reasonable time. Where mobile lounges (vehicles which transport passengers from aircraft parked at maintenance facilities to terminals) are used, it is necessary to have the chair on board the lounge before it leaves the terminal. Disabled travelers have reported that, in spite of advance notice, such chairs are not always available. On other occasions, chairs are not provided even when the pilot has been asked to "radio ahead".

2.6.1. Should a boarding chair be kept at each gate or jetway?

2.6.2. Should a boarding chair be kept on each mobile lounge?

2.6.3. Should a boarding chair be kept at some measurable distance from each gate or jetway? If so, what should that distance be?

2.6.4. Should a maximum time be established between gate arrival of the aircraft and availability of the boarding chair? If so, what should it be?
2.7. Boarding Chairs: Other Concerns. In addition to the above mentioned questions, are there other issues which should be addressed in this advisory standard for boarding chairs?

Part 3. Procedural Issues. Even if the ATBCB develops an advisory specification for the chair, resolution of the problems may also depend on the adequacy of the training received by chair users, airport and airline personnel and the extent to which the chair is maintained in proper working order. While these procedural issues are beyond the scope of an advisory standard which may be developed by the ATBCB, information about such problems may assist the Board in weighing the relative importance of various design features. Moreover, this information may be of value to the airline industry by highlighting particular problem areas which the industry may need to address by developing better training and maintenance programs. In addition, the answers to questions in this part may be useful to other Federal agencies, such as the Department of Transportation, in developing their own regulations in this area. In order for the industry and other agencies to properly address this subject, information on existing programs and indentified problems is needed.

3.1. Training. Some of the problems with current boarding chairs appear to result from inadequate training or failure to train the appropriate personnel. Some supervisory personnel have been reported to have "recruited" the nearest able bodied person rather than anyone with specific training. It is also not always clear whether the assisting personnel are airline or airport employees. In addition, a new type of chair may necessitate specific training.

3.1.1. Is specific training necessary to assist in enplaning and deplaning?

3.1.2. What training programs are currently used? Which personnel are being trained?

3.1.3. Who currently provides boarding assistance and who currently provides the training?
3.1.4. What type of training should be provided and to which airport and airline personnel?

3.1.5. What retraining schedule is used? How is the need for retraining determined?

3.1.6. Can elements from existing programs be combined to form a model?

3.2. Maintenance. Some of the problems seem to have been caused by a failure to maintain equipment in proper working order.

3.2.1. What maintenance practices are currently followed? On what schedule?

3.2.2. Are there specific maintenance standards for boarding chairs or similar equipment?

3.2.3. Who currently performs maintenance? Airport personnel? Airline personnel? Other?

3.2.4. Is the maintenance program verified? If so, who is responsible? If not, who should be?
Airport?

Air carrier?

3.2.5. Does the manufacturer supply a suggested maintenance schedule?

If so, is the schedule adequate?

Part 4. Demographics. Answers to the questions in this part will be used for statistical purposes only to help develop a profile for reports to the Board and other Federal agencies. Supplying this information is optional and failure to do so will not in any way affect the validity of responses to other questions. Please include this sheet or a reasonable facsimile with your comments. (Check all answers that apply).

4.1. Which of the following categories apply to you?

4.1.1. Wheelchair user.

4.1.2. Walker, crutch, other mobility aid user.

4.1.3. Visually impaired.

4.1.4. Hearing impaired.

4.1.5. Able-bodied.

4.1.6. Other (specify) __________

4.2. If you have a disability, what type of aids do you use primarily?


4.2.2. Power wheelchair (except three-wheeled) with gel or dry cell battery.

4.2.3. Power wheelchair (except three-wheeled) with wet cell battery.

4.2.4. Three-wheeled power chair with gel or dry cell battery.

4.2.5. Three-wheeled power chair with wet cell battery.
4.2.6. Walker, cane or other mobility aid.
4.2.7. Crutches.
4.2.8. Hearing-ear or helping dog.
4.2.9. White cane (visually impaired).
4.2.10. Dog guide. (visually impaired)
4.2.11. Hearing aid.
4.2.12. Other (specify) _______________________________________

4.3. Are the comments submitted on behalf of an organization or as an individual?
4.3.1. Officially. (Please name organization or agency.)
4.3.2. For myself.

4.4. Are you a member of, or employed by, any of the following organizations, companies, or agencies?
4.4.1. Consumer organization.
4.4.2. Social service agency.
4.4.3. Air carrier.
4.4.4. Airport operator.
4.4.5. Air carrier trade association.
4.4.6. Airport operator trade association.
4.4.7. Manufacturer/supplier of mobility aids.
4.4.8. Engineer/designer
4.4.10. State or local government.
4.4.11. Manufacturer/supplier of aircraft or related equipment.
4.4.12. Rehabilitation professional.
4.4.13. Airline personnel labor or professional organization.
4.4.14. Other (specify) ______________________________________
4.5. On the average, how frequently do you travel by air?

4.5.1. Less than once a year.
4.5.2. From one time to five times a year.
4.5.3. Five to ten times a year.
4.5.4. More than ten times a year.

4.6. Have you ever used a boarding chair? If so, which type?

4.6.1. High-back dolly, (standard chair described previously)
4.6.2. Amigo Escort.
4.6.3. Manten Airport Buggy.
4.6.4. Whilshire.
4.6.5. Newton.
4.6.6. Other (specify) ________________________________

4.7. Are you familiar with any of the following boarding chairs, even though you may never have used one?

4.7.1. High-back dolly (standard).
4.7.2. Amigo Escort.
4.7.3. Manten Airport Buggy.
4.7.4. Whilshire.
4.7.5. Newton.
4.7.6. Other (specify) ________________________________

D. Other Areas of Concern. Complaints filed both with the CAB and the ATBCB indicate that enplaning and deplaning is only one of several areas where barriers to air travel have been encountered by disabled persons. Other problems have resulted, for example, from the absence or inadequacy of lifting devices for boarding aircraft, the absence or inadequacy of provisions for oxygen, and problems with transporting electric wheelchairs with wet cell batteries. Should issues such as these and others be addressed by future ATBCB advisory rules? Please identify specific problems disabled travelers have encountered.
Part III

Department of Labor

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions; Notices
DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

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 on construction projects 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 5.1 (including the statutes listed at 36 FR 306 (1970) 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, 46 FR 19533 (1983) and of Secretary of Labor’s Orders 9–83, 48 FR 35736 (1983), and 6–84, 49 FR 32473 (1984). 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 the effective date as prescribed in that section, because the necessity to issue construction industry wage determinations 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 work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas Decisions to General Wage Determination Decisions

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued. The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 5.1 (including the statutes listed at 36 FR 306 (1970) 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, 46 FR 19533 (1983) and of Secretary of Labor’s Orders 9–83, 48 FR 35736 (1983), and 6–84, 49 FR 32473 (1984). 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 in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Office of Program Operations, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

Modification 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.

Arkansas:

- A R 84-4090
- A R 84-4091
- A R 84-4092
- A R 84-4093

California:

- CA 84-5001
- CA 84-5002

Illinois:

- IL 84-2207

Indiana:

- IN 84-4027
- IN 84-4028

Michigan:

- MI 84-4029

New Mexico:

- NM 84-4030

Nevada:

- NV 84-5017

Pennsylvania:

- PA 84-3047
- PA 84-3048

Tennessee:

- TN 84-1223

Texas:

- TX 84-4039
- TX 84-4040

Wisconsin:

- WI 84-5005

Supersedeas Decisions to General Wage Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the Federal Register are listed with each State. Supersedeas decision numbers are in parentheses following the number of the decisions being superseded.

Missouri:

- MO 84-4014 (MO 84-4054)

New York:

- NY 83-3003 (NY 83-3006)

Signed at Washington, D.C. this 7th day of September 1984.

James L. Vail, Assistant Administrator.

BILLING CODE 4510-27-M
<table>
<thead>
<tr>
<th>DECISION NO. AR84-4091-MOD. #5</th>
<th>DECISION NO. AR84-4092-MOD. #7</th>
<th>DECISION NO. AR84-4093-MOD. #6</th>
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</table>

**FOOTNOTE:**

A- 3-3/4% + 1.00

**DECISION NO. AR84-4094-MOD. #7**

| **GROUP 1** | **GROUP 1** |
| **LABORERS** | **LABORERS** |
| **$6.41** | **$6.41** |
| **$1.45** | **$1.45** |
| **GROUP 2** | **GROUP 2** |
| **$6.66** | **$6.66** |
| **$1.45** | **$1.45** |
| **GROUP 3** | **GROUP 3** |
| **$6.81** | **$6.81** |
| **$1.45** | **$1.45** |
| **GROUP 4** | **GROUP 4** |
| **$6.91** | **$6.91** |
| **$1.45** | **$1.45** |
| **GROUP 5** | **GROUP 5** |
| **$7.06** | **$7.06** |
| **$1.45** | **$1.45** |
| **GROUP 6** | **GROUP 6** |
| **$7.31** | **$7.31** |
| **$1.45** | **$1.45** |
| **GROUP 7** | **GROUP 7** |
| **$7.21** | **$7.21** |
| **$1.45** | **$1.45** |

**LINE CONSTRUCTION:**

| **Electrical contracts** | **Electrical contracts** |
| **$20,000 or less** | **$20,000 or less** |
| **$14.71** | **$14.71** |
| **GROUP 1** | **GROUP 1** |
| **$6.41** | **$6.41** |
| **$1.45** | **$1.45** |
| **Group 2** | **Group 2** |
| **$6.66** | **$6.66** |
| **$1.45** | **$1.45** |
| **Group 3** | **Group 3** |
| **$6.81** | **$6.81** |
| **$1.45** | **$1.45** |
| **Group 4** | **Group 4** |
| **$6.91** | **$6.91** |
| **$1.45** | **$1.45** |
| **Group 5** | **Group 5** |
| **$7.06** | **$7.06** |
| **$1.45** | **$1.45** |
| **Group 6** | **Group 6** |
| **$7.31** | **$7.31** |
| **$1.45** | **$1.45** |
| **Group 7** | **Group 7** |
| **$7.21** | **$7.21** |
| **$1.45** | **$1.45** |

**FOOTNOTE:**

A- 3-3/4% + 1.00

**DECISION NO. AR84-4095-MOD. #8**

**LINE CONSTRUCTION:**

| **Steel Workers** | **Steel Workers** |
| **$20,000 or less** | **$20,000 or less** |
| **$14.71** | **$14.71** |
| **GROUP 1** | **GROUP 1** |
| **$6.41** | **$6.41** |
| **$1.45** | **$1.45** |
| **Group 2** | **Group 2** |
| **$6.66** | **$6.66** |
| **$1.45** | **$1.45** |
| **Group 3** | **Group 3** |
| **$6.81** | **$6.81** |
| **$1.45** | **$1.45** |
| **Group 4** | **Group 4** |
| **$6.91** | **$6.91** |
| **$1.45** | **$1.45** |
| **Group 5** | **Group 5** |
| **$7.06** | **$7.06** |
| **$1.45** | **$1.45** |
| **Group 6** | **Group 6** |
| **$7.31** | **$7.31** |
| **$1.45** | **$1.45** |
| **Group 7** | **Group 7** |
| **$7.21** | **$7.21** |
| **$1.45** | **$1.45** |

**FOOTNOTE:**

A- 3-3/4% + 1.00

**POWER EQUIPMENT OPERATORS:**

| **Steel Equipment** | **Steel Equipment** |
| **$20,000 or less** | **$20,000 or less** |
| **$14.71** | **$14.71** |
| **GROUP 1** | **GROUP 1** |
| **$6.41** | **$6.41** |
| **$1.45** | **$1.45** |
| **Group 2** | **Group 2** |
| **$6.66** | **$6.66** |
| **$1.45** | **$1.45** |
| **Group 3** | **Group 3** |
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| **Group 5** | **Group 5** |
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| **Group 7** | **Group 7** |
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| **$1.45** | **$1.45** |

**FOOTNOTE:**

A- 3-3/4% + 1.00

**POWER EQUIPMENT OPERATORS:**

| **Steel Equipment** | **Steel Equipment** |
| **$20,000 or less** | **$20,000 or less** |
| **$14.71** | **$14.71** |
| **GROUP 1** | **GROUP 1** |
| **$6.41** | **$6.41** |
| **$1.45** | **$1.45** |
| **Group 2** | **Group 2** |
| **$6.66** | **$6.66** |
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| **Group 3** | **Group 3** |
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| **$1.45** | **$1.45** |
| **Group 4** | **Group 4** |
| **$6.91** | **$6.91** |
| **$1.45** | **$1.45** |
| **Group 5** | **Group 5** |
| **$7.06** | **$7.06** |
| **$1.45** | **$1.45** |
| **Group 6** | **Group 6** |
| **$7.31** | **$7.31** |
| **$1.45** | **$1.45** |
| **Group 7** | **Group 7** |
| **$7.21** | **$7.21** |
| **$1.45** | **$1.45** |
### DECISION NO. CA84-5001

<table>
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<th>MODIFICATIONS P. 3</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
<th>MODIFICATIONS P. 4</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
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<tr>
<td><strong>BRICKLAYERS:</strong></td>
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<tr>
<td>Area 3</td>
<td>$16.34 4.91</td>
<td>3%</td>
<td><strong>Group 1:</strong></td>
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<tr>
<td>Area 4</td>
<td>$16.34 4.91</td>
<td>3%</td>
<td>Truck Drivers:</td>
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<tr>
<td>Area 5</td>
<td>$17.54 5.45+</td>
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<td>Group 1</td>
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<tr>
<td>Area 7</td>
<td>$16.34 4.91</td>
<td>3%</td>
<td>Group 2</td>
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<td><strong>CARPENTERS:</strong></td>
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<td>Area 1:</td>
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<td>Carpenters</td>
<td>$20.77 6.455</td>
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<td>Hardwood Floorlayers, Shinglers, Power Saw Operators; Steel Scaffolding Erector and Steel Shoring Saw Filers; Millwrights; Pile drivers</td>
<td>$29.38 8.885</td>
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<td>Group 4</td>
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### DECISION NO. CA84-5001

<table>
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<tr>
<th>CONT'D</th>
<th>Basic Hourly Rates</th>
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<tr>
<td><strong>GLAZIERS:</strong></td>
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<tr>
<td>Area 5</td>
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<td>Area 6</td>
<td>$13.58 3.04</td>
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<td><strong>IRONWORKERS:</strong></td>
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<td>Fence Erector</td>
<td>$17.16 8.78</td>
<td>3%</td>
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<td>Reinforcing, Ornamental &amp; Structural</td>
<td>$18.05 8.78</td>
<td>3%</td>
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<td><strong>LINE CONSTRUCTION:</strong></td>
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<tr>
<td>Area 1: Groundmen</td>
<td>$18.87 5.45+</td>
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<tr>
<td>Line Equipment Operators</td>
<td>$27.64 5.45+</td>
<td>3%</td>
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<tr>
<td>Linemen</td>
<td>$25.16 5.45+</td>
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<tr>
<td>Cable Splicers</td>
<td>$27.16 5.45+</td>
<td>3%</td>
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<tr>
<td>Area 6: Groundmen</td>
<td>$14.17 6.30+</td>
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<tr>
<td>Linemen, Technicians, Equipment Operators</td>
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<td>Cable Splicers</td>
<td>$21.25 7.48+</td>
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<td><strong>Area 9:</strong> Groundmen &amp; Truck Drivers</td>
<td>$18.42 7.29+</td>
<td>3%</td>
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<td>Linemen</td>
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<td>Heavy Equipment Operators</td>
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<td><strong>Area 13:</strong> Groundmen</td>
<td>$22.07 7.26+</td>
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<tr>
<td>Linemen, Technicians</td>
<td>$25.95 7.26+</td>
<td>3%</td>
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<td>Cable Splicers</td>
<td>$29.21 7.26+</td>
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<td>PAINTERS</td>
<td>$19.27 3.53</td>
<td>3%</td>
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<td><strong>AREA 4:</strong> Brush</td>
<td>$21.08 4.12</td>
<td>3%</td>
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<tr>
<td>Tapers</td>
<td>$22.38 4.12</td>
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<td><strong>AREA 7:</strong> Brush</td>
<td>$20.43 4.68</td>
<td>3%</td>
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<tr>
<td>Spray; Sandblasting; Steam Cleaning</td>
<td>$20.91 4.68</td>
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<tr>
<td>Drywall Finisher</td>
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<tr>
<td>Paperhangers</td>
<td>$22.45 4.68</td>
<td>3%</td>
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**PAINTERS** (CONT'D)

| Area 10: Brush | $12.00 2.41 | 3% |
| Spray; Sandblasting; Structural Steel; Swing Stages; Stagers; Tapers; | $12.24 2.41 | 3% |
| Paperhangers | $17.92 8.25 | 3% |
| **PLASTERERS:**  |
| Area 5  |
| **MASTIC WORKERS:**  |
| Area 1: | $17.00 7.37 | 3% |
| **GROUP:** | $16.35 7.37 | 3% |
| Mastic Workers; Kettlemen (2 kettles w/o pumps) | $17.25 7.37 | 3% |
| Bitumastic; Enamellers; Pipewrapers; Coal Tar Build-up | $19.00 7.37 | 3% |
| **GROUP:** | $16.10 7.65 | 3% |
| Mastic Workers; Kettlemen (2 kettles w/o pumps) | $16.35 7.65 | 3% |
| Bitumastic; Enamellers; Pipewrapers; Coal Tar Build-up | $18.10 7.65 | 3% |
| **GROUP:** | $16.80 6.40 | 3% |
| Roofers | $16.80 6.40 | 3% |
| Mastic Workers; Kettlemen (2 kettles w/o pumps) | $17.05 6.40 | 3% |
| Bitumastic; Enamellers; Pipewrapers; Coal Tar Build-up | $18.80 6.40 | 3% |
| **GROUP:** | $26.36 6.76 | 3% |
| Sheet Metal Workers | $26.36 6.76 | 3% |
| **GROUP:** | $21.46 7.50 | 3% |
| Area 5 | $21.46 7.50 | 3% |
| **GROUP:** | $26.19 6.76 | 3% |
| Area 9 | $26.19 6.76 | 3% |
| **GROUP:** | $26.34 6.30 | 3% |
| Area 10 | $26.34 6.30 | 3% |
| **GROUP:** | $22.92 6.86 | 3% |
| Area 11 | $22.92 6.86 | 3% |
| **GROUP:** | $25.64 9.21 | 3% |
| Area 12 | $25.64 9.21 | 3% |

### DECISION NO. CA84-5001

| TILE SETTERS:  |
| Area 1 | $22.01 4.32 | 3% |
### DRILL BOATS:
- **Engineer**
- **Blaster**
- **Fireman**
- **Driller, Welder, Machinist**
- **Oiler**

### FLOATING EQUIPMENT
- **Engineer & Operator**
- **Equipment Operator**
- **Fireman**
- **Oiler**

### Projects less than $250,000:
- **Engineer & Operator**
- **Equipment Operator**
- **Fireman**
- **Oiler**

### Projects $250,000 or more:
- **Engineer & Operator**
- **Equipment Operator**
- **Fireman**
- **Oiler**

### DELETE:
- Footnotes e and f

### Change:
- **Power Equipment Ops.**
  - **General Building Const:**
    - **Group I:**
      - $11.08 + $1.95
    - **Group II:**
      - $12.22 + $1.95
    - **Group III:**
      - $12.30 + $1.95
    - **Group IV:**
      - $12.51 + $1.95
  - **Heavy Construction:**
    - **Group V:**
      - $12.57 + $1.95
    - **Group VI:**
      - $12.67 + $1.95
    - **Group VII:**
      - $12.77 + $1.95
    - **Group VIII:**
      - $13.95 + $1.95

### DECISION NO. TX84-4036 - MOD. #3
(49 FR 22189 - 5/25/84) Jefferson & Orange Cos., Texas

- **Boilermakers**
  - $16.125 + $2.95
- **Bricklayer & stonemason**
  - Refractory & acid-proofing work
    - $19.22 + $2.20
  - All other work
    - $17.58 + $2.20
  - Pipefitters
    - $17.94 + $2.20
### SUPERSEDES DECISION

STATE: NEW YORK  
COUNTY: CHENANGO  


DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including 4 stories), Heavy Construction (except water well drilling) and Highway Construction.

#### ASBESTOS WORKERS

<table>
<thead>
<tr>
<th>Basic Hourly Rate</th>
<th>Fringe Benefits</th>
</tr>
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<tbody>
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<td>18.21</td>
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#### BOILERSMAKERS

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<tr>
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#### BRICKLAYERS & STONE MASON WORKERS

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#### CEMENT MASON WORKERS

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#### ELEVATOR CONSTRUCTORS, BELLEMAKERS

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#### ELEVATOR CONSTRUCTORS, HELPS (PROBATIONARY)

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#### GLASSER

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#### IRONWORKERS

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#### LABORERS (HEAVY and HIGHWAY)

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### DECISION NO. NY84-3036

#### LINE CONSTRUCTION (CONT'D)

<table>
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<th>Basic Hourly Rate</th>
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<tr>
<td>16.38</td>
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</tr>
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</table>

#### LINE CONSTRUCTION:

- Substations and switching structures; Pipe type cable installation and maintenance jobs or projects; Railroad catenary installation and maintenance; Bonding of rails; Lineman; Technician

- Cable splicer

- Groundman digging machine operator; dynamite man

- Groundman truck driver (tractor trailer unit)

- Mobile equipment operator; groundman truck driver; mechanic

- Overhead transmission line work (where no other work is or has been involved); Overhead & underground distribution work; Lineman; Technician

- Groundman digging machine operator; groundman dynamite man

- Groundman truck driver (tractor trailer unit)

- Groundman mobile equipment operator; groundman truck driver; mechanic

- Groundman

### DECISION NO. NY84-3036

#### POWER EQUIPMENT OPERATORS (HEAVY AND HIGHWAY)

<table>
<thead>
<tr>
<th>Basic Hourly Rate</th>
<th>Fringe Benefits</th>
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<tbody>
<tr>
<td>19.61</td>
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</tbody>
</table>

#### Power equipment operators:

- Group 1
- Group II
- Group III
- Group IV

#### Power equipment operators:

- Boilermakers
- Bricklayers
- Ironworkers
- Elevator Constructors

#### Power equipment operators:

- Electricians
- Bricklayers
- Ironworkers
- Elevator Constructors

#### Power equipment operators:

- Electricians
- Bricklayers
- Ironworkers
- Elevator Constructors

#### Power equipment operators:

- Electricians
- Bricklayers
- Ironworkers
- Elevator Constructors

#### Power equipment operators:

- Electricians
- Bricklayers
- Ironworkers
- Elevator Constructors

#### Power equipment operators:

- Electricians
- Bricklayers
- Ironworkers
- Elevator Constructors

#### Power equipment operators:

- Electricians
- Bricklayers
- Ironworkers
- Elevator Constructors
Welders - Receive rate prescribed for craft performing operation to which welding is incidental.

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR 5.5(a)(1)(ii)).

FOOTNOTES:

Paid Holidays: A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

a. 6 paid holidays: A through F, provided employee works days before and day after the holiday.
b. 7 paid holidays: A through F, plus day after Thanksgiving.
c. Employer contributes 8% of basic hourly rate for 5 years or more of service or 6% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.
d. Paid Holidays: New Year's Day, Washington's Birthday, Good Friday, Decoration Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day and Election Day for the President of the United States and election day for the Governor of New York State, provided the employee works the day before or the day after the holiday.
e. 6 paid holidays: A through F, provided employee has worked 5 consecutive days before and the working day after the holiday.
f. Labor Day and Thanksgiving Day, provided the employee has worked the week prior to the holiday.
g. 6 paid holidays: A through F, provided the employee has worked any of the 5 working days immediately preceding or any of the 5 working days immediately following the holiday.
POWER EQUIPMENT OPERATORS: BUILDING CONSTRUCTION (CONT'D);

Class 2: "A" Frame truck; Blacktop plant (non-automatic); Boring machine; Bulldozer; Cage hoist; Carry-all scarper; Central mix plant (non-automated); Cherry picker five (5) tons and under; Compressor (500 c.f. and over); Concrete paver (single drum over 168); Concrete pump; Core boring machine; Drill rigs (tractor mounted); Elevators -- as a material hoist; Forklift (factory rating less than 15 ft.); Front end loader (under 4 cu. yds.); Gunnite machine; High pressure boiler (15 lbs. and over); Hoist (one drum); Hydraulic breaking hammer (Drop hammer); Kolman plant loader (screening gravel); Maintenance grease man; Mixer for stabilized base -- self-propelled (seaman mixer); Monorail machine; Parapet concrete or pavement grinder; post hole digger (truck or tractor mounted); Power sweeper (Wayne or similar); Pump 4" and over; Pump-crate or squeeze-crate; Road widener (front end of grader or self-propelled); Shell winder (motorized); Snorkel (overhead arms); Roller; Trenching machine (digging capacity of 4 ft. or less); Tugger hoist; Vibro tamp; Well drill; Well point system (submersible pumps when used in lieu of well-point system); Winch (motor driver); Winch cat; Winch truck

Class 3: Compressor (under 500 cu. ft.); Concrete paver or mixer (under 168); Concrete pavement spreaders and finishers (not automated); Conveyor (over 12 ft.); Electric submersible pump (4" and over); Farm tractor with or without accessories; Fine grade machine (not automated); Fireman; Form tamper; Generator (2,500 watts and over); Hydraulic pump; Grout pump; Mechanical heaters -- more than two (2) mechanical heaters or any mechanical heater or heaters whose combined output exceeds 600,000 BTU per hour (manufacturer's rating); Mulching machine; Oilier; Power driven welding machine -- 300 amp. and over (other than all electric); Power heat exchanger (hay dryer); Pump (under 4"); Revius widner (road widener); Steam cleaner or Jenny; Tractor with or without towed accessories, post driver (truck or tractor mounted)

Class 4: Quad 9 bulldozer or multibowl scarper

Class 5: Crane or Derrick with a boom length over 300 ft., including jib

Class 6: Crane or Derrick with a boom length over 150 ft., including jib, and on a piledriver with leads or boom length over 100 ft.

Class 7: Master mechanic
DECISION NO. NY84-3036

TRUCK DRIVERS (BUILDING Except Ready-mix):
Class 1: Truck drivers, parts chasers.
Class 2: Tractor Trailer drivers, farm tractor and fuel truck drivers.
Class 3: Material check and receiver.
Class 4: Euclid driver.

TRUCK DRIVERS (READY-MIX):
Class 1: Ready-mix driver.
Class 2: Truck driver.

TRUCK DRIVERS (HEAVY & HIGHWAY - Except Ready-mix):
Class 1: Warehouseman, yardmen, pickups, panel trucks, flatboy material trucks (straight jobs), single axle dump trucks, dupsters, material checkers and receivers, greasers, truck tiremen and parts chaser.
Class 2: Tandems, batch trucks, mechanics and dispatcher.
Class 3: Semi-trailers, low-boy trucks, asphalt distributors trucks, agitator, mixer trucks and dumpcrete type vehicles, truck mechanic.
Class 4: Specialized earth moving equipment - euclid type or similar off-highway equipment, where not self-loaded, and straddle (ross) carrier.
Class 5: Off-highway tandem back-dump, twin engine equipment and double hitched equipment where not self-loaded.

SUPERSEDES DECISION
STATE: Missouri COUNTY: Pulaski
DECISION NO.: MO84-4054 DATE: Date of Publication
Supersedes Decision No. MO84-4014 dated March 9, 1984 in 49 FR 9080.
DESCRIPTION OF WORK: Building Projects (excluding single family homes and apartments up to 4 stories)

<table>
<thead>
<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
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<tbody>
<tr>
<td>ASBESTOS WORKERS</td>
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<tr>
<td>BOILERMAKERS</td>
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<td>Plumbers laborers and mason tenders</td>
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<tr>
<td>Powderman</td>
<td>13.25</td>
<td>1.95</td>
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<tr>
<td>PAINTERS: Brush &amp; roller</td>
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<tr>
<td>Taping, paperhanging &amp; floor work</td>
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Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5(a)(1)(ii)).
DECISION NO.: MD84-4054

Power Equipment Operators

**Group I** - Backhoe; cableway; crane, crawler or truck; crane, hydraulic-truck or crane-mounted; 16 tons & over; crane locomotive; derrick, steam; derrick car & derrick boat; dragline; dredge; grader, crawler or tire mounted; locomotive, gas, steam & other powers; pile driver, land or floating; scoop, skimmer; shovel, power (steam, gas, electric, or other powers); switch boat; whizley.

**Group II** - air tugger/air compressor; anchor-placing barge; asphalt spreader; ashray force feeder loader (self-propelled); backfilling machine; boat operator-push boat or tow boat (jobsite); boiler, high pressure breaking in period; boom truck, placing or erecting; boring machine, footing foundation; bullfloat; cherry picker; combination concrete hoist & mixer (such as mixermobile); compressors, two, not more than 50 ft. apart; compressor (when operator runs throttle); compressor-generator combination, compressor-pump combination; generators, two 30 KW or over, or any number developing over 30 KW; generator-pump combination; compressor-welder combination; concrete breaker (truck or tractor mounted); concrete pump, such as pumpcrete machine; concrete spreader; conveyor, large (not self-propelled), hoisting or moving brick and concrete into, or into and on floor level, one or both; crane, hydraulic-rough terrain, self-propelled; crane hydraulic-truck or cruiser mounted-under 16 tons; drilling machine, self-powered, used for earth or rock drilling or boring (wagon drills and any hand drills obtaining power from other sources including concrete breakers, jackhammers and barco equipment; no engineer required); elevating grader; engineman, derrick; excavator or powerhaul machine finishing machine, self-propelled oscillating screed; forklift; grader, road with power blade; highlift; hoist; concrete and brick (brick cages or concrete skips operating in or on tower, towermobile, or similar equipment); hoist; stacky; hydromat; lad-a-vator, hoisting brick or concrete; loading machine (such as barber-green); mechanic, on job site; mixer, paving; mixer-mobile; mucking machine; pipe cleaning machine; pipe wrapping machine; plant, asphalt plant, concrete producing or ready-mix job site; plant heating-job site; plant mixing-job site; plant power, generating-job site; pumps, two self-powered over 2" through 6"; pumps, electric, eummersible, one through three, over 4"; quad-track; roller, asphalt, top or sub-grade; running metal, spreader box; sub-grader; tractor-crawler, or wheel type with or without power unit, power take-offs, and attachments regardless of size; trenching machine; tunnel boring machine; vibrating machine automatic, automatic proportioning, vibrating machines (gasoline or diesel) more than one but not over four (regardless of size); well drilling machine.

**Group III** - Conveyor, large (not self-propelled); conveyor, large (not self-propelled) moving brick and concrete (distributing) on floor level; mixer, with one mixer of one bag capacity or less, air tugger or plant air, boiler, for power or heating on construction projects; boiler, temporary; compressor, air-one; compressor air (mounted on truck; concrete saw, self-propelled-ditch finishing machine; ditch paving machine; elevator (building construction or alteration); endless chain hoist; form grade); generator, one over 30 KW or any number developing over 30 KW; grate; hoist, one drum regardless of size (except brick or concrete); lad-a-vator, other hoisting; manlift; mixer, asphalt, over 8 cu. ft. capacity, mixer, if two or more mixers of one bag capacity or less are used by one employer on job an operator is required; mixer, with outside loader, 2 bag capacity or more; mixer, with side loader, regardless of size, not pave; oiler on dredge; oiler on truck crane; pump mill operator; pump, sump-self-powered, automatic controlled over 2" during use in connection with construction work; sweeper, street; welding machine, one over 400 amp.; winch operating from truck; scissor lift (used for hoisting); liquor, small wheel type 50 h.p. & under with grader blade & similar equipment.

**Group III (a)** - Truck crane and derrick

**Group IV** - Boat operator-outboard motor (job site); conveyor (such as com-vay-sis) regardless of how used; oiler; sweeper, floor

**Group IV (a)** - Crawler type

**Group V (a)** - Air pressure, oiler engineer, operating under ten pounds

**Group V (b)** - Air pressure, oiler engineer operating over ten pounds

**Group V (c)** - Air pressure, oiler engineer operating under ten pounds

**Group V (d)** - Air pressure, oiler engineer operating over ten pounds

**Group V (e)** - Air pressure, oiler engineer operating over ten pounds

**Group V (f)** - Air pressure, oiler engineer operating over ten pounds

**Group V (g)** - Air pressure, oiler engineer operating over ten pounds

**Group V (h)** - Air pressure, oiler engineer operating over ten pounds

**Group V (i)** - Air pressure, oiler engineer operating over ten pounds

**Group V (j)** - Air pressure, oiler engineer operating over ten pounds

**Group V (k)** - Air pressure, oiler engineer operating over ten pounds

**Group V (l)** - Air pressure, oiler engineer operating over ten pounds

**Group V (m)** - Air pressure, oiler engineer operating over ten pounds

**Group V (n)** - Air pressure, oiler engineer operating over ten pounds

**Group V (o)** - Air pressure, oiler engineer operating over ten pounds

**Group V (p)** - Air pressure, oiler engineer operating over ten pounds

**Group V (q)** - Air pressure, oiler engineer operating over ten pounds

**Group V (r)** - Air pressure, oiler engineer operating over ten pounds

**Group V (s)** - Air pressure, oiler engineer operating over ten pounds

**Group V (t)** - Air pressure, oiler engineer operating over ten pounds

**Group V (u)** - Air pressure, oiler engineer operating over ten pounds

**Group V (v)** - Air pressure, oiler engineer operating over ten pounds

**Group V (w)** - Air pressure, oiler engineer operating over ten pounds

**Group V (x)** - Air pressure, oiler engineer operating over ten pounds

**Group V (y)** - Air pressure, oiler engineer operating over ten pounds

**Group V (z)** - Air pressure, oiler engineer operating over ten pounds

**Group V (aa)** - Air pressure, oiler engineer operating over ten pounds

**Group V (ab)** - Air pressure, oiler engineer operating over ten pounds

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**Group V (am)** - Air pressure, oiler engineer operating over ten pounds

**Group V (an)** - Air pressure, oiler engineer operating over ten pounds

**Group V (ao)** - Air pressure, oiler engineer operating over ten pounds

**Group V (ap)** - Air pressure, oiler engineer operating over ten pounds

**Group V (aq)** - Air pressure, oiler engineer operating over ten pounds

**Group V (ar)** - Air pressure, oiler engineer operating over ten pounds

**Group V (as)** - Air pressure, oiler engineer operating over ten pounds

**Group V (at)** - Air pressure, oiler engineer operating over ten pounds

**Group V (au)** - Air pressure, oiler engineer operating over ten pounds

**Group V (av)** - Air pressure, oiler engineer operating over ten pounds

**Group V (aw)** - Air pressure, oiler engineer operating over ten pounds

**Group V (ax)** - Air pressure, oiler engineer operating over ten pounds

**Group V (ay)** - Air pressure, oiler engineer operating over ten pounds

**Group V (az)** - Air pressure, oiler engineer operating over ten pounds

**Group VI** - Winch trucks; steel haulers, derrick & A-trucks; distributors drivers & operators; tank truck; tandem & semi-tractors; wheel tractors; oilers, greasers & mechanic helpers; heavy excavating & hauling equipment, dumpsters, etc.

**Group VII** - Fork lifts & high lifts, etc., when unloading or carrying

**Group VIII** - Mechanics
Department of Health and Human Services
Public Health Service

48 CFR Ch. 3, Appendix A
Acquisition Regulation; Final Rule
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

48 CFR Ch. 3, Appendix A

Acquisition Regulation

AGENCY: Public Health Service (PHS), HHS.

ACTION: Final rule with request for comments.

SUMMARY: This rule establishes the Public Health Service Acquisition Regulation (PHSAR) as Appendix A to the Department of Health and Human Services Acquisition Regulation (HHISAR), Chapter 3 of Title 48, Code of Federal Regulations (49 FR 13990, April 9, 1984). The PHSAR implements and supplements HHISAR and the Federal Acquisition Regulation (FAR), Title 48 CFR Chapter 1. Since these regulations affect only PHS acquisitions, a decision was made to publish them separately from the HHISAR.

The FAR was jointly promulgated on September 19, 1983 (48 FR 42102) by the Department of Defense, General Services Administration, and National Aeronautics and Space Administration as the uniform, simplified, government-wide acquisition regulation required by Executive Order 12352, Federal Procurement Reform. The FAR supersedes the Defense Acquisition Regulation, the Federal Procurement Regulations, and the National Aeronautics and Space Administration Procurement Regulation on April 1, 1984.

As a result of the promulgation of the FAR, all civilian agency implementations of the Federal Procurement Regulations, including the HHISAR Procurement Regulations, became obsolete on the effective date. For this reason, the Department of Health and Human Services is establishing the PHSAR to effect policies and procedures governing the acquisition processes which were formerly found in the HHISAR Procurement Regulations, Chapter 3 of Title 41, Code of Federal Regulations, and PHS Procurement Regulations.

DATES: This final rule is effective April 1, 1984. Comment due date is October 15, 1984.

ADDRESS: Any person or organization wishing to submit comments pertaining to the PHSAR may do so by mailing them to the Contracts Management Branch, Division of Grants and Contracts, Room 18A-11, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Comments received after October 15, 1984 will not be considered. Oral comments will not be taken.

FOR FURTHER INFORMATION CONTACT: Stephen R. Gane, Procurement Analyst, at (301) 443-2710.

SUPPLEMENTARY INFORMATION: The PHSAR implements the HHISAR and FAR where required or considered necessary and supplements the HHISAR and FAR in areas where there is no coverage or the coverage is considered inadequate. The PHSAR is the result of reformating the existing HHISAR and PHS Procurement Regulations, removing portions of the PHS Procurement Regulations which would duplicate HHISAR or FAR coverage of subject matter not contained in the Federal Procurement Regulations, and inserting needed internal procedural guidance in areas where the FAR and HHISAR require implementation.

The Department highlights the following areas which were previously contained in the HHISAR Procurement Regulations and are now in the PHSAR:

Subpart PHS 380.1—Acquisitions Involving Human Subjects
Subpart PHS 380.2—Acquisitions Involving the Use of Laboratory Animals
Subpart PHS 380.3—Acquisition of Drugs and Medical Supplies
Subpart PHS 380.4—Contracts under the Indian Self-Determination Act
Subpart PHS 380.5—Acquisitions under the Buy Indian Act

The HHISAR, including the PHSAR, 48 CFR Chapter 3, supersedes the HHISAR Procurement Regulations, 41 CFR Chapter 3, as of April 1, 1984. However, the HHIS and PHS Procurement Regulations remain in effect for those contracts awarded, or based upon solicitations issued, before the effective date.

Executive Order 12291

In accordance with the memorandum of October 4, 1982 from the Director, Office of Management and Budget, this final rule is exempt from the provisions of Executive Order 12291.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, Pub. L. 99-36, requires the preparation of a regulatory flexibility analysis for any rule which is likely to have a significant economic impact on a substantial number of small entities. Since this rule reformats existing procurement policies and procedures which would impact the public, it has been determined that this rule will not have a significant economic impact on a substantial number of small entities, and, thus, a regulatory flexibility analysis has not been prepared.

Paperwork Reduction Act

Parts PHS 352 and 360 contain information collection or reporting requirements. As required by the Paperwork Reduction Act of 1980, the Department has submitted a copy of this final rule to the Office of Management and Budget for its review of these information requirements. Individuals and organizations desiring to submit comments on the information requirements should direct them to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503.

Attention: Desk Officer for HHS.

Administrative Procedure Act

The Administrative Procedure Act (APA) exempts rules relating to contracts from the prior notice and comment procedures normally required for formal rulemaking (5 U.S.C. 553(a)). This Department, however, as a matter of policy, utilizes the public participation procedures of the APA for rules relating to contracts except when, as authorized by the APA, "the agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." (36 FR 2532; 5 U.S.C. 553(b)(B)).

The Department has determined that this rule falls within the authorized exceptions to the APA. Because this rule merely reformats the Department's existing procurement regulations to conform them to FAR, and inserts needed internal procedural guidance in areas where the FAR requires implementation, prior public comment is deemed unnecessary. Further, since the Department's procurement regulations became obsolete on April 1, 1984, it is impracticable to provide for prior public comment on this rule. Lastly, it would be contrary to the public interest to utilize a prior public comment procedure, since that procedure would result in PHS not having any acquisition regulations in effect on or after April 1, 1984.

OFPP Policy Letter No. 83-2

The Office of Federal Procurement Policy, in Policy Letter No. 83-2, requires that an agency must provide an opportunity for public comment before adopting procurement (acquisition) regulations if the regulations represent a "significant" change to existing regulations. A change to existing regulations "is generally considered to be significant if it has an effect beyond
the internal procedures of the issuing agency, or a cost or administrative impact on contractors.”

The Department has determined that this rule does not represent a significant change. As indicated earlier in the preamble, the changes made to the Department’s procurement (acquisition) regulations are in the areas of format and internal procedures. Accordingly, the Department has concluded that the requirements of the Policy Letter do not apply.

For these reasons, the Department is issuing the PHS Acquisition Regulation as a final rule. However, the Department will accept comments on the regulation until October 15, 1984, and will review all comments for possible revisions to the regulation.

The provisions of this regulation are issued under 5 U.S.C. 301; 40 U.S.C. 480(c).

List of Subjects in 48 CFR Ch. 3

Government procurement.

Accordingly, the Department amends Title 48, Code of Federal Regulations, by establishing Appendix A—Public Health Service, to Chapter 3 as set forth below.

List of Subjects in 48 CFR Ch. 3

Government procurement.

Accordingly, the Department amends Title 48, Code of Federal Regulations, by establishing Appendix A—Public Health Service, to Chapter 3 as set forth below.

List of Subjects in 48 CFR Ch. 3

Government procurement.
Acquisition Management Advisory Committee (AMAC) to assist and facilitate the planning and development of acquisition policies and procedures, and the resolving of operational problems affecting all acquisition activities in the PHS.

(b) The AMAC consists of members and alternates from the Office of the Assistant Secretary for Health, Alcohol, Drug Abuse, and Mental Health Administration, Centers for Disease Control, Food and Drug Administration, Health Resources and Services Administration, and National Institutes of Health.

PHS 301.271 Timing of PHSAR revisions.
PHSAR revisions will be issued throughout the year as the need arises. PHS issuances shall be effective on the date cited in the Federal Register issuance or on the date of the transmittal notice which distributes it to PHSAR Staff Manual holders, unless otherwise directed.

Subpart PHS 301.4—Deviations From the FAR

PHS 301.470 Procedure.
(a) Requests for deviations from the FAR, HHSAR or any PHSAR issuance for implementation or supplementation shall be submitted in writing by the PHS agency principal official responsible for acquisition to the Director, Division of Grants and Contracts, ORM/OM/PHS for approval and/or further processing as may be required. When it is recognized that a deviation will be required prior to the issuance of a solicitation, the request for deviation must be processed and approved prior to release of the solicitation. When completion of a contract action is contingent on approval of a deviation, the request for deviation must be processed and approval granted by the appropriate level, prior to contract execution. In an exigency situation, initial verbal contact should be made with the Chief, Contracts Management Branch, DGC/ORM/OM/PHS or his/her designee. Only deviations to the PHSAR may be granted by the Director, Division of Grants and Contracts.

(b) Each request for deviation shall provide sufficient information to permit PHS compliance with the HHSAR. Generally, such requests shall contain the following:

(1) A clear statement of the deviation requested.
(2) The reason the deviation is considered necessary or would be in the best interest of the Government.
(3) The name of the contractor and contract number, or the name of the proposed contractor and the solicitation number.
(4) A statement indicating whether or not the deviation had been previously requested. If so, outline the circumstances involved and the disposition of that request.
(5) All pertinent background information which will contribute to a full understanding of the desired deviation.

PART PHS 302—DEFINITIONS OF WORDS AND TERMS

Subpart PHS 302.1—Definitions

PHS 302.170 Definitions of terms.
The following terms, when utilized in PHS contracting activities.

(1) A clear statement of the deviation requested.
(2) The reason the deviation is considered necessary or would be in the best interest of the Government.
(3) The name of the contractor and contract number, or the name of the proposed contractor and the solicitation number.
(4) A statement indicating whether or not the deviation had been previously requested. If so, outline the circumstances involved and the disposition of that request.
(5) All pertinent background information which will contribute to a full understanding of the desired deviation.

PART PHS 304—ADMINISTRATIVE MATTERS

Subpart PHS 304.1—Contract Execution

PHS 304.170 Ratification of unauthorized contract awards.

(c)(2) Where ratification of an unauthorized contract action within a PHS agency is requested, the contracting officer shall forward the file through acquisition channels to an official at an organizational level above the contracting officer. He/she in turn shall analyze and evaluate the contracting officer's submission and make appropriate recommendations regarding ratification to the head of the contracting activity.

The Administrative Services Center (ASC), Office of Management (OM), will submit its requests for ratification to the Director, OM through the Division of Grants and Contracts (DGC), Office of Resource Management (ORM/PHS).

(c)(4)(i) PHS agencies, and ASC, ORM/PHS, shall submit a report of ratification data as specified in 304.170. PHS agencies with several contracting offices will be required to collect the required information from these activities and submit a consolidated agency report.

(ii) These reports shall be submitted to DGC/ORM/PHS within 20 days following the expiration of the reporting period. A consolidated PHS report will be prepared for submission to the Deputy Assistant Secretary for Procurement, Assistance, and Logistics as specified in 304.170.

Subpart PHS 304.6—Contract Reporting

PHS 304.670 PHS Contract Information System (PHSCIS).
The PHS Contract Information System consolidates all PHS contract data for the Department-wide Contract Information System (DCIS) from the PHS contracting activities.

PHS 304.670-1 Policy

The PHS principal officials responsible for acquisition (PORA) are responsible to ensure that all required contract information is collected, submitted, and received into the PHSCIS on or before the 10th day of each month for all contracts and contract modifications of any value and other acquisitions over $10,000 of the prior month.

PHS 304.670-2 PHS agency implementation.

It is the responsibility of the PORAs to develop and implement appropriate
procedures within their activities to ensure that data submissions to the PHSCIS are timely, error free, and contain all the required information.

Subpart PHS 304.71—Review and Approval of Proposed Contract Awards

PHS 304.7101 Contracts requiring review and approval.

(b)(2)(i) In addition to the reviews required by 304.7101(a) and PHS 304.7101(c), internal reviews are to be conducted of National Cancer Institute (NCI), National Institutes of Health (NIH), acquisitions expected to be in the range from $300,000-$750,000. The officials responsible for these reviews shall be the Chief, Research Contracts Branch, Office of Administrative Management, NCI, NIH, and the Chief, Contracts Operations Branch, Division of Extramural Research, NHLBI, NIH, respectively.

(ii) Furthermore, to assure that an adequate review of smaller dollar acquisitions is made prior to award, a statistically significant sample of contract actions of dollar values, less than those amounts referenced in this section is required to be approved prior to award. This review and approval will be by the designated reviewing official listed in paragraph (c) (but see PHS 304.7102(a)). Records of such review actions will be maintained and will include documentation of the resolution of any significant issue raised by the review.

(c) Reviewing officials. For PHS agency contract awards expected to exceed the dollar amounts stated in this paragraph, the reviewing official indicated will personally approve the award. Other than these specified requirements for the designated reviewing official, PHS agencies may assign other review and approval responsibilities at their discretion. The following officials shall be responsible for preaward contract review and approval of all proposed contracts and modifications which are expected to exceed the dollar limits expressed below:

<table>
<thead>
<tr>
<th>Review and approval required for contracts expected to exceed</th>
<th>PHS acquisition activity</th>
<th>Reviewing official</th>
</tr>
</thead>
<tbody>
<tr>
<td>$300,000 Administrative Services Center Office of Management</td>
<td>Director, Administrative Services Center.</td>
<td></td>
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<tr>
<td>$300,000 National Institute on Drug Abuse</td>
<td>Director, Division of Grants and Contracts Management.</td>
<td></td>
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<tr>
<td>$300,000 National Institute on Alcohol Abuse and Alcoholism</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$300,000 National Institute of Mental Health</td>
<td>Do.</td>
<td></td>
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<tr>
<td>$300,000 St. Elizabeth Hospital, NIH</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$50,000 Addiction Research Center</td>
<td>Do.</td>
<td></td>
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<tr>
<td>$100,000 Centers for Disease Control</td>
<td>Director, Procurement and Grants Office.</td>
<td></td>
</tr>
<tr>
<td>$300,000 Negotiated Contracts Branch</td>
<td>Director, Division of Contracts and Grants Management.</td>
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</tr>
<tr>
<td>$300,000 National Center for Toxicological Research</td>
<td>Do.</td>
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<tr>
<td>$300,000 Procurement, Property, and Facilities Management Branch</td>
<td>Director, Division of Management Services.</td>
<td></td>
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<tr>
<td>$1,000,000 National Cancer Institute</td>
<td>Director, Division of Contracts and Grants.</td>
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<tr>
<td>$750,000 National Heart, Lung, and Blood Institute</td>
<td>Do.</td>
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<tr>
<td>$750,000 National Institute of Neurological and Communicative Disorders and Stroke</td>
<td>Do.</td>
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<tr>
<td>$500,000 National Institute of Child Health and Human Development</td>
<td>Do.</td>
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<tr>
<td>$500,000 National Institute of Allergy and Infectious Diseases</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$500,000 National Library of Medicine (Research and development awards only)</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$500,000 National Institute of Dental Research</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$250,000 National Institute of Arthritis, Metabolism and Digestive Diseases</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$250,000 Centralized procuring activity for all other National Institutes of Health Research Organizations.</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$250,000 National Library of Medicine (Awards other than research and development)</td>
<td>Director, Division of Administrative Services.</td>
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<tr>
<td>$100,000 Procurement Branch, Division of Administrative Services</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$100,000 National Institute of Environmental Health Services</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>$300,000 Health Resources and Services Administration</td>
<td>Director, Division of Grants and Procurement Management.</td>
<td></td>
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</tbody>
</table>

PHS 304.7102 Conduct of the review.

(a) General. The reviewing official is not required to personally perform the review, but he or she is responsible for ensuring that the reviewer is knowledgeable in the acquisition field and has sufficient expertise to perform a comprehensive review and to make cogent recommendations to the
reviewing official for actions exceeding the dollar amounts stated in this subpart. The reviewing official shall approve each proposed contract award that is reviewed.

**SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES**

**PART PHS 314—FORMAL ADVERTISING**

Subpart PHS 314.4—Opening of Bids and Award of Contract

Sec.

PHS 314.409-3 Other mistakes disclosed before award

PHS 314.406-4 Mistakes after award

PHS 314.407-8 Protests against award

PHS 314.470 Protest control officer procedures.


Subpart PHS 314.4—Opening of Bids and Award of Contract

PHS 314.406-3 Other mistakes disclosed before award.

PHS 314.406-4 Mistakes after award.

PHS 314.407-8 Protests against award.

PHS 314.470 Protest control officer procedures.


PHS 314.407-8 Protests against award.

(a) General. (2) Reports concerning protests before or after award, shall include the following documentation:

(i) A statement by the PHS contracting activity’s protest control officer. This statement shall be in the form of a transmittal letter to the PHS Protest Control Officer and shall summarize the allegations and the main thrust(s) of the protest; recapitulate the contracting activity’s position leading to logical conclusions and appropriate recommendations for disposition of the protest and reflect the action proposed or taken to correct Government deficiencies whenever applicable.

(ii) Each contracting officer’s statement of facts and circumstances shall include a brief acquisition history and a specific comment on each individual protestant allegation, implication and innuendo; and shall refer to supportive statements obtained from program personnel whenever applicable.

(iii) The contracting officer’s conclusions and recommendations. These should be supported by factual data and logical rational and bolstered whenever possible by reference to Comptroller General decision and other authoritative sources.

(iv) Other documentation relevant to the protest. These include but are not limited to: the specifications, or where too bulky, that part which is relevant to the protest; a copy of the protest, and any correspondence relating thereto (e.g., General Accounting Office (GAO), IHS, and PHS transmittals and decisions); cost advisory/audit reports; technical evaluations; etc.

(4) Whenever the contracting officer deems it advisable to obtain the views of higher authority or when such submission is required by 314.407-8(b)(2), the protest files shall be forwarded in triplicate to the PHS Protest Control Officer, CMB/DGC/ORM/OM/PHS. These protest files shall be forwarded by transmittal letter signed by the contracting activity’s principal official responsible for acquisition. The block of the transmittal letter should reflect information as follow:

Protest Before Award—Protestant’s Name

Solicitation Number

OR

Protest After Award—Contract Number

Contractor’s Name

Protestant’s Name

Upon receipt of the file, the PHS Protest Control Officer will analyze the submission, assure that all pertinent aspects of the protest have been addressed, prepare comments, and continue processing of the file to the DHHS Protest Control Officer, Office of Evaluation and Compliance.

(5) Reports on protests filed with GAO shall be processed in accordance with PHS 314.406-8(a)(4) above.

(6) Each PHS agency shall designate a protest control officer, who shall be qualified and function in accordance with the criteria and guidance in PHS 314.470, Protest control officer procedures. The designations and the termination of such appointments shall be forwarded to the PHS Protest Control Officer, CMB/DGC/ORM/OM/PHS. Other PHS contracting activities, e.g., the Administrative Services Center, OM/PHS need not appoint protest control officers but should route all protests filed above the level of the contracting officer to the PHS Protest Control Officer, and call on him/her for any assistance which may be required on protest related matters.

(b) Protest before award. (2) All protest correspondence, which is required by 314.407-8(b)(2), to be submitted to the Director, Office of Evaluation and Compliance, OPAL/OS, shall be processed in accordance with PHS 314.407-8(a)(4) above.

(c) Protests after award. All formal protests after award shall be processed in accordance with PHS 314.407-8(a)(4) above.

(d) Protest file disposition. A copy of the protest file and the administrative determinations relating thereto, shall be retained as part of the official contract file.

PHS 314.470 Protest control officer procedures.

(a) Each PHS agency shall designate a protest control officer to monitor protests from the time of initial notification that a protest is imminent to the completion of protest file. The protest control officer may be the PHS contracting activity’s chief contracting official or an individual, senior in the contracting organization, who is designated by management to perform this function due to his/her depth of contract knowledge, experience, and professional acumen.

(b) Specifically, the designated protest control officer should be qualified to address the questions of form which frequently arise in regard to formally advertised acquisitions, as well as the technical and more sophisticated questions of fact which occur in both advertised and negotiated acquisitions. In this regard, he/she must have a broad enough experience base to articulate objectively the Government’s positions on questions of restrictive or improper specifications, competitive range, technical evaluations, etc., and generally be in position to render immediate assistance to contracting officers to assure the validity of fundamental decisions relating to protests.

(c) With the appointment of protest control officers, processing procedures are visualized as follows:
(1) Contracting officer receives notification of protest.
(2) Contracting officer notifies the protest control officer of the protest and schedules a meeting to discuss the facts and circumstances involved in the solicitation and/or contract in question and the contractor allegations relating thereto. If technical aspects are involved, responsible and qualified technical personnel may also be required to attend.

If the protest is considered valid, a course of action designed to rectify the situation is agreed upon. If the protest has been lodged at the contracting officer level, remedial action may be immediately effected. However, where a protest is lodged at a higher level, the protest file should be documented and recommendations for remedial action should be processed through channels and acted upon after receipt of proper approval.

(4) If the protest is not considered valid, a plan of action is adopted which leads the contracting officer to the collection and accumulation of information required to document the protest file fully. The protest control officer then establishes a suspense date for submission of the complete protest file. (Note: Where contracting officers are located at distant field locations, telephone coordination may be substituted for the desired personal contact between the protest control officer and the contracting officer.) Each individual allegation, implication, and innuendo should be related to the contracting officer’s Statement of Facts leading to logical conclusions on the thrust of the protest and the recommendation that the protest be denied.

(5) While the protest control officer plays a key role in defining the basic approach and in providing advice as to what additional documentation or action should be taken, the contracting officer is still responsible for full compliance with the provisions of FAR, HHSAR, and PHSAR issuances regarding the handling of the protest and the preparation of the contract file. During this documentation phase, the protest control officer remains available for further consultation and follows up to assure compliance with the established suspense date. When the protest file is completely assembled, documented, and indexed, it is returned to the protest control officer for evaluation and analysis. If additional refinements of Government documentation are still required, he/she takes action to obtain it; otherwise, he/she prepares a summary statement of the Government’s position in regard to the protest and makes appropriate recommendations to the next level of review.

(6) The protest control officer will perform the same advisory and consultant functions in processing both protests before and after award. However, on protests after award, it is imperative that an early, knowledgeable decision be made on the validity of the protest, so that performance may either be permitted to continue or curtailed. In such situations, aggressive action is required to preclude contract expiration or product delivery, whenever the validity of the protest brings into serious consideration the nullification of the initial award.

PART PHS 315—CONTRACTING BY NEGOTIATION

Subpart PHS 315.2—Negotiation Authorities

Sec. PHS 315.202 Public exigency.
PHS 315.205 Services of educational institutions.

Subpart PHS 315.3—Determination and Findings To Justify Negotiation

PHS 315.307 Signatory authority.

Subpart PHS 315.10—Preaward and Postaward Notifications, Protests, and Mistakes

PHS 315.1003 Protests against award.

Subpart 315.71—Noncompetitive Acquisitions

PHS 315.7101 Policy.
(a) Noncompetitive acquisitions are to be authorized as required by PHS 315.71 and as set forth herein. The following types of actions are covered:
(i) New contracts to be awarded noncompetitively.
(ii) Whole project buys, as defined by PHS 315.7108. The approval official will be determined by the cumulative value of all acquisitions; i.e., the amount of the basic award, whether competitive or noncompetitive, plus all planned follow-on work.
(iii) Legislative or executive directions which preclude competition (or require award to a specific source) are considered noncompetitive and require approval by the appropriate official.
(iv) Contract modifications for additional work which were not authorized under (a)(ii) above. Contract modifications which exercise options, provide incremental funding, or award the noncompetitive portions of approved whole project buys are exempt from this procedure provided they were authorized as part of the initial award.

PHS 315.7103 Criteria.

(i) Certain PHS requirements can be performed only by the National Academy of Sciences (NAS) because of its preeminent position in the health field as the objective, independent, counterpart to the Government (PHS). In those circumstances where proposed awards to NAS are inappropriate for competition, but yet do not meet any of the existing criteria in PHS 315.71, the following criterion is authorized to justify noncompetitive award.
(1) The NAS, by virtue of a committee/panel of scientific experts in the area of concern, its independent and objective point of reference in examining and reporting on this subject, conducted acceptance by the target audience(s) of NAS' findings and opinions on the matter under study, is the only source which can provide the measure of expertise, independence, objectivity, and audience acceptance necessary to meet the program requirements.

(2) It must be shown that the success of the proposed acquisition is critically dependent upon performance by the NAS. In addition, the justification for Noncompetitive Acquisition (JNCA) must contain a statement that the other NAS, in addition, the Justification for the program, is necessary to meet the program's objective.

$100,000-$749,999: Head of the PHS agency or successor.

$750,000 or more: DASHO.

The policy and procedures to be used in all contracts involving human subjects:

Protection of Human Subjects:

(a) The Contractor agrees that the rights and welfare of human subjects involved in performance of the work will be protected in accordance with procedures specified in its current Institutional Assurance. The Contractor also agrees not to approve or serve as an agent or employee of the Government.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible.

This review shall assure that the project described herein involves the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate.

The Contractor agrees that the rights and welfare of the individuals involved are adequately protected. The Contractor shall furnish evidence of such registration to the Contracting Officer.

The Contractor shall acquire animals used in research and development programs from a dealer licensed by the Secretary of Agriculture, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without incurring liability to the Government for the acts of the Contractor's employees.

Subpart PHS 352.3—Provision and Clause Matrices


PHS 352.280-6 Demurrage Charge Provisions for Reusable Cylinders and Containers.

PHS 352.280-8 Demurrage Charge Provisions for Reusable Cylinders and Containers.

Subpart PHS 352.2—Texts of Provisions and Clauses

PHS 352.280-1 Protection of Human Subjects.

PHS 352.280-2 Care of Laboratory Animals.

PHS 352.280-3 Maximum Allowable Cost for Drugs.


PHS 352.280-6 Demurrage Charge Provisions for Reusable Cylinders and Containers.

Subpart PHS 352.2—Texts of Provisions and Clauses

PHS 352.280-1 Protection of Human Subjects.

The policy and procedures to be followed whenever individuals may be at risk as a consequence of participation as subjects in research, development, demonstration, or other activities being conducted under a contract are provided in Subpart PHS 380.1.

(a) The following provision shall be included in solicitations expected to involve human subjects:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Human Subjects (Apr. 1984)

Prospective contractors being considered for award will be required to give acceptable assurance that the project described herein will be subject to initial and continuing review by an appropriate institutional committee. This review shall assure that the rights and welfare of the individuals involved are adequately protected.

The Contractor shall furnish evidence of such registration to the Contracting Officer.

(b) The Contractor shall acquire animals used in research and development programs from a dealer licensed by the Secretary of Agriculture, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without incurring liability to the Government for the acts of the Contractor's employees.
program agency, a separate dispensing fee will not be recognized.

(b) The Contractor agrees:
(1) To include the following solicitation notification in all applicable solicitations issued under this contract and to ensure that subcontractors include it in any subsequent applicable solicitation:
This acquisition is subject to the Maximum Allowable Cost (MAC) regulation set forth in Part 19 of Subtitle A of Title 45 of the Code of Federal Regulations.
(2) To include this clause, including this paragraph (b), in all applicable subcontracts, regardless of tier, awarded pursuant to this contract.
(3) To include the furnished MAC determination or acquisition cost date in all applicable solicitations issued under this contract and in all resultant subcontracts awarded pursuant to this contract.

(End of clause)

(a) Insert the following clauses in cost-reimbursement contracts awarded under the Indian Self-Determination Act as described in subpart PHS 300.4.

Clause No. 1—Definitions (June 1977)

As used throughout this contract, the following terms shall have the meaning set forth below:
(a) The term "Secretary" means the Secretary, the Under Secretary, or any Assistant Secretary of the Department of Health and Human Services (HHS); and the term "his/her duly authorized representative" means any person, persons, or board (other than the Contracting Officer) authorized to act for the Secretary.
(b) The term "Contracting Officer" means the person executing this contract on behalf of the Government, and any other officer or employee who is properly designated Contracting Officer. The term includes, except as otherwise provided in this contract, the authorized representative of the Contracting Officer acting within the limits of his/her authority.
(c) The term "Project Officer" means the person representing the Government for the purpose of monitoring contract performance. The Project Officer is not authorized to issue any instructions or directions which effect any increase or decrease in the cost of this contract or which change the period of this contract.
(d) The term "Department" means the Department of Health and Human Services.
(e) Except as otherwise provided in this contract, the term "subcontract" includes purchase orders under this contract.

(End of clause)

Clause No. 2—Disputes (June 1977)

(a) Except as otherwise provided in this contract, any dispute concerning a question of fact arising under this contract which is not disposed of by agreement shall be decided by the Contracting Officer, who shall reduce his/her decision to writing and mail or otherwise furnish a copy thereof to the Contractor. The decision of the Contracting Officer shall be final and conclusive unless within 30 days from the date of receipt of such copy, the Contractor mails or otherwise furnishes to the Contracting Officer a written appeal addressed to the Secretary. The decision of the Secretary or his/her duly authorized representative for the determination of such appeals shall be final and conclusive unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with any appeal proceeding under this clause, the Contractor shall be afforded an opportunity to be heard and to offer evidence in support of its appeal. Pending final decision of a dispute hereunder, the Contractor shall proceed diligently with the performance of the contract and in accordance with the Contracting Officer's decision.
(b) This "Disputes" clause does not preclude consideration of law questions in connection with decisions provided for in paragraph (a) above. Provided, That nothing in this contract shall be construed as making final the decision of any administrative official, representative, or board on a question of law.

(End of clause)

Clause No. 3—Limitation of Cost (June 1977)

(a) It is estimated that the total cost to the Government for the performance of this contract will not exceed the estimated cost set forth in this contract and the Contractor agrees to use its best efforts to perform all work and all obligations under this contract within such estimated costs. If at any time the Contractor has reason to believe that the costs which it expects to incur in the performance of this contract in the next succeeding sixty (60) days, when added to all costs previously incurred, will exceed seventy-five percent (75%) of the estimated cost set forth in the contract, or, if at any time the Contractor has reason to believe that the total cost to the Government, for the performance of this contract, will be substantially greater or less than the estimated cost thereof, the Contractor shall notify the Contracting Officer in writing to that effect, giving its revised estimate of such total cost for the performance of this contract.

(b) The Government shall not be obligated to reimburse the Contractor for costs incurred in excess of the estimated cost set forth in the contract and the Contractor shall not be obligated to continue performance under the contract or to incur costs in excess of such estimated cost unless and until the Contractor shall have notified the Contracting Officer in writing that such estimated cost has been increased and shall have specified in such notice a revised estimated cost which shall thereupon constitute the estimated cost of performance of this contract. When and to the extent that the estimated cost set forth in this contract has been increased by the Contracting Officer in writing, any costs incurred by the Contractor in excess of such estimated cost prior to the increase in estimated cost shall be allowable to the same
extent as if such costs had been incurred after such increase in estimated cost.

(End of clause)

Clause No. 4—Allowable Cost (June 1977)

(a) Compensation for Contractor's performance. Payment for the allowable cost, as herein defined and as actually incurred by the Contractor shall constitute full and complete compensation for the performance of the work under this contract.

(b) Allowable cost. The allowable cost of performing the work under this contract shall be the cost actually incurred by the Contractor, either directly incident or properly allocable to the contract, in the performance of this contract in accordance with its terms. The allowable cost, direct and indirect, including acceptability of cost allocation methods, shall be determined by the Contracting Officer in accordance with:

(i) "A Guide for Nonprofit Institutions Entitled to Use Indirect Cost Rates for Research Grants and Contracts with the Department of Health and Human Services, HHS Publication OASC-5" or

(ii) "A Guide for Hospitals, Grants and Contracts with the Department of Health and Human Services, HHS Publication OASC-3" or

Subpart 1—15.7 of the Federal Procurement Regulations (41 CFR Subpart 1—15.7) if the contract is with a state or local government agency, or

Subpart 1—15.4 of the Federal Procurement Regulations (41 CFR Subpart 1—15.4) if the contract is for the procurement of construction or architect-engineer services.

(2) The terms of the contract.

(End of clause)

Clause No. 5—Negotiated Overhead Rates (June 1977)

(a) Notwithstanding the provisions of the clause of this contract entitled "Allowable Cost," the allowable indirect costs shall be obtained by applying negotiated overhead rates to billing indirect cost principles set forth in paragraph (b)(1) of Clause 4, so as to effect on the date of this contract, and the same hereby incorporated herein by reference.

(b) The Contractor, as soon as possible, but not later than six (6) months after the expiration of each of the Contractor's financial years or such period as may mutually be agreed upon by the Government and the Contractor, shall submit to the Contracting Officer, with a copy to the cognizant audit agency, a proposed final overhead rate or rates for that period based on the Contractor's cost experience during that period, together with supporting cost data. Negotiation of final overhead rates by the Contractor and the Contracting Officer shall be undertaken as promptly as practicable after receipt of the Contractor's proposal.

(c) Allowability of costs and acceptability of cost allocation methods shall be determined in accordance with the applicable cost principles set forth in paragraph (b)(1) of Clause 4, as in effect on the date of this contract, and the same hereby incorporated herein by reference.

(d) The results of each negotiation shall be set forth in an amendment to this contract, which shall be signed by the agreed-to final rate, (2) the bases to which the rates apply, and (3) the periods for which the rates apply.

(e) Pending establishment of final overhead rates for any period, the Contractor shall be reimbursed either at negotiated provisional rates as provided in this contract or at billing rates acceptable to the Contracting Officer, subject to appropriate adjustment when the final rates for that period are established. To prevent substantial over or under payment, the provisional or billing rates may, at the request of the Contractor, be revised by mutual agreement, either retroactively or prospectively. Any such revision of negotiated provisional rates provided in this contract shall be set forth in an amendment to this contract.

(f) Any failure by the parties to agree on any final rate or rates under this clause shall be considered a dispute concerning a question of fact for decision by the Contracting Officer within the meaning of the clause of this contract entitled "Disputes."

(g) Submission of proposed provisional and/or final overhead rates, together with appropriate data in support thereof, to the Secretary or his/her duly authorized representative, and agreements on provisional and/or final overhead rates entered into between the Contractor and the Secretary or his/her duly authorized representative, as evidenced by Negotiated Overhead Rate Agreements signed by both parties, shall be deemed to satisfy the requirements of (b), (d), and (e) above.

(End of clause)

Clause No. 6—Payment (June 1977)

(a) Payment on account of allowable cost. Once each month (or at more frequent intervals if approved by the Contracting Officer) the Contractor may submit to the Contracting Officer, in such form and reasonable detail as may be required, an invoice or voucher supported by a statement of costs incurred by the Contractor in the performance of this contract and claimed to constitute allowable costs. Promptly after receipt of each invoice or voucher, the Government shall, subject to the provisions of (b) below, make payment thereon as approved by the Contracting Officer.

(b) Audit Adjustments. At any time or times prior to settlement under this contract the Contractor may have invoices or vouchers and statements of cost audited. Each payment therefore made shall be subject to reduction for amounts included in the related invoice or voucher which are found by the Contracting Officer, on the basis of such audit, not to constitute allowable cost. Any payment may be reduced for overpayment, or increased for underpayments on preceding invoices or vouchers.

(c) Completion voucher. On receipt and approval of the invoice or voucher designated by the Contractor as the "completion invoice" or "Completion Voucher" and upon compliance by the Contractor with all the provisions of this contract (including without limitation, the provisions relating to patents and provisions of (d) below) the Government shall promptly pay to the Contractor any balance of allowable cost. The completion invoice or voucher shall be submitted by the Contractor promptly following completion of the work under this contract but in no event later than 6 months (or such longer period as the Contracting Officer may in his/her discretion approve in writing) from the date of such completion.

(d) Applicable credits. The Contractor agrees that any final or interim credits, rebates, credits, or other amounts (including any interest thereon) accruing to or received by the Contractor or any assignee under this contract shall be paid by the Government, to the extent that they are properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract. Reasonable expenses incurred by the Contractor for the purpose of securing such refunds, rebates, credits, or other amounts shall be allowable cost hereunder when approved by the Contracting Officer.

(e) Financial settlement. Prior to final payment under this contract, the Contractor and each assignee under this contract whose assignment is in effect at the time of final payment under this contract shall execute and deliver:

(1) An assignment to the Government in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including any interest thereon) allocable to costs for which the Contractor has been reimbursed by the Government under this contract, and

(3) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, subject only to the following exceptions:

(i) Specified claims in stated amounts or in estimated amounts where the amounts are susceptible to exact statement by the Contractor;

(ii) Claims, together with reasonable expenses incidental thereto, based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, such such claims are not known to the Contractor on the date of the execution of the release; and provided further, that the Contractor gives notice of such claims in writing to the Contracting Officer not more than 6 years after the date of the release; and provided further, that such claims are known to the Contractor that the Government is prepared to make final payment, whichever is earlier; and

(iii) Claims for reimbursement of costs (other than expenses of the Contractor by reason of its indemnification of the Government against patent liability), including reasonable expenses incidental thereto, incurred by the Contractor under the provisions of this contract relating to patents.

(End of clause)

Clause No. 7—Advance Payments (June 1977)

(a) Amount of Advance. At the request of the Contractor, and subject to the conditions hereinafter set forth, the Government shall make an advance payment, or advance payments from time to time, to the Contractor. No advance payment shall be made (1) without the approval of the office administering advance payments (hereinafter called the "Administering Office") and designated in paragraph (a)(4) as with all
withhold further payments to the Contractor and apply the amounts withheld against the Contractor’s obligation to repay such advance payments until such advance payments shall be liquidated. If upon completion, termination, or retrocession of the contract all advance payments have not been fully liquidated, the balances therefor shall be deducted from any sums otherwise due or which may be due due to the Contractor from the Government, and any deficiency shall be paid by the Contractor to the Government upon demand.

(1) Bank Agreement. Before an advance payment is made hereunder, the Contractor shall transmit to the Administering Office, in the form prescribed by such office, an Agreement in triplicate from the bank in which the Special Bank Account is established, clearly setting forth the special character of the account and the responsibilities of the bank thereunder. Wherever possible, such bank shall be a member bank of the Federal Reserve System, or an “insured” bank within the meaning of the Act of March 4, 1933, 48 Stat. 1221, as amended (12 U.S.C. 181a).

(g) Lien on Special Bank Account. The Government shall have a lien upon any balance in the Special Bank Account, paramount to all other liens, which lien shall secure the repayment of any advance payments made hereunder.

(h) Lien on Property Under Contract. Any and all advance payments made under this contract shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, upon any property acquired for or material and other property. The lien shall be a security for any nonliquidated balance of advance payments made hereunder.

(i) Liquidation. If not otherwise liquidated, the advance payments made hereunder shall be liquidated as herein provided. When the sum of all payments under this contract and advances, other than advances hereunder, exceeds the total advance payments made hereunder, the advance payments shall not exceed the amount specified in paragraph (k)(1) hereof. In the event the Contractor fails to repay such unliquidated balance of advance payments when so required by the Administering Office, all or any part thereof may be withdrawn from the Special Bank Account by checks payable to the Contractor to the extent that such termination shall be made only if approved by the Administering Office, which approval shall constitute a release to the Contractor hereunder to the extent that such termination is sold or retained, and to the extent that the proceeds of the sale, or the credit allowed for such retention on the Contractor’s termination claim, is applied in reduction of advance payments then outstanding hereunder.

(j) Insurance. The Contractor represents and warrants that it is now maintaining with responsible insurance carriers, (1) insurance upon its own plant and equipment against fire and other hazards to the extent that like properties are usually insured by others operating plants and properties of similar character in the same general locality; (2) adequate insurance against liability on account of damage to persons or property; (3) and (3) adequate insurance under all applicable workers’ compensation laws. The Contractor agrees that, until work under this contract has been completed and all advance payments made hereunder have been liquidated, it will (i) maintain such insurance; (ii) maintain adequate insurance upon any materials, parts, assemblies, subassemblies, supplies, equipment and other property acquired for or assignable to this contract and subject to the Government lien hereunder; and (iii) furnish such certificates with respect to its insurance as the Administering Office may from time to time require.

(k) Provisions Against Assignment. Notwithstanding any other provision of this contract, the Contractor shall not transfer, pledge, or otherwise assign this contract, or any interest therein, to any party or parties, bank, trust company, or other financing institution. The amount of advance payments made hereunder shall not exceed $-

(1) Depository. The bank designated for the deposit of payments made hereunder shall be:

(3) Interest Charge. No interest shall be charged for advance payments made hereunder. The Contractor shall charge interest at the rate of 6 percent per annum on subadvances or down payments to subcontractors, and such interest will be credited to the account of the Government. However, interest need not be charged on subcontracts or nonprofit subcontracts with nonprofit educational or research institutions for experimental, research or development work.

(4) Administering Office. The office administering advance payments shall be the office designated as having responsibility for awarding the contract.

(l) Other Security. The terms of this contract shall be considered adequate security for advance payments hereunder, except that if at any time the administering office deems the security furnished by the Contractor to be inadequate, the Contractor...
shall furnish such additional security as may be satisfactory to the administering office, to the extent that such additional security is available.

(End of clause)

Clause No. 8—Examination of Records (June 1977)

(a) This clause is applicable if the amount of this contract exceeds $2,500 and was entered into by means of negotiation including small business restricted advertising, but is not applicable if this contract was entered into by means of formal advertising.

(b) The Contractor agrees that the Comptroller General of the United States and the Secretary, or any of their duly authorized representatives, shall, until expiration of 3 years after final payment under this contract or of the time period for the particular records in Part 1–20 of the Federal Procurement Regulations (41 CFR Part 1–20) whichever expires earlier, have access to and the right to examine any directly pertinent books, documents, papers, and records of the Contractor involving transactions related to this contract.

(c) The Contractor further agrees to include in all its subcontracts hereunder a provision to the effect that the subcontractor agrees that the Comptroller General of the United States, or his/her duly authorized representatives shall, until expiration of 3 years after final payment under the subcontract or of the time periods for the particular records specified in Part 1–20 of the Federal Procurement Regulations (41 CFR Part 1–20) whichever expires earlier, have access to and the right to examine any directly pertinent books, documents, papers, and records of such subcontractor involving transactions related to the subcontract. The term "subcontract" as used in this clause excludes (1) purchases orders not exceeding $2,500 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public.

(d) The periods of access and examination described in (b) and (c) above, for records which relate to (1) appeals under the "Disputes" clause of this contract, (2) litigation or the settlement of claims arising out of the performance of this contract, or (3) costs and expenses of this contract as to which exception has been taken by the Comptroller General or any of his/her duly authorized representatives, shall continue until such appeals, litigation, claims, or exceptions have been disposed of.

(End of clause)

Clause No. 9—Inspection and Reports (June 1977)

(a) Inspection of work. The Government shall have the right to inspect the work and activities under this contract, including without limitation, premises where any Government property may be located at such reasonable times and in such manner as it may deem appropriate and the Contractor shall afford the Government proper facilities and assistance for such inspection.

(b) Reports. The Contractor shall furnish such progress reports, schedules, financial and cost reports, and other reports, concerning the work under this contract as specified elsewhere in this contract. Cost and other financial data and projections furnished pursuant to this paragraph (b) shall not relieve the Contractor of the requirements for furnishing information specified in the clause of this contract entitled "Limitation of Cost."

(c) In addition, where Federal financial assistance is involved in the contract effort, the following clause will apply:

Reports to the Indian People

- The contractor, as a recipient of Federal financial assistance, shall make reports and information available to the Indian people served or represented by the contractor. Such reports will reflect how the Federal assistance funds were utilized to the benefit of the Indian people served or represented as follows: (specific reporting requirements, formats and methods of distribution to the Indian people will be prescribed in the scope of the contract.)

(d) Annual Reporting.

(1) For each fiscal year during which a tribal organization receives or expends funds pursuant to a contract under this Part, the tribe which requested the contract must submit a report to the Contracting Officer. The report shall include, but not be limited to, an accounting of the amounts and purposes for which the contract funds were expended and information on the conduct of the program or services involved. The reports shall include any other information requested by the Contracting Officer and may be submitted as follows:

(i) When the contract is with the governing body of an Indian tribe, the tribe shall submit the report to the Contracting Officer.

(ii) When the contract is with a tribal organization other than the governing body of the tribe, the tribe has the option of having the tribal organization prepare the report and submit it to the tribe for review and approval before the tribe submits it to the Contracting Officer.

(iii) When the contract benefits more than one tribe, the tribal organization shall prepare and submit the report to each of the tribes benefiting under the contract. Each tribe shall endorse the report before submitting it to the Contracting Officer.

(2) The annual report shall be submitted to the Contracting Officer within 90 days of the end of the fiscal year in which the contract was performed. However, the period for submitting the report may be extended if there is just cause for such extension.

(3) In addition to the yearly reporting requirement given in paragraphs (a) and (b) of this section, the tribal contractor shall furnish other reports when and as required by the Secretary.

(End of clause)

Clause No. 10—Subcontracting (June 1977)

(a) Prior approval required. Except as provided in (c) below, the Contractor shall not enter into any subcontract or purchase order not otherwise expressly authorized elsewhere in this contract without the prior written approval of the Contracting Officer and subject to such conditions as the Contracting Officer may require.

(b) Request for approval. The Contractor's request for approval to enter into a subcontract pursuant to this clause shall include: (1) A description of the supplies or services to be called for by the subcontract; (2) Identification of the proposed subcontractor and an explanation of why and how the proposed subcontractor was selected, including the degree of competition obtained; (3) the proposed subcontract price, together with the Contractor's cost or price analysis thereof; (4) identification of the type of subcontract to be used; (5) a copy or draft of the proposed subcontract, if available; and (6) any other information which the Contracting Officer may require.

(c) Certain purchases of property and services. Prior written approval shall not be required for firm-fixed-price subcontracts for the purchase or rental of items of personal property having a unit acquisition cost of less than $200 or for subcontracts in a total amount less than $1,000 unless otherwise specified elsewhere in this contract:

Provided, however, that advance notification shall be given to the Contracting Officer of any subcontract which exceeds in dollar amount 5 percentum of the total estimated cost of this contract.

(d) Contractor's procurement system. The contractor shall use methods, practices or procedures in subcontracting or purchasing (hereinafter referred to as the Contractor's "procurement system") acceptable to the Contracting Officer. The Contracting Officer may, at any time during the performance of this contract, require the Contractor to provide information concerning its procurement system.

(e) Effect of subcontracting. Subcontracts shall be made in the name of the Contractor and shall not bind nor purport to bind the Government. The making of subcontracts hereunder shall not relieve the Contractor of any requirement under this contract (including, but not limited to, the duty to properly supervise and coordinate the work of subcontracts, and the duty to maintain and account for property pursuant to the clause of this contract entitled "Property"). Approval of the provisions of any subcontract by the Contracting Officer shall not be construed to constitute a determination of the allowability of any cost under this contract, unless such approval specifically provides that it constitutes a determination of the allowability of such cost. In no event shall approval of any subcontract by the Contracting Officer be construed as effecting any increase in the estimated cost set forth in this contract. No subcontract placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis.

(f) Procurements from contractor-controlled sources. Procurement or transfer of equipment, materials, supplies, or services from contractor-controlled sources (any division or other organizational component of the prime contractor, exclusive of the contracting component, and any subsidiary or affiliate of the Contractor under a common control) shall be considered a subcontract for the purpose of this clause.
The foregoing constitutes "records" for the purposes of this clause.

(b) The Contractor’s facility(ies), or such part thereof as may be engaged in the performance of this contract, and its records shall be subject at all reasonable times to inspection and audit by the Contracting Officer or his/her authorized representative.

c) The contractor shall preserve and make available its records (1) until the expiration of 3 years from the date of final payment under this contract, or the time periods for the particular records specified in (41 CFR Part 1-20), whichever expires and (2) for such longer period, if any, as is required by applicable statute, or by other clause of this contract, or by (i) or (ii) below.

(i) If this contract is completely or partially retroceded or reassumed by the Government, the records relating to the work terminated shall be preserved and made available for a period of 3 years from the date of any resulting final settlement.

(ii) If the records relate to (A) appeals under the "Disputes" clause of this contract, (B) litigation or the settlement of claims arising out of the performance of this contract, or (C) costs and expenses of this contract to which exception has been taken by the Contracting Officer or any of his/her duly authorized representatives, shall be retained until such appeals, litigation, claims, or exceptions have been disposed of.

d) The Contractor shall insert the substance of this clause, including this paragraph (d), in each subcontract hereunder that is not firm-fixed-price or fixed-price with escalation. If so inserted, changes shall be made to designate the higher-tier subcontractor at this level involved in place of the Contractor's code or number and in place of the Government prime contract in place of "this contract" in (B) of subparagraph (c)(ii) above.

Federal Register / Vol. 49, No. 180 / Friday, September 14, 1984 / Rules and Regulations 36247

Clause No. 11—Accounts, Audit and Records (June 1977)

(a) The Contractor shall maintain books, records, documents, and other evidence, accounting procedures, and practices, sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred and anticipated to be incurred for the performance of this contract. The foregoing constitutes "records" for the purposes of this clause.

(b) The Contractor's facility(ies), or such part thereof as may be engaged in the performance of this contract, and its records shall be subject at all reasonable times to inspection and audit by the Contracting Officer or his/her authorized representative.

c) The contractor shall preserve and make available its records (1) until the expiration of 3 years from the date of final payment under this contract, or the time periods for the particular records specified in (41 CFR Part 1-20), whichever expires and (2) for such longer period, if any, as is required by applicable statute, or by other clause of this contract, or by (i) or (ii) below.

(i) If this contract is completely or partially retroceded or reassumed by the Government, the records relating to the work terminated shall be preserved and made available for a period of 3 years from the date of any resulting final settlement.

(ii) If the records relate to (A) appeals under the "Disputes" clause of this contract, (B) litigation or the settlement of claims arising out of the performance of this contract, or (C) costs and expenses of this contract to which exception has been taken by the Contracting Officer or any of his/her duly authorized representatives, shall be retained until such appeals, litigation, claims, or exceptions have been disposed of.

d) The Contractor shall insert the substance of this clause, including this paragraph (d), in each subcontract hereunder that is not firm-fixed-price or fixed-price with escalation. If so inserted, changes shall be made to designate the higher-tier subcontractor at this level involved in place of the Contractor's code or number and in place of the Government prime contract in place of "this contract" in (B) of subparagraph (c)(ii) above.
The Contractor shall require the subcontractor to assume responsibility for any loss or destruction of or damage to Government property while in the latter's possession or control, and the subcontract shall contain appropriate provisions requiring the return of all Government property in as good condition as when received (except for reasonable wear and tear or for the utilization of the property in accordance with the provisions of this contract). Provided, however, that the subcontractor may be relieved from such liability only to the extent that the subcontract, with the prior approval of the Contracting Officer, so provides.

(5) The Contractor shall not be reimbursed for, and shall not include as an item of overhead, the cost of insurance, or any provisions for a reserve, covering the risk of loss or damage to the Government property, except to the extent that the Government may have required the Contractor to carry such insurance under any other provision of this contract.

(6) Upon the happening of loss or destruction of or damage to the Government property, the Contractor shall notify the Contracting Officer thereof, and shall take all reasonable steps to protect the Government property from further damage, separate the damaged and undamaged Government property, and keep the Government property in the best order, and furnish to the Contracting Officer a statement of:

(i) The lost, destroyed, and damaged Government property;

(ii) The time and origin of the loss, destruction or damage;

(iii) All known interests in commingled property of which the Government property is a part, and

(iv) The insurance, if any, covering any part or interest in such commingled property.

The Contractor shall make repairs and renovation of the damaged Government property, or take such other actions as the Contracting Officer directs.

(7) In the event the Contractor is indemnified, reimbursed, or otherwise compensated for any loss or destruction of or damage to the Government property, it shall use the proceeds to repair, renovate, or replace the Government property involved, or shall credit such proceeds against the cost of the work covered by the contract, or shall otherwise reimburse the Government, as directed by the Contracting Officer. The loss, destruction or damage and, upon the request of the Contracting Officer, shall, at the Government's expense, furnish to the Government all reasonable assistance and cooperation (including assistance in the prosecution of suit and the execution of instruments in favor of the Government) in obtaining recovery. In addition, where a subcontractor has not been relieved from liability for any loss or destruction of or damage to Government property, the subcontractor shall enforce the liability of the subcontractor for such loss or destruction of or damage to the Government property for the benefit of the Government.

Disposition of Government property.

(1) The Contractor shall make repairs and regularly report to the Contracting Officer, in such form and manner as the Contracting Officer may direct, concerning the status of Government property under the contract, including all Government property in the Contractor's possession which is not in use or which is excess to the needs of the contract. The Contractor shall make such disposition of Government property as the Contracting Officer may direct. The Contractor shall in no way be relieved of responsibility for Government property without the prior written approval of the Contracting Officer.

(2) Upon completion or expiration of this contract, or at such earlier date as may be fixed by the Contracting Officer, the Contractor shall render an accounting, as prescribed by the Contracting Officer, of all Government property which had come into the possession or custody of the Contractor under this contract. Such accounting shall include inventory schedules covering all items of Government property not consumed in the performance of this contract, or not theretofore determined by the Government, or for which the Contractor has not otherwise been relieved of responsibility. The Contractor shall deliver or make such other disposition of Government property covered in such inventory schedule as the Contracting Officer may direct.

(3) The net proceeds of any disposition of Government property, in accordance with (1) and (2) above, shall be credited to the cost of the work covered by the contract or shall be paid in such form as the Contracting Officer may direct.

Restoration of premises. Unless otherwise provided herein, the Government shall not be under any duty or obligation to restore or rehabilitate, or to pay the costs of the restoration or rehabilitation of the Contractor's facility or any portion thereof which is affected by removal of any Government property.

End of clause

Clause No. 13—Changes (June 1977)

The Contracting Officer may at any time, with the consent of the Contractor, by a written order, and without notice to the sureties, if any, make changes, within the general scope of this contract, in any one or more of the following: (a) Drawings, designs, or specifications; (b) method of shipment or packing; (c) place of inspection, delivery, or acceptance; and (d) the amount of Government furnished property. If any such change causes an increase or decrease in the estimated cost of, or the time required for performance of this contract, or otherwise affects any other provisions of this contract, whether changed or not by any such order, an equitable adjustment shall be made (a) in the estimated cost or delivery schedule, or both, and (b) in such other provisions of the contract as may be so affected, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within thirty (30) days from the date of receipt by the Contractor of the notification of change; Provided, however, that the Contracting Officer, if he/she decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Where the cost of property made obsolete or excess as a result of a change is included in the Contractor's claim for adjustment under this clause, the Government shall have the right to prescribe the manner of disposition of such property. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled 'Disputes.' However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

End of clause

Clause No. 14—Notice to the Government of Delays (June 1977)

Whenever the Contractor has knowledge that any actual or potential situation, including, but not limited to, labor disputes, is delaying or threatens to delay the timely performance of the work under this contract, the Contractor shall inform the Contracting Officer thereof, including all relevant information with respect thereto, to the Contracting Officer.

End of clause

Clause No. 15—Retrocession (June 1977)

(a) The Indian Tribe that initially requested this contract may also request its retrocession, notwithstanding the fact that the Contractor may be a tribal organization other than the Tribe.

(b) Should the Tribe request retrocession of the contract and the Contractor is other than the Tribe, the Contracting Officer will notify the Contractor of the request and in consultation with the Tribe and the Contractor shall establish the effective date of the retrocession. The retrocession will become effective no later than 120 days after the Contracting Officer receives the Tribe's request unless the Tribe and the Contracting Officer mutually agree on a later date.

(c) Immediately after receipt of the request for retrocession and where applicable notifying the Contractor, the Contracting Officer will meet with the Contractor and, where applicable, the tribal governing body or bodies, mutually agree to:

(1) A plan for the orderly transfer of responsibilities;

(2) A plan for inventorying materials and supplies on hand;

(3) An accounting for funds, including but not limited to current and anticipated obligations;

(4) The cost of operation until retrocession;

(5) The identification of all records relating to the contract and the contracted function.

End of clause

Clause No. 16—Assignment and Reassignment of Contract Programs (June 1977)

(a) When the Director or his/her delegate determines that the performance of the Contractor under these regulations involves (1) the violation of the rights or endangerment of the health, safety, or welfare of any persons, or (2) gross negligence or the mismanagement in the handling or use of funds under the contract, he/she will, in
writing, notify the contractor of such determinations and will request that the Contractor take such corrective action within such period of time as the Director or his/her delegate may prescribe.

(b) When the Director or his/her delegate determines that a Contractor has not taken corrective action (as prescribed by him/her under paragraph (a) of this section) to his/her satisfaction, he/she may, after the Contractor has been provided an opportunity for a hearing in accordance with paragraph (c) of this section, rescind the contract in whole or in part and, if he/she deems it appropriate, assume or resume control or operation of the program, activity, or service involved.

(c) (1) When the Director or his/her delegate has made a determination described in paragraph (b) of this section, he/she shall in writing notify the Contractor of such determination and of the Contractor's right to request a review of such determination and of the determination described in paragraph (a) of this section. Such notification by the Director or his/her delegate shall set forth the reasons for the determination in sufficient detail to enable the Contractor to respond and shall inform the Contractor of its right to a hearing on the record before a Contract Appeals Board established pursuant to paragraph (d) of this section. Upon the request of the Contractor for a hearing, the Board, established pursuant to paragraph (d) of this section shall in writing within 10 days of the establishment notify the Contractor of the time, place and date of the hearing which will be held not later than 45 days after the request for a hearing.

(2) Where the Director or his/her delegate determines that a Contractor's performance under a contract awarded under this subpart poses an immediate threat to the safety of any person, he/she may immediately rescind the contract in whole or in part and, if he/she deems it appropriate, assume or resume control or operation of the program, activity, or service involved. Upon such a determination he/she shall immediately notify the Contractor of such determination and of the Contractor's right to a hearing on the record before a Contract Appeals Board established pursuant to paragraph (d) of this section to be held within 10 days of such action.

(d) (1) The Contract Appeals Board shall be composed of 3 persons appointed by the Director, Indian Health Service. Such persons may not be selected from the immediate office of any person participating in the determination at issue. The Board shall afford the Contractor the right:
   (i) To notice of the issues to be considered;
   (ii) To be represented by counsel;
   (iii) To present witnesses on Contractor's behalf;
   (iv) To cross-examine other witnesses either orally or through written interrogatories; and
   (v) To compel the appearance of Indian Health Service personnel or to take depositions of such persons at reasonable times and places.

(2) The Contract Appeals Board shall make an initial written decision which shall become final unless the Director, Indian Health Service or his/her representative modifies or reverses the decision. Any such decision by the Director of the Indian Health Service or his/her delegate shall be specific as to the reasons for such decision, and shall be considered final.

(3) Where the Board is considering issues arising under paragraph (2) of this section, the Board shall within 25 days after the conclusion of the hearing, notify all parties in writing of its decision.

(c) In any case where the officer has rescinded a contract under paragraph (b) or (c) of this section, he/she may declare to enter into a new contract agreement with the Contractor until such time as he/she is satisfied that the basis for the rescission has been corrected.


(End of clause)

Clause No. 17—Key Personnel (June 1977)

Where "key personnel" have been identified in this contract, it has been determined that such named personnel are necessary for the successful performance of the work under this contract and the Contractor agrees to assign such personnel to the performance of the work under this contract, and shall not reassign or remove any of them without the consent of the Contracting Officer. Whenever, for any reason, one or more of the aforementioned personnel is unavailable for assignment for work under the contract, the Contractor shall immediately notify the Contracting Officer to that effect and shall, subject to the approval of the Contracting Officer, replace such personnel with personnel of substantially equal ability and qualifications.

(End of clause)

Clause No. 18—Litigation and Claims (June 1977)

The Contractor shall give the Contracting Officer immediate notice in writing of (a) any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to, the performance of any subcontract hereunder; and (b) any claim against the Contractor the cost and expense of which is allowable under the clause entitled "Allowable Cost," except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent papers received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the approval of the Contracting Officer, settle any such action or claim. If required by the Contracting Officer, the Contractor shall (a) effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and (b) authorize representatives of the Government to settle any such action or claim and to represent the Contractor in, or to take charge of, any action. If the settlement or defense of an action or claim is undertaken by the Contractor, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any cost resulting from the loss hereof to the extent that the Contractor would have been compensated by insurance which was required by law or regulation or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence.

In any event, unless otherwise expressly provided in this contract, the Contractor shall not be reimbursed or indemnified by the Government for any liability loss, cost or expense, which the Contractor may incur or be subject to by reason of any loss, injury, or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

Clause No. 19—Indemnity and Insurance (June 1977)

(a) The Contractor shall indemnify and save and keep harmless the Government against any or all loss, cost, damage, claim, expense or liability whatsoever, because of accident or injury to persons or property or others occurring in connection with any program included as a part of this contract, by procuring where applicable, the insurance described below:

(b) The Contractor shall secure, pay the premium for, and keep in force until the expiration of this contract, or any renewal period thereof, insurance as follows:

   (1) The Contractor shall provide workers' compensation insurance as required by law of the state.
   (2) The Contractor shall provide medical, dental and other health insurance as follows:

   (3) The Contractor shall provide property damage liability insurance with limits of not less than $25,000 for each occurrence and $500,000 for each accident.
   (4) The Contractor shall provide automobile bodily injury liability insurance with limits of not less than $50,000 for each person and $500,000 for each accident.
   (5) The Contractor shall provide product liability insurance with limits of not less than $50,000 for each accident.
   (6) The Contractor shall provide professional malpractice insurance where medical, dental and other health professional services are involved.
   (7) The Contractor shall provide liability insurance not specifically mentioned when required.

(c) Each policy of insurance shall contain an endorsement providing that cancellation of
by the insurance company shall not be effective unless a copy of the cancellation is mailed (registered) to the Contracting Officer 30 days prior to the effective date of cancellation.

(d) A certificate of each policy of insurance, and any change therein, shall be furnished to the Contracting Officer immediately upon receipt from the insurance company.

(e) Insurance companies of the Contractor shall be satisfactory to the Contracting Officer. When in his/her opinion an insurance company is not satisfactory for reasons that will be stated, the Contractor shall provide insurance through companies that are satisfactory to the Contracting Officer.

(f) Each policy of insurance shall contain a provision that the insurance carrier waives any rights it may have to raise as a defense the tribe's sovereign immunity from suit, but such waivers shall extend only to claims the amount and nature of which are within the coverage and limits of the policy of insurance. The policy shall contain no provision, either expressed or implied, that will serve to authorize or empower the insurance carrier to waive or otherwise limit the tribe's sovereign immunity outside or beyond the coverage and limits of the policy insurance.

(End of clause)

Clause No. 20—Overtime (June 1977)

Except as provided in this contract, the Contractor shall not perform overtime work under or in connection with this contract for which premium compensation is required to be paid, without specific written approval from the Contracting Officer.

(End of clause)

Clause No. 21—Foreign Travel (June 1977)

Foreign travel shall not be performed without the prior written approval of the Contracting Officer. As used in this clause "Foreign Travel" means travel outside the United States, its Territories and Possessions, and Canada.

(End of clause)

Clause No. 22—Questionnaire and Surveys (June 1977)

In the event the performance of this contract involves the collection of information upon identical items from 10 or more persons, other than Federal employees, the Contractor shall obtain written approval from the Contracting Officer, prior to the use thereof, of schedules, questionnaires, survey plans or other documents, and any revisions thereto, intended to be used in such collection.

(End of clause)

Clause No. 23—Printing (June 1977)

Unless otherwise specified in this contract, the Contractor shall not engage in, nor subcontract for, any printing (as that term is defined in Title I of the Government Printing and Binding Regulations in effect on the effective date of this contract) in connection with the performance of work under this contract. Provided, however, That

performance of a requirement under this contract involving the reproduction of less than 5,000 production units of any one page or less than 25,000 production units in the aggregate per page, will not be deemed to be printing. A production unit is defined as one sheet, size 8 by 10 and 1/4 inches, one side only, one color.

(End of clause)

Clause No. 24—Services of Consultants (June 1977)

Except as otherwise expressly provided elsewhere in this contract, and notwithstanding the provisions of the clause of this contract entitled "Subcontracting," the prior written approval of the Contracting Office shall be required:

(a) Whenever any employee of the Contractor is to be reimbursed as a "consultant" under this contract; and

(b) For the utilization of the services of any consultant under this contract exceeding the daily rate set forth elsewhere in this contract or, if no amount is set forth, $100, exclusive of travel costs or where the services of any consultant under this contract will exceed 10 days in any calendar year. Whenever Contracting Officer approval is required, the Contractor will obtain and furnish to the Contracting Officer information concerning the need for such consultant services and the reasonableness of the fees to be paid, including but not limited to, whether fees to be paid to any consultant exceed the lowest fee charged by the Consultant to others for performing consultant services of a similar nature.

(End of clause)

Clause No. 25—Assignment of Claims (June 1977)

(a) Pursuant to the provisions of the Assignment of Claims Act of 1940, as amended (31 U.S.C. 203, 41 U.S.C. 15), if this contract provides for payments aggregating $1,000 or more, claims for moneys due or to become due under this contract may be assigned to a banking or lending institution, including any Federal lending agency, and may thereafter be further assigned and reassigned to any such institution. Any such assignment or reassignment shall cover all amounts payable under this contract and not already paid, and shall not be made to more than one party, except that any such assignment or reassignment may be made to one party as agent or trustee for two or more parties participating in such financing. Unless otherwise provided in this contract, payment to assignee of moneys due or to become due under this contract shall not, to the extent provided in said Act, as amended, be subject to reduction or setoff. (The preceding sentence applies only if this contract is made in time of war or national emergency as defined in said Act and is with the Department of Defense, the General Services Administration, the Atomic Energy Commission, the National Aeronautics and Space Administration, the Federal Aviation Agency or any other department or agency of the United States designated by the President pursuant to Clause 4 of the proviso of section 1 of the Assignment of Claims Act of 1940, as amended by the Act of May 15, 1951, 65 Stat. 41.)

(b) In no event shall copies of this contract or of any plans, specifications, or other similar documents relating to work under this contract, if marked "Top Secret," "Secret," or "Confidential," be furnished to any assignee of any claim arising under this contract or to any other person not entitled to receive the same. However, a copy of any part or all of this contract so marked may be furnished, or any information contained therein may be disclosed, to such assignee upon the prior written authorization of the Contracting Officer.

(End of clause)

Clause No. 26—Contract Work Hours and Safety Standard Act—Overtime Compensation (June 1977)

This contract, to the extent that it is of a character specified in the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-330), is subject to the following provisions and to all other applicable provisions and exceptions of such Act and the regulations of the Secretary of Labor thereunder.

(a) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any laborer or mechanic in any workweek in which he/she is employed on such work to work in excess of eight hours in any calendar day or in excess of forty hours in any workweek on work subject to the provisions of the Contract Work Hours Standards Act unless such laborer or mechanic receives compensation at a rate not less than one and one-half times his/her basic rate of pay for all such hours worked in excess of eight hours in any calendar day or in excess of forty hours in any workweek, whichever is the greater number of overtime hours.

(b) Violation: liability for unpaid wages: liquidated damages. In the event of any violation of the provisions of paragraph [a], the Contractor and any person for whose benefit such work is responsible therefor shall be liable to any affected employee for his/her unpaid wages. In addition, such Contractor and subcontractor shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic employed in violation of the provisions of paragraph [a] in the sum of $10 for each calendar day on which such employee was required or permitted to be employed on such work in excess of eight hours or in excess of the standard workweek of forty hours without payment of the overtime wages required by paragraph [a]. Withholding for unpaid wages and liquidated damages. The Contracting Officer may withhold from the Government Prime Contractor, from any moneys payable on account of work performed by the Contractor or subcontractor, such sums as may be necessary to satisfy any liabilities of such Contractor or subcontractor for unpaid wages.
and liquidated damages as provided in the provisions of paragraph (b).
(d) Subcontracts. The Contractor shall insert paragraph (d) of this clause in all subcontracts, and shall require their inclusion in all subcontracts for any tier.
(e) Records. The Contractor shall maintain payroll records containing the information specified in 29 CFR 516.2(a). Such records shall be preserved for three years from the completion of the contract. This requirement does not apply where the tribal contractor is the governing body of the tribe and the work is being performed by the tribal contractor or the tribe with its regular employees.

(End of clause)

Clause No. 27—Walsh-Healey Public Contracts Act (June 1977)

If this contract is for the manufacture or furnishing of materials, supplies, articles, or equipment in an amount which exceeds or may exceed $10,000, and is otherwise subject to the Walsh-Healey Public Contracts Act, as amended by title 41, section 258 of title 41, there are hereby incorporated by reference all representations and stipulations required by said Act and regulations issued thereunder by the Secretary of Labor, such representations and stipulations being subject to all applicable rulings and interpretations of the Secretary of Labor which are now or may hereafter be in effect. This requirement does not apply where the tribal contractor is the governing body of the tribe and the work is being performed by the tribal contractor or the tribe with its regular employees.

(End of clause)

Clause No. 28—Equal Opportunity (June 1977)

Subject to the Indian preference in training and employment of Clause 29 during the performance of this contract, the Contractor agrees as follows:
(a) The Contractor shall give preference in employment because of race, creed, color, or national origin. The Contractor will take affirmative action to ensure that applicants are employed and that employees are treated during employment, without regard to their race, creed, color, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoffs or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship.

(End of clause)

Clause No. 29—Indian Preference in Training and Employment (June 1977)

(a) The Contractor shall give preference in employment for all work performed under the contract, including subcontracts thereunder, to qualified Indians regardless of age, religion, or sex, and to the extent feasible consistent with the efficient performance of the contract, provide for meaningful training opportunities to Indians, regardless of age, religion, or sex, that are not fully qualified to perform under the contract. The Contractor shall comply with any Indian preference requirements established by the Tribe receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.
(b) If the Contractor or any of its subcontractors is unable to fill its employment openings after giving full consideration to Indians as required in paragraph (a) above, these employment openings may then be filled by other than Indians under the conditions set forth in the Equal Opportunity clause of this contract.
(c) The Contractor agrees to include this clause or one similar thereto in all subcontracts issued under the contract.

(End of clause)

Clause No. 30—Certificate of Nonsegregated Facilities (June 1977)

By signing the contract the Contractor certifies that it does not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. It certifies further that it will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it will not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. The Contractor agrees that a breach of this certification is a violation of the Equal Opportunity clause in this contract. As used in this certification, the term “segregated facilities” means any waiting rooms, work areas, rest rooms, and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees which are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin, because of habit, local custom or otherwise. It further agrees that (except where it has obtained identical certifications from proposed subcontractors for specific time periods) it will obtain identical certifications from proposed subcontractors prior to the award of subcontracts exceeding $10,000 which are not exempt from the provisions of the Equal Opportunity clause; that it will retain such certifications in its files; and that it will forward the following notice to such proposed subcontractors:

Notice to prospective subcontractors of requirement for certifications of nonsegregated facilities. A certificate of Nonsegregated Facilities must be submitted prior to the award of a subcontract exceeding $10,000 which is not exempt from the provisions of the Equal Opportunity clause.

The certification may be submitted either for each subcontract or for all subcontracts during a period (i.e., quarterly, semiannually, or annually).
Clause No. 31—Convict Labor (June 1977)

In connection with the performance of work under this contract, the Contractor agrees not to employ any person undergoing sentence of imprisonment at hard labor, except as provided by Public Law 89-178, September 10, 1965 (18 U.S.C. 4082(c)(2)), and Executive Order No. 11755, December 29, 1973.

(End of clause)

Clause No. 32—Officials Not To Benefit (June 1973)

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this contract, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this contract if made with a corporation for its general benefit.

(End of clause)

Clause No. 33—Buy American Act for Supply and Service Contracts (June 1977)

(a) In acquiring end products, the Buy American Act (41 U.S.C. 40a-d) provides that the Government give preference to domestic source end products. For the purpose of this clause:

(i) “Components” means those articles, materials, and supplies which are directly incorporated in the end products;

(ii) “End products” means those articles, materials, and supplies which are to be acquired under this contract for public use; and

(iii) A “domestic source end product” means (A) an unmanufactured end product which has been mined or produced in the United States and (B) an end product manufactured in the United States if the cost of the components thereof which are mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. For the purpose of this (a)(i)(B), components of foreign origin of the same type or kind as the products referred to in (b) or (ii) or (iii) of this clause shall be treated as components mined, produced or manufactured in the United States.

(b) The Contractor agrees that there will be delivered under this contract only domestic source end products, except end products:

(i) Which are for use outside the United States;

(ii) Which the Government determines are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality;

(iii) As to which the Secretary determines the domestic preference to be inconsistent with the public interest; or

(iv) As to which the Secretary determines the cost to the Government to be unreasonable.

(The foregoing requirements are administered in accordance with Executive Order No. 10582, dated December 17, 1954).

(End of clause)

Clause No. 34—Anti-Kickback Act (June 1977)

(a) Public Law 89-665, September 2, 1960 (41 U.S.C. 51-54) among other things prohibits the payment, directly or indirectly, by or on behalf of a subcontractor in any tier under any Government negotiated contract of any fee, gift or gratuity to the prime contractor or any higher tier subcontractor or any officer, agent, partner or employee thereof, as an inducement or acknowledgment for the award of a subcontract or order.

(b) The provisions of Public Law 86-665 are applicable to this contract and any subcontracts entered into under the contract.

(End of clause)

Clause No. 35—Use of Indian Business Concerns (June 1977)

(a) As used in this clause, the term “Indian business concern” means Indian organizations or an Indian-owned economic enterprise as defined in 42 FR 36,204(i).

(b) The Contractor agrees to give preference to qualified Indian business concerns in the awarding of contracts entered into under the contract consistent with the efficient performance of the contract. The contractor shall comply with any preference requirements regarding Indian business concerns established by the Tribe(s) receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.

(c) If no Indian business concerns are available under the conditions in paragraph (b) above, the Contractor agrees to accomplish the maximum amount of subcontracting, as the Contractor determines is consistent with its efficient performance of the contract, with small business concerns, labor surplus area concerns or minority business concerns, the definitions for which are contained in Subparts 1-1.7, 1-1.8, and 1-1.13 of the Federal Procurement Regulations. The contractor is not, however, required to establish a small business, labor surplus, or minority business subcontracting program as described in 1-1.710-3(b), 1-1.805-3(b), and 1-1.1310-2(b), respectively, of the Federal Procurement Regulations (41 CFR Chaper 1).

(End of clause)

Clause No. 36—Payment of Interest on Contractor’s Claims (June 1977)

(a) If an appeal is filed by the Contractor from a final decision of the Contracting Officer under the Disputes clause of this contract, denying a claim arising under the contract, simple interest on the amount of the claim finally determined owed by the Government shall be payable to the Contractor. Such interest shall be at the rate determined by the Secretary of the Treasury pursuant to P.L. 87-653, from the date the Contractor furnished to the Contracting Officer his written appeal under the Disputes clause of this contract, to the date of (1) a final judgment by a court of competent jurisdiction, or (2) mailing to the Contractor of a supplemental agreement for execution either confirming completed negotiations between the parties or carrying out a decision of a board of contract appeals.

(b) Notwithstanding (a), above, (1) interest shall be paid only from the date payment was due and less than the filing of appeals, and (2) interest shall not be paid for any period of time that the Contracting Officer determines the Contractor has unduly delayed in pursuing its remedies before a board of contract appeals or a court of competent jurisdiction.

The Contractor further agrees to comply with any rules, regulations and reporting requirements which may be imposed by the HHS Office for Civil Rights for purposes of insuring the proper exercise of this authority. The Contractor agrees to insert this clause in all subcontract(s) under this contract.

(End of clause)

Clause No. 37—Fair and Equal Treatment of Indian People (June 1977)

(a) The Contractor agrees consistent with medical needs to make no discriminatory distinctions among Indian patients or beneficiaries of this contract. For the purpose of this contract discriminatory distinctions include but are not limited to the following:

(i) denying a patient a service or benefit; or

(ii) providing any service or benefit to a patient which is different, or is provided in a different manner or at a different time from that provided to other patients under this contract; or subjecting a patient to segregation or separate treatment in any manner related to his/her receipt of any service; restricting a patient in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service or benefit; treating a patient differently from others in determining whether he/she satisfies any admission, enrollment, quota, eligibility membership, or other requirements of condition which individuals must meet in order to be provided any service or benefit; the assignment of times or places for the provision of services on the basis of discriminatory distinctions which may be made of the patients to be served.

(b) The Government reserves the right to require the Contractor to use in whole or in part whenever the Contractor fails to comply with the requirements of this clause.

(End of clause)

Clause No. 38—Price Reduction for Defective Cost or Pricing Data (June 1977)

The following clause applies to all contracts where cost and pricing data is required in accordance with P.L. 87-653.

Price Reduction for Defective Cost or Pricing Data (June 1977)

(a) If the Contracting Officer determines that any price negotiated in connection with this contract or any cost reimbursable under this contract was increased by any significant error because the Contractor, or any subcontractor pursuant to the Clause of this contract entitled “Subcontractor Cost or Pricing Data,” furnished incomplete or inaccurate cost or
Subcontractor Cost and Pricing Data (June 1977)

(a) Any officer, director, agent, employee or such other person connected in any capacity with this contract or any subcontract hereunder that embezzles, willfully misapplies, steals or obtains by fraud any of the money, funds, assets or property provided through the contract shall be fined not more than $10,000 or imprisoned for more than two years, or both; Provided, That if the amount embezzled, misapplied, stolen, or obtained by fraud does not exceed $100, such person shall be fined not more than $1,000 or imprisoned not more than one year, or both.

(b) The Contractor agrees to insert the clause in all subcontracts.

(End of clause)

Clause No. 41—Effect on Existing Rights (June 1977)

(a) Nothing in this contract shall be construed as:

(1) affecting, modifying, diminishing, or otherwise impairing the sovereign immunity for suit enjoyed by an Indian tribe; or,

(2) authorizing or requiring the termination of any existing trust responsibility of the United States with respect to the Indian people.

(End of clause)

Clause No. 42—General Services Administration (GSA) Supply Sources

Indian tribal organizations which are awarded cost-reimbursement type contracts under the Indian Self-Determination Act may be authorized to utilize GSA supply sources. The following clause will be inserted in all cost-reimbursement type contracts under which the Contractor may be authorized to acquire items for the account of the Government from GSA supply sources:

General Services Administration Supply Sources (June 1977)

The Contractor, in exercising his/her authority.

Clause No. 49—Penalties (June 1977)

(a) Nothing in this contract shall be construed as:

(1) affecting, modifying, diminishing, or otherwise impairing the sovereign immunity for suit enjoyed by an Indian tribe; or,

(2) authorizing or requiring the termination of any existing trust responsibility of the United States with respect to the Indian people.

(End of clause)
authorized to issue any instructions or directions which effect any increase or decrease in the cost of this contract or which change the period of this contract.

(End of clause)

Clause No. 2—Disputes (June 1977)

(a) Except as otherwise provided in this contract, any dispute concerning a question of fact arising under this contract which is not decided by the Contractor shall be decided by the Contracting Officer, who shall reduce his/her decision to writing and mail or otherwise furnish a copy thereof to the Contractor. The decision of the Contracting Officer shall be final and conclusive unless, within ten days after receiving a written request for a de novo proceeding under this clause, the Contractor shall be afforded an opportunity to be heard and to offer evidence in support of its appeal. Pending final decision of a dispute hereunder, the Contractor shall proceed diligently with the performance of the contract and in accordance with the Contracting Officer's decision.

(b) This "Disputes" clause does not preclude consideration of law questions in connection with decisions provided for in paragraph (a) above; Provided, That nothing in this contract shall be construed as making final the decision of any administrative official, representative, or board on a question of law.

(End of clause)

Clause No. 3—Contract Work Hours and Safety Standard Act—Overtime Compensation (June 1977)

This contract, to the extent it is of a character specified in the Contract Work Hours and Safety Standards Act (40 U.S.C. 327–330), is subject to the following provisions and exceptions of such Act and the regulations of the Secretary of Labor thereunder.

(a) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any laborer or mechanic in any workweek in which he/she is employed on such work to work in excess of eight hours in any calendar day or in excess of forty hours in any workweek on work subject to the provisions of the Contract Work Hours Standard Act unless such laborer or mechanic receives compensation at a rate not less than one and one-half times his/her basic rate of pay for all such hours worked in excess of eight hours in any calendar day or in excess of forty hours in such workweek, whichever is the greater numbers of overtime hours.

(b) Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the provisions of paragraph (a), the Contractor and any subcontractor hereunder shall be liable to any affected employee for his/her unpaid wages. In addition, such Contractor and subcontractor shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic employed in violation of the provisions of paragraph (a) at the sum of $10 for each calendar day on which such employee was required or permitted to be employed on such work in excess of eight hours or in excess of the standard workweek of forty hours without payment of the overtime wages required by paragraph (a). (End of clause)

Clause No. 4—Walsh-Healey Public Contracts Act (June 1977)

If this contract is for the manufacture or furnishing of materials, supplies, articles, or equipment in an amount which exceeds or may exceed $1,000 and is otherwise subject to the Walsh-Healey Public Contracts Act, as amended (41 U.S. Code 35–44), there are hereby incorporated by reference all representations and stipulations required by the Secretary of Labor, such representations and stipulations being subject to all applicable rulings and interpretations of the Secretary of Labor which are now or may hereafter be in effect. This requirement does not apply where the tribal contractor is the governing body of the Tribe and the work is being performed by the tribal organization or Tribe with its own regular employees.

(End of Clause)

Clause No. 5—Convict Labor (June 1977)

In connection with the performance of work under this contract, the Contractor agrees not to employ any person undergoing sentence of imprisonment at hard labor except as provided by Public Law 89–176, September 10, 1965 (16 U.S.C. 6820c);(2) and Executive Order No. 11755, December 29, 1973.

(End of clause)

Clause No. 6—Notices to the Government of Delays (June 1977)

Whenever the Contractor has knowledge that any actual or potential situation is delaying or threatens to delay the timely performance of this contract, the Contractor shall within ten days give notice thereof, including all relevant information or respect thereto, to the Contracting Officer.

(End of clause)

Clause No. 7—Assignment of Claims (June 1977)

(a) Pursuant to the provisions of the Assignment of Claims Act of 1940, as amended (31 U.S.C. 203, 41 U.S.C. 15), if this contract provides for payment aggregating $1,000 or more, claims for moneys due or to become due the Contractor from the Government under this contract may be assigned to a bank, trust, or other financing institution, including any Federal lending agency, and may thereafter be further assigned and reassigned to any such institution. Any such assignment or reassignment shall cover all amounts payable under this contract and not already paid, and shall not be made to more than one party, except that any such assignment or reassignment may be made to one party as agent or trustee for two or more parties participating in such financing. Unless otherwise provided in this contract payments to assignee of any moneys due or due to become due under this contract shall not, to the extent provided in said Act, as amended, be subject to reduction or setoff. (The preceding sentence applies only if this contract is made in time of war or national emergency as defined in said Act and is with the Department of Defense, the General Services Administration, the Atomic Energy Commission, the National Aeronautics and Space Administration, the Federal Aviation Agency, or any other department or agency of the United States designated by the President pursuant to Clause 4 of the proviso of section 1 of the Assignment of Claims Act of 1940, as amended by the Act of May 15, 1951, 65 Stat. 417.)

(b) In no event shall copies of this contract or any plans, specifications, or other similar documents relating to work under this contract, if marked "Top Secret," "Secret," or "Confidential," be furnished to any assignee of any claim arising under this contract or to any other person not entitled to receive the same. However, a copy of any part or all of this contract so marked may be furnished, or any information contained therein may be disclosed, to such assignee upon the prior written authorization of the Contracting Officer.

(End of clause)

Clause No. 8—Officials Not To Benefit (June 1977)

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this contract, or to any benefit that may arise therefrom, but this provision shall not be construed to extend to...
this contract if made with a corporation for its general benefit.

(End of clause)

Clause No. 9—Anti-Kickback Act (June 1977)

(a) Public Law 86-695, September 2, 1960
(41 U.S.C. 51-54) among other things, prohibits the payment, directly or indirectly, by or on behalf of a subcontractor in any tier under any Government negotiated contract of any fee, gift, or gratuity to the prime contractor or any officer, agent, partner or employee thereof, as an inducement or acknowledgement for the award of a subcontract or order.

(b) The provisions of Public Law 86-695 are applicable this contract and any subcontracts entered into under the contract.

(End of clause)

Clause No. 10—Penalties (June 1977)

Any officer, director, agent, employee or such other person connected in any capacity with this contract or any subcontract therewith that embezzles, willfully misapposes, steals or obtains by fraud any of the money, funds, assets or property provided through the contract shall be fined not more than $10,000 or imprisoned for not more than two years, or both: Provided, That if the amount embezzled, misapplied, stolen, or obtained by fraud does not exceed $100, such person shall be fined not more than $100 or imprisoned not more than one year, or both.

(b) The Contractor agrees to insert this clause in all subcontracts.

(End of clause)

Clause No. 11—Buy American Act (June 1977)

(a) In acquiring end products, the Buy American Act (41 U.S.C. 10a-d) provides that the Government give preference to domestic source end products. For the purpose of this clause:

(i) “Components” means those articles, materials, and supplies, which are directly incorporated in the end products.

(ii) “End products” means those articles, materials, and supplies, which are to be acquired under this contract for public use.

(iii) “A domestic source end product” means (A) an unmanufactured end product which has been mined or produced in the United States and (B) an end product manufactured in the United States if the cost of the components thereof which are mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. For the purposes of this clause:

(a) “B” components of foreign origin of the same type or kind as the products referred to in (b) (i) or (iii) of this clause shall be treated as components mined, produced, or manufactured in the United States.

(b) The Contractor agrees that there will be delivered under this contract only domestic source end products, except end products:

(1) Which are for use outside the United States;

(ii) Which the Government determines are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality;

(iii) As to which the Secretary determines the domestic preference to be inconsistent with the public interest to be served;

(iv) As to which the Secretary determines the cost to the Government to be unreasonable. (The foregoing requirements are administered in accordance with Executive Order No. 10682, dated December 17, 1954).

(End of clause)

Clause No. 12—Equal Opportunity (June 1977)

Subject to the Indian preference requirements of Clause 17, during the performance of this contract the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, creed, color, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to race, creed, color, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff and termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employment placed by him or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, creed, color, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which it has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or representative of (i) The Contractor’s commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, and of the rules, regulations and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to its books, records, and accounts by the contracting agency and the secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor’s noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, orders, this contract may be cancelled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965. In such cases, sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance.

Provided, however, That in the event the Contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may require the United States to enter into such litigation to protect the interests of the United States.

(End of clause)

Clause No. 13—Certificate of Nonsegregated Facilities (June 1977)

By signing the contract the Contractor certifies that it does not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. It certifies further that it will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it will not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. The Contractor agrees that a breach of this certification is a violation of the Equal Opportunity clause in this contract. As used in this certification, the term "Segregated facilities" means any waiting rooms, work areas, rest rooms and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees which are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin, because of habit, local custom, or otherwise. It further agrees that (except where it has obtained identical certification from proposed subcontractors for specific time periods) it will obtain identical certifications from proposed subcontractors prior to the award of the contract and any subcontracts exceeding $10,000 which are not exempt from the provisions of the Equal Opportunity clause of this contract or with any of the said certifications in its files; and that it will forward the following notice to such proposed subcontractors (except where the proposed subcontractors have submitted
$10,000 which is not exempt from the nonsegregated facilities. A certification of identical certifications for specific time periods:

Notice to prospective subcontractors of nonsegregated facilities. A certification of Nonsegregated Facilities must be submitted prior to the award of a subcontract exceeding $10,000 which is not exempt from the provisions of the Equal Opportunity clause. The certification may be submitted either for each subcontract or all subcontracts during a period (i.e., quarterly, semiannually, or annually).

Clause No. 14—Subcontracting (June 1977)
The Contractor shall not enter into subcontracts for any of the work contemplated under this contract without obtaining the prior written approval of the Contracting Officer and subject to such conditions and provisions as he/she may deem necessary, in his/her discretion, to protect the interests of the Government. Provided, however, That notwithstanding the foregoing, unless otherwise provided herein, such prior written approval shall not be required for the purchase by the Contractor of articles, supplies, equipment and services which are both necessary for and merely incidental to the performance of the requirements under this contract; Provided, further, however, That the aforesaid right of Contractor to engage such services shall in no event be construed to permit the Contractor to subcontract with a third-party for the performance of any major function contemplated under this contract to be performed by the Contractor, and Provided, further, however, That no provision of this clause and no such approval by the Contracting Officer of any subcontract shall be deemed in any event or in any manner to provide for the incurrence of any obligation of the Government in addition to the total contract price.

Clause No. 15—Competition in Subcontracting (June 1977)
The Contractor agrees to select subcontractors on a competitive basis to the maximum practical consistent with the objectives and requirements of this contract.

Clause No. 16—Use of Indian Business Concerns (June 1977)
(a) As used in this clause, the term, "Indian business concern" means Indian organizations or an Indian-owned economic enterprise as defined in 42 CFR 36.204(i).
(b) The Contractor agrees to give preference to qualified Indian business concerns in the awarding of any subcontract entered into under the contract consistent with efficient performance of the contract. The Contractor shall comply with any preference requirements regarding Indian business concerns in the awarding of any subcontract(s) receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.
(c) If no Indian business concerns are available, the conditions in paragraph (b) above, the Contractor agrees to accomplish the maximum amount of subcontracting, as the Contractor determines is consistent with its efficient performance of the contract, including small business concerns, labor surplus area concerns or minority business enterprises, the definitions for which are contained in Subparts 1-1.7, 1-1.8, and 1-1.13 of the Federal Procurement Regulations. The Contractor is not, however, required to establish a small business, labor surplus, or minority business subcontracting program as described in sections 1-1.710-3(b), 1-1.805-3(b), and 1-1.1310-2(b), respectively of the Federal Procurement Regulations (41 CFR Chapter 1).

Clause No. 17—Indian Preference in Training and Employment (June 1977)
(a) The Contractor shall give preference in employment for all work performed under the contract, including subcontracts thereunder, to qualified Indians regardless of age, religion, or sex, and to the extent feasible, consistent with the efficient performance of the contract, provide training and employment opportunities to Indians, regardless of age, religion, or sex, that are not fully qualified to perform under the contract. The Contractor shall comply with any Indian preference requirements established by the tribe receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.
(b) The Contractor or any of its subcontractors is unable to fill its employment openings after giving full consideration to Indians as required in paragraph (a) above, these employment openings may then be filled by other than Indians under the conditions set forth in the Equal Opportunity clause of this contract.
(c) The Contractor agrees to include this clause or one similar thereto in all subcontracts issued under this contract.

Clause No. 18—Inspection (June 1977)
The Government, through any authorized representatives, has the right, at all reasonable times, to inspect, or otherwise evaluate the work, or being performed hereunder and the premises in which it is being performed. If any inspection, or evaluation is made by the Government on the premises of the Contractor or a subcontractor, the Contractor shall provide and shall require its subcontractors to provide all reasonable facilities and assistance for the safety and convenience of the Government representatives in the performance of their duties. All inspections and evaluations shall be performed in such a manner as will not unduly delay the work.

Clause No. 19—Changes (June 1977)
The Contracting Officer may at any time, with the consent of the Contractor, by a written order, and without notice to the sureties, if any, make changes, within the general scope of this contract, in any one or more of the following: (i) drawings, designs, or specifications, (ii) place of inspection, delivery, or acceptance, and (iii) the amount of Government-furnished property. If any such change causes an increase or decrease in the cost of, or the time required for performance of, this contract, or otherwise affects any of the provisions of this contract, whether changed or not changed by any such order, an equitable adjustment shall be made (i) in the contract price or time of performance, or both, and (ii) in such provisions of the contract as may be so affected, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within thirty (30) days from the date of receipt by the Contractor of the notification of change. Provided, however, the Contractor is not, however, the Contracting Officer, if he/she decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Where the cost of property made obsolete or excess as a result of a change is included in the Contractor’s claim for adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of such property. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled “Disputes.” However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

Clause No. 20—Retrocession (June 1977)
(a) The Indian tribe that initially requested this contract may also request its retrocession, notwithstanding the fact that the Contractor may be a tribal organization other than the Tribe.
(b) Should the Tribe request retrocession of the contract and the Contractor is other than the Tribe, the Contracting Officer will notify the Contractor of the request and in consultation with the Tribe and the Contractor establish the effective date of the retrocession. The retrocession will become effective no later than 120 days after the Contracting Officer receives the Tribe’s request unless the Tribe and the Contracting Officer mutually agree on a later date.
(c) Immediately after receipt of the request for retrocession and where applicable, notifying the Contractor, the Contracting Officer will meet with the Contractor and, where applicable, the tribal governing body or bodies mutually agree to:
(1) A plan for the orderly transfer of responsibilities;
(2) A plan for inventorying materials and supplies on hand;
(3) An accounting for funds, including but not limited to current and anticipated obligations:
(4) The cost of operation until retrocession;
(5) The identification of all records relating to the contract and the contracted function.

Clause No. 21—Assumption and Reassumption of Contract Programs (June 1977)
When the Contracting Officer determines that the performance of a
Director under these regulations involves (1) the violation of the rights or endangerment of the health, safety, or welfare of any person or (2) gross negligence or the mismanagement in the handling or use of funds under the contract, the Contracting Officer will, in writing, notify the Contractor of such determination and will request that the Contractor take such corrective action within such period of time as the Secretary may prescribe.

(b) When the Director or his/her delegate determines that a Contractor has not taken corrective action (as prescribed by him/her under paragraph (a) of this section) to his/her satisfaction, he/she may, after the Contractor has been provided an opportunity for a hearing in accordance with paragraph (c) of this section, rescind the contract in whole or in part and, if he/she deems it appropriate, assume or resume control or operation of the program, activity, or service involved.

(c)(1) When the Director or his/her delegate has made a determination described in paragraph (b) of this section, he/she shall in writing notify the Contractor of such determination and of the contractor's right to request a review of such determination and of the determination described in paragraph (a) of this section. Such notification by the Director or his/her delegate shall set forth the reason for the determination in sufficient detail to enable the Contractor to respond and shall inform the Contractor of its rights to a hearing on the record before a Contract Appeals Board described in paragraph (d) of this section. Upon the request of the Contractor for a hearing, the Board established pursuant to paragraph (d) of this section, shall in writing within 10 days of the establishment notify the Contractor of the time, place and date of the hearing which will be held not later than 45 days after the request for a hearing.

(c)(2) Where the Director or his/her delegate determines that a Contractor's performance under a contract awarded under this subsection poses an immediate threat to the safety of any person, he/she may, after the Contractor has been provided an opportunity for a hearing on the record before a Contract Appeals Board established pursuant to paragraph (d) of this section to be held within 10 days of such request, rescind the contract in whole or in part and, if he/she deems it appropriate, assume or resume control or operation of the program, activity, or service involved. Upon such a decision he/she shall equitably adjust the delivery or performance dates, the contract price, or both, and any other contractual provision affected by the delay.

(d)(1) The Contract Appeals Board shall be composed of 3 persons appointed by the Director, Indian Health Service. Such persons may not be selected from the immediate office of any person participating in the determinations at issue. The Board shall afford the Contractor the right:

(i) To notice of the issues to be considered;
(ii) To be represented by counsel;
(iii) To present witnesses on contractor's behalf;
(iv) To cross-examine other witnesses, either orally or through written interrogation; and
(v) To compel the appearance of Indian Health Service personnel or to take depositions of such persons at reasonable times and places.

(2) The Contract Appeals Board shall make an initial written decision which shall become final within 20 days unless the Director, Indian Health Service or his/her representative modifies or reverses the decision. Any such decision by the Director of the Indian Health Service or his/her representative shall be in writing, shall be specific as to the reasons for such decision, and shall be considered final.

(3) Where Board is considering issues arising under paragraph (2) of this section, the Board shall within 25 days after the conclusion of the hearing, notify all parties in writing of its decision.

(e) In any case where the officer has rescinded a contract under paragraphs (b) or (c) of this section, he/she may decline to enter into a new contract agreement with the Contractor until such time as he/she is satisfied that the basis for the rescission has been corrected.

Nothing in this section shall be construed as contravening the Occupational Safety and Health Act of 1970 (84 Stat. 1500) as amended (29 U.S.C. 651).

(End of clause)

Clause No. 22—Payment of Interest on Contractual Claims (June 1977)

(a) If an appeal is filed by the Contractor from a final decision of the Contracting Officer under the Disputes clause of this contract, denying a claim arising under the contract, simple interest on the amount of the claim finally determined owed by the Government shall be payable to the Contractor. Such interest shall be at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 87, from the date the Contractor furnished to the Contracting Officer his written appeal under the Disputes clause of this contract, to the date of (1) a final judgment by a court of competent jurisdiction, or (2) mailing to the Contractor of a supplemental agreement for execution, or (3) completion of negotiations between the parties or carrying out a decision of a board of contract appeals.

(b) Notwithstanding (a), above, (1) interest shall be applied only from the date payment was due, if such date is later than the filing of appeal, and (2) interest shall not be paid for any period of time that the Contracting Officer determines the Contractor has unduly delayed in pursuing its remedies before a board of contract appeals or a court of competent jurisdiction.

(End of clause)

Clause No. 23—Government-Furnished Property (June 1977)

(a) The Government shall deliver to the Contractor, for use in connection with and under the terms of this contract, the property described elsewhere in this contract, together with such related data and information as the Contracting Officer may request and as may reasonably be required for the intended use of such property (hereinafter referred to as "Government-Furnished Property"). The delivery or performance dates for the supplies or services to be furnished by the Contractor under this contract are based upon the expectation that Government-Furnished Property suitable for use will be delivered to the Contractor at the times stated elsewhere in this contract or, if not so stated, in sufficient time to enable the Contractor by such time or times, to meet such delay or performance dates. In the event that Government-Furnished Property is not delivered to the Contractor to meet such delivery or performance dates, the Contracting Officer shall, upon timely written request made by the Contractor, make a determination of the delay occasioned, and the Contractor shall equitably adjust the delivery or performance dates, the contract price, or both, and any other contractual provision affected by the delay. In the event that Government-Furnished Property is received by the Contractor in a condition not suitable for its intended use, the Contractor shall, upon receipt thereof, notify the Contracting Officer of such fact and, as directed by the Contracting Officer, either (1) return such property at the Government's expense or otherwise dispose of such property, or (2) effect repairs or modifications. Upon completion of (1) or (2) above, the Contracting Officer upon timely written request of the Contractor shall equitably adjust the delivery or performance dates, the contract price, or both, and any other contractual provision affected by the return, disposition, repair, or modification. The foregoing provisions for adjustment are exclusive and the Government shall not be liable to suit for breach of contract by reason of any delay in delivery of Government-Furnished Property or delivery of such property in a condition not suitable for its intended use.

(b) By notice in writing the Contracting Officer may decrease the property furnished or to be furnished by the Government under this contract. In any such case, the Contracting Officer upon timely written request of the Contractor shall equitably adjust the delivery or performance dates, the contract price, or both, and any other contractual provision affected by the decrease.

(End of clause)
been assumed by the Government under this contract, the Government shall replace such items or the Contractor shall make such repair or replacement of the property, as the Contracting Officer directs; provided, however, that if the Contractor cannot effect such repair within the time required, the Contractor may reject such property. The contract price includes no compensation to the Contractor for the performance of any repair or replacement for which the Government is responsible; and an equitable adjustment will be made in the contract price for any such repair or replacement of Government-Furnished Property made at the direction of the Government. Any repair or replacement for which the Contractor is responsible under the provisions of this contract shall be accomplished by the Contractor at its own expense.

(f) The Contractor also agrees to maintain and administer, in accordance with sound business practice, a property control system which will provide the following: Contract number, item number, item quantity received; issued; and balance on hand; posting reference to include date received, issued unit price and location; marking or identification of item; adequate maintenance, storage, and security of Government-Furnished Property, until disposed of by the Contractor in accordance with this clause. The Contractor further agrees to receive promptly for all Government property in a form and manner as prescribed by the Contracting Officer.

(g) The Contractor agrees to make available to authorized representatives of the Contracting Officer at all reasonable times at the office of the Contractor all of its property records under this contract, and access to any premises where any of the Government-Furnished Property is located.

(h) (i) The Contractor shall not be liable for any loss or damage to the Government-Furnished Property, or for expenses incidental to such loss or damage, except that the Contractor shall be liable for any such loss or damage (including expenses incidental thereto): (A) Which results from willful misconduct or lack of good faith on the part of any of the Contractor's representatives, including, but not limited to, the part of any of its managers, superintendents, or other equivalent representatives who have supervision or direction of all or substantially all of the Contractor's business, or all or substantially all of the Contractor's operations at any one plant, laboratory, or separate location in which this contract is being performed; or

(ii) Which results from a failure on the part of the Contractor, due to the willful misconduct or lack of good faith on the part of any of its directors, officers, or other representatives mentioned in subparagraph (a) above, to maintain and administer, in accordance with sound business practice, the program for maintenance, repair, protection and preservation of Government-Furnished Property as required by subparagraph (e) above; or

(C) For which the Contractor is otherwise responsible under the express terms of the contract or clauses designated in this contract; or

(D) Which results from a risk expressly required to be insured under some other provision of this contract, or of the schedules, or task orders thereunder, but only to the extent of such insurance actually procured and maintained, whichever is greater; or

(E) Which results from a risk which is in fact expressly insured or for which the Contractor is otherwise reimbursed but only to the extent of such insurance or reimbursement; Provided, That, if more than one of the above exceptions shall be applicable in any case, the Contractor's liability under any one exception shall not be limited by any other exception.

(ii) The Contractor represents that it is not including the price hereunder, and agrees that it will not hereafter include in any price to the Government, any charge or reserve for insurance (including self-insurance funds or reserves) covering loss or destruction of or damage to the Government-Furnished Property, except the amount that the risk of loss is insured on the Contractor under (i)(C) above, or insurance has been required under (i)(D) above.

(iii) Upon the happening of loss or destruction of or damage to any Government-Furnished Property, the Contractor shall notify the Contracting Officer thereof and shall take all reasonable steps to protect the Government-Furnished Property from further damage, separate the damaged and undamaged Government-Furnished Property in the best possible order, and furnish to the Contracting Officer a statement of:

(A) The lost, destroyed and damaged Government-Furnished Property;

(B) The time and origin of the loss, destruction or damage;

(C) All known interest in commingled property of which the Government-Furnished Property is a part and

(D) The insurance, if any, covering any part or all of the Government-Furnished Property which has been damaged.

The Contractor shall be reimbursed for the expenditures made by it in performing its obligations under the subparagraph (iii), to the extent approved by the Contracting Officer and set forth in a supplemental agreement or amendment to this contract.

(iv) With the prior written approval of the Contracting Officer after loss or destruction of or damage to Government-Furnished Property, and subject to such conditions and limitations as may be imposed by the Contracting Officer, the Contractor may, in order to minimize the loss to the Government or in order to permit resumption of business or the like, sell for the account of the Government any item of Government-Furnished Property which has been damaged beyond practicable repair, or which is so commingled or combined with property of other, including the Contractor, that separation is impracticable.

(v) Except to the extent of any loss or destruction of or damage to Government-Furnished Property for which the Contractor is relieved of liability under the foregoing provisions of this clause, and except for reasonable wear and tear or depreciation, or the utilization of the Government-Furnished Property in accordance with the provisions of this contract, the Government-Furnished Property (other than property permitted to be sold) shall be returned to the Government in as good condition as when received by the Contractor in connection with this contract, or as repaired under paragraph (e) above.

(vi) In the event the Contractor is reimbursed or compensated for any loss or destruction of or damage to the Government-Furnished Property, it shall equitably reimburse the Government. The Contractor shall do nothing to prejudice the Government's rights to recover against third parties for any such loss, destruction or damage and, upon the request of the Contracting Officer, shall include the Government's reasonable assistance and cooperation (including assistance in the prosecution of suit and the execution of instruments of assignment in favor of the Government) in obtaining recovery.

(i) Upon completion or expiration of this contract, any Government property which has not been consumed in the performance of this contract or which has not been previously disposed of in accordance with the provisions of this clause, or for which the Contractor has not otherwise been relieved of responsibility, shall be disposed of as the Contracting Officer may direct. The Contractor shall in no way be relieved of responsibility for Government property without the prior written approval of the Contracting Officer.

(j) If the Contracting Officer determines that the interests of the Government require removal of any Government-Furnished Property, or if the Contractor shall not, in the opinion of the Contracting Officer, dispose of any Government-Furnished Property to be in excess of its need under this contract such Government-Furnished Property shall be disposed of in the same manner as covered by paragraph (i) above. In the event that the Government-Furnished Property is insured under any Government-Furnished Property under this paragraph (j) or paragraph (i) above, upon timely written request of the Contractor, an equitable adjustment shall be made in the contract price to cover the direct cost to the Contractor of such property damage occasioned thereby.

(End of clause)

Clause No. 23—Examination of Records by the Comptroller General (June 1977)

(a) The Contractor agrees that the Comptroller-General of the United States or any of his/her duly authorized representatives shall, until expiration of 3 years after final payment under this contract, or of the time periods for the particular records specified in Part 1–20 of the Federal Procurement Regulations (41 CFR Part 1–20), whichever expires earlier, have access to and the right to examine any directly pertinent books, documents, papers, and records of the Contractor involving transactions related to this contract.

(b) The Contractor further agrees to include in all its subcontracts hereunder a provision to the effect that the subcontractor agrees that the Comptroller General of the United States or any of his/her duly authorized representatives shall, until expiration of 3
Clause No. 25—Indemnity and Insurance (June 1977)

(a) The Contractor shall indemnify and save and keep harmless the Government against any or all loss, cost, damage, claim, expense or liability whatsoever, because of accident or damage to any property or property or persons occurring in connection with any program, project or activity as a part of this contract, by providing where applicable, the insurance described below:

(b) The Contractor shall, as a recipient of Federal financial assistance, accept and assume by this contract, any liability or obligations to indemnify the Government, including any indemnification agreements which may be made of the patients to be served, by the contractor or the tribe, by the contractor and the tribe, and by the contractor and the tribe's employees.

(c) Each policy of insurance shall contain a provision stating the liability assumed by the Contractor under this contract.

(d) A certificate of each policy of insurance shall be furnished to the Contracting Officer within 90 days of the effective date of the contract, or of a subsequent change in the insurance coverage.

(e) Insurance companies of the Contractor shall provide insurance through companies that are satisfactory to the Contracting Officer.

(f) Each policy of insurance shall contain a provision that the insurance carrier waives any rights it may have to raise as a defense the tribe’s sovereign immunity from suit, but such waiver shall extend only to claims the amount and nature of which are within the coverage and limits of the policy of insurance. The policy shall contain no provision, either expressed or implied, that will serve to authorize or empower the insurance carrier to waive or otherwise limit the tribe's sovereign immunity outside or beyond the coverage and limits of the policy of insurance.

 Clause No. 26—Fair and Equal Treatment of Indian People (June 1977)

(a) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(b) The Contractor further agrees to make no discriminatory distinctions among Indian patients or contractors.

(c) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(d) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(e) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(f) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(g) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(h) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(i) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(j) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(k) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(l) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(m) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(n) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(o) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(p) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(q) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(r) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(s) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(t) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(u) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(v) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(w) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(x) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(y) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

(z) The Contractor agrees to make no discriminatory distinctions among Indian patients or contractors.

Clause No. 27—Reports to the Indian People and Annual Reports (June 1977)

(a) The Contractor, as a recipient of Federal financial assistance, shall make reports and information available to the Indian people served or represented by the Contractor. Such reports shall reflect how the Federal assistance funds were utilized to benefit the Indian people served or represented as follows: (specific reporting requirements, forms and methods of distribution to the Indian people will be prescribed in the scope of the contract.)

(b) Annual reports.

(f) Each fiscal year during which a contract is in effect, the Contractor shall prepare and submit to the Contracting Officer a report reflecting how the Federal assistance funds were utilized to benefit the Indian people served or represented by the Contractor. Such reports shall reflect how the Federal assistance funds were utilized to benefit the Indian people served or represented as follows: (specific reporting requirements, forms and methods of distribution to the Indian people will be prescribed in the scope of the contract.)
Price Reduction for Defective Cost or Pricing Data (June 1977)

(a) If the Contracting Officer determines that any price negotiated in connection with this contract or any cost reimbursable under this contract, which shall be determined by the Contracting Officer, is not supported by any significant sums because the Contractor, or any subcontractor pursuant to the clause of this contract entitled “Subcontractor Cost, or Pricing Data” or “Subcontractor Cost or Pricing Data—Price Adjustments,” or any subcontract cost or pricing data required, furnished incomplete or inaccurate cost or pricing data or data not current as certified in its Contractor’s Certificate of Current Cost or Pricing Data, then such price or cost shall be reduced accordingly and the contract shall be modified in writing to reflect such reduction.

(b) Failure to agree on a reduction shall be a dispute concerning a fact within the meaning of the “Disputes” clause of this contract.

(End of clause)

Clause No. 31—Subcontractor Cost and Pricing Data

The following clause should be included in all contracts when the subcontracts of the type and size described therein are contemplated.

Subcontractor Cost and Pricing Data (June 1977)

(a) The Contractor shall require subcontractors hereunder to submit in writing cost or pricing data under the following circumstances:

(1) Prior to award of any cost-reimbursable type, time and material, labor-hour, incentive, or price redeterminable subcontract, the price of which is expected to exceed $100,000; and

(2) Prior to the award of any other subcontract, the price of which is expected to exceed $100,000, or to the pricing of any subcontract change or other modification for which the price adjustment is expected to exceed $100,000, where the price or price adjustment is not based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(b) The Contractor shall require subcontractors hereunder to submit cost or pricing data under the following circumstances:

(1) Prior to award of any cost-reimbursable type, time and material, labor-hour, incentive, or price redeterminable subcontract, the price of which is expected to exceed $100,000; and

(2) Prior to award of any other subcontract, the price of which is expected to exceed $100,000, or to the pricing of any subcontract change or other modification for which the price adjustment is expected to exceed $100,000, where the price or price adjustment is not based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(c) The Contractor shall require subcontractors hereunder to certify, substantially the same form as that used in the certificate by the Prime Contractor to the Government, that, to the best of their knowledge, the price and costing data submitted under (b) above are accurate, complete, and current as of the date of the execution, which date shall be as close as possible to the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(d) The Contractor shall insert the substance of this clause including this paragraph (c) in each of its cost-reimbursement type, time and material, labor-hour, price redeterminable, or incentive subcontract hereunder, and in any other subcontract hereunder which exceeds $100,000 unless the price thereof is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation. In each such subcontract hereunder which exceeds $100,000, the Contractor shall insert the substance of the following clause:

Subcontractor Cost and Pricing Data—Price Adjustment

(a) Paragraphs (b) and (c) of this clause shall become operative only with respect to any change or other modification made pursuant to order made of this contract which involves a price adjustment in excess of $100,000. The requirements of this clause shall be limited to such price adjustments.

(b) The Contractor shall require subcontractors hereunder to submit cost or pricing data under the following circumstances:

(1) Prior to award of any cost-reimbursable type, time and material, labor-hour, incentive, or price redeterminable subcontract, the price of which is expected to exceed $100,000; and

(2) Prior to award of any other subcontract, the price of which is expected to exceed $100,000, or to the pricing of any subcontract change or other modification for which the price adjustment is expected to exceed $100,000, where the price or price adjustment is not based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(End of clause)

Clause No. 32.—Advance Payment (June 1977)

(a) Amount of Advance. At the request of the Contractor and subject to the conditions hereinafter set forth, the Government shall make an advance payment, or advance payments from time to time, to the Contractor. No advance payment shall be made hereunder. Whenever so requested by the Administering Office, all or any part thereof may be withdrawn from the Special Bank Account by checks payable to the Treasurer of the United States signed by the Contractor or countersigned by a duly authorized officer of the United States.

(b) Special Bank Account. Until all advance payments made hereunder are liquidated and the Administering Office approves in writing the release of any funds due and payable thereunder, all advance payments and all other payments under the contract shall be made by check payable to the Contractor, and be marked for deposit only in a Special Bank Account with the bank designated in paragraph (k)(3) hereof. No part of the funds in the Special Bank Account shall be mingled with other funds of the Contractor prior to withdrawal thereof from the Special Bank Account as hereinafter provided. Except as hereinafter provided, each withdrawal shall be made only by check of the Contractor countersigned on behalf of the Government by the Contracting Officer or such other person or persons as he/she may designate in writing (hereinafter called the “Countersigning Agent”). Until otherwise determined by the Administering Office, countersignature on behalf of the Government will not be required.

(c) Use of Funds. The funds in the Special Bank Account may be withdrawn by the Contractor solely for the purpose of making payments for items of allowable cost or to reimburse the Contractor for such items of allowable cost, and or such other purposes as the Administering Office may approve in writing. Any interpretation required as to the proper use of funds shall be made in writing by the Administering Office.

(d) Return of Funds. The Contractor may at any time repay all or any part of the funds advanced hereunder. Whenever so requested in writing by the Administering Office, the Contractor shall repay to the Government such part of the unliquidated balance of advance payments as shall in the opinion of the Administering Office be in excess of current requirements, or when added to total advance payments previously advanced, is in excess of the amount specified in paragraph (k)(4) hereof. In the event the Contractor fails to repay such part of the unliquidated balance of advance payments when so requested by the Administering Office, all or any part thereof may be withdrawn from the Special Bank Account by checks payable to the Treasurer of the United States signed by the Countersigning Agent and applied in reduction of advance payments then outstanding hereunder.

(e) Liquidation. If the advance payments made hereunder shall be liquidated as herein provided. When the sum of all payments under this contract, other than advance payments, plus the unliquidated amount of advance payments are greater than the total estimated cost for the work under this contract or such lesser amount to which the total estimated cost under this contract may have been reduced, plus increases, if any, in this total estimated cost not exceeding, in the aggregate, (including with any previously reimbursable costs) $100,000, such advance payments shall be repayable to the Government.

(f) In the event the advance payments made hereunder shall be liquidated as herein provided. When the sum of all payments under this contract, other than advance payments, plus the unliquidated amount of advance payments are greater than the total estimated cost for the work under this contract or such lesser amount to which the total estimated cost under this contract may have been reduced, plus increases, if any, in this total estimated cost not exceeding, in the aggregate, (including with any previously reimbursable costs) $100,000, such advance payments shall be repayable to the Government.
Federal Register / Vol. 49, No. 130 / Friday, September 14, 1984 / Rules and Regulations 36261

retrocession as estimated by the Contracting Officer, the Government shall thereafter withhold further payments to the Contractor and apply the amounts withheld against the Contractor’s obligation to repay such advance payments until such advance payments have been fully liquidated. If upon completion of the contract, after retrocession of the contract all advance payments have not been fully liquidated, the balances thereof shall be deducted from any sums otherwise due or which may become due to the Contractor from the Government, and any deficiency shall be paid by the Contractor to the Government upon demand.

(i) Bank Agreement. Before an advance payment is made hereunder, the Contractor shall transmit to the Administering Officer, in the form prescribed by such office, an Agreement in triplicate from the bank in which the Special Bank Account is established, clearly setting forth the special character of the account and the responsibilities of the bank thereunder. Wherever possible, such bank shall be a member bank of the Federal Reserve System, or an “insured” bank within the meaning of the Act creating the Federal Deposit Insurance Corporation (Stat. 835, as amended (12 U.S.C. 264).

(j) Lien on Special Bank Account. The Government shall have a lien upon any balance in the Special Bank Account for amounts which the Contractor shall secure the repayment of or any advances made hereunder.

(k) Lien on Property under Contract. Any and all advance payments made under this contract shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, upon the supplies or other things covered by this contract and on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other provision of this contract, or otherwise, shall have valid title to such supplies, materials, or other property as against other creditors of the Contractor. The Contractor shall identify, by marking or segregation, which is subject to a lien in favor of the Government by virtue of any provision of this contract in such a way as to indicate that it is subject to such lien and that it has been acquired for or allocated to the performance of this contract. If for any reason such supplies, materials, or other property are not identified by marking or segregation, the Government shall be deemed to have a lien to the extent of the Government’s interest under this contract on any mass of property with which such supplies, materials, or other property are commingled. The Contractor shall maintain adequate accounting control over such property on its books and records. And if at any time during the progress of the work on the contract it becomes necessary to deliver any item or items and materials upon which the Government has a lien as aforesaid to a third person, the Contractor shall notify such third person of the lien herein provided and shall obtain from him or her a receipt, in duplicate, acknowledging, inter alia, the existence of such lien. A copy of each receipt shall be delivered by the Contractor to the Contracting Officer. If this contract is terminated in whole or in part and the Contractor is authorized to sell or retain termination inventory acquired for or allocated to this contract, such sale or retention shall be made only if approved by the Contracting Officer, which approval shall constitute a release of the Government’s lien hereunder to the extent that such termination inventory is sold or retained, and to the extent that the proceeds of the sale, or the credit allowed for such retention on the Contract, when added to the payment claim, is applied in reduction of advance payments then outstanding hereunder.

(l) Insurance. The Contractor represents and warrants that it is now maintaining with responsible insurance carriers, (1) insurance upon its own plant and equipment against fire and other hazards to the extent that like properties are usually insured by other operating plants and properties of similar character in the same general locality; (2) adequate insurance against liability for account of damage to persons or property; and (3) adequate insurance under all applicable workmen’s compensation laws. The Contractor agrees that, until work under this contract is completed and all advance payments made hereunder have been liquidated, it will (i) maintain such insurance; (ii) maintain adequate insurance upon any materials, parts, assemblies, subassemblies, supplies, equipment and other property acquired for or allocable to this contract and subject to the Government lien hereunder; and (iii) furnish such certificates with respect to its insurance as the Administering Office may from time to time require.

(m) Prohibition against Assignment. Notwithstanding any other provision of this contract, the Contractor shall not transfer, pledge, or otherwise assign this contract, or any interest therein, or any claim arising thereunder, to any party or parties, bank, trust company, or other financing institution.

(n) Designations and Determinations. (1) Amount. The amount of advance payments at any time outstanding hereunder shall not exceed $——$— .

(2) Depository. The bank designated for the deposit of payments made hereunder shall be:

(3) Interest Charge. No interest shall be charged for advance payments made hereunder. The Contractor shall charge interest at the rate of 5 percent per annum on subadvances or down payments to subcontractors, and such interest will be credited to the account of the Government. However, interest need not be charged on subadvances to nonprofit subcontractors with nonprofit educational or research institutions for experimental, research or development work.

(4) Administering Office. The office administering advance payments shall be the office designated by the Contracting Officer with responsibility for awarding the contract.

(i) Other Security. The terms of this contract shall be considered adequate security for advance payments hereunder, except that if any advance payment claim is not paid by the Administering Office, the security furnished by the Contractor to be inadequate, the Contractor shall furnish such additional security as may be satisfactory to the administering office, to the extent that such additional security is available.

(End of clause)

Clause No. 33—Effect on Existing Rights (June 1977)

(a) Nothing in this contract shall be construed to:

(1) Affecting, modifying, diminishing, or otherwise impairing the sovereign immunity for suit enjoyed by an Indian tribe; or

(2) Authorizing or requiring the termination of any existing trust responsibility of the United States with respect to the Indian people.

(End of clause)

Clause No. 34—Federal, State, and Local Taxes (June 1977)

(a) Except as may be otherwise provided in this contract, the contract price includes all applicable Federal, State, and local taxes and duties.

(b) Nevertheless, with respect to any Federal excise tax or duty on the transactions or property covered by this contract, if a statute, court decision, written ruling, or regulation takes effect after the contract date, and (1) Results in the Contractor being required to pay or bear the burden of any such Federal excise tax or duty or increase in the rate thereof which would not otherwise have been payable on such transactions or property, the contract price shall be increased by the amount of such tax or duty or rate increase; Provided, That the Contractor if requested by the Contracting Officer, warrants in writing that no amount for such newly imposed Federal excise tax or duty or rate increase was included in the contract price as a contingency reserve or otherwise; or

(2) Results in the Contractor not being required to pay or bear the burden of, or in its obtaining a refund or drawback of, any such Federal excise tax or duty which would otherwise have been payable on such transactions or property or which was the basis of an increase in the contract price, the contract price shall be decreased by the amount of the relief, refund, or drawback, or the amount shall be paid to the Government, as directed by the Contracting Officer. The contract price shall be similarly decreased if the Contractor, through its fault or negligence or its failure to follow instructions of the Contracting Officer, is required to pay or bear the burden of, or does not obtain, a refund or drawback of, any such Federal excise tax or duty.

(c) No adjustment pursuant to paragraph (b) above will be made under this contract unless the aggregate amount thereof is or may reasonably be expected to be over $100.

(d) As used in paragraph (b) above, the term “contract date” means the date set for the bid opening, or if this is a negotiated contract, the date of this contract. As to additional supplies or services procured by modification to this contract, the term “contract date” means the date of such modification.
(c) Unless there does not exist any reasonable basis to sustain an exemption, the Government, upon request of the Contractor, without further liability, agrees, except as otherwise provided in this contract, to furnish evidence appropriate to establish exemption from any tax which the Contractor warrants in writing was excluded from the contract price. In addition, the Contracting Officer may furnish evidence to establish exemption from any tax that may, pursuant to this clause, give rise to either an increase or decrease in the contract price. Except as otherwise provided in this contract, evidence appropriate to establish exemption from duties will be furnished only at the direction of the Contracting Officer.

(f) The Contractor shall promptly notify the Contracting Officer of matters which will result in either an increase or decrease in the contract price, and shall take action with respect thereto as directed by the Contracting Officer.

(End of clause)

PHS 352.280-6 Demurrage charge provisions for reusable cylinders and containers.

The clause set forth below shall be inserted in solicitations and resultant contracts when delivery of the items may be in contractor-furnished reusable gas cylinders or other containers.

Demurrage Charge Provisions for Reusable Cylinders and Containers (Apr. 1984)

(a) Reusable gas cylinders or other containers identified below by offerors shall remain the property of the Contractor (except as provided in (c) below), and will be loaned without charge to the Government for the period stipulated below. In computing the periods involved, such free loan period shall commence on the first day after date of delivery of each container to the herein specified f.o.b. point(s). Offers who specify less than the established free loan period, or vary from the free loan period specified by the offeror above, will not be considered.

(b) Empty containers will be delivered to the Contractor's designated carrier (offeror to identify applicable carrier below) f.o.b. points of original delivery specified in the solicitation/contract.

OFFERORS SHALL FURNISH THE FOLLOWING INFORMATION, AS APPLICABLE, FOR CONTAINERS

<table>
<thead>
<tr>
<th>Applicable Item No.</th>
<th>Type and size of container</th>
<th>Quantity</th>
<th>Free loan period</th>
<th>Demurrage charge per day per cylinder</th>
</tr>
</thead>
</table>

(c) When the offeror indicates that containers have a replacement value of less than $10, the Government shall have the option to purchase containers and add the cost to the offered price. When purchase option is exercised, offers shall be evaluated accordingly. In this event, the container shall become the property of the Government.

(End of clause)

Subpart PHS 352.3—Provision and Clause Matrices

PHS 352.380-4 Contract clauses for contracts awarded under the Indian Self-Determination Act.

(a) PHS Acquisition Regulations (PHSAR) Clauses for Cost-Reimbursement Contracts Awarded under the Indian Self-Determination Act.

Number, PHSAR Clause No., and Title and Date of Clause

1. 352.280-4(a)(1) Definitions. (June 1977)
2. 352.280-4(a)(2) Disputes. (June 1977)
4. 352.280-4(a)(4) Allowable Cost. (June 1977)
5. 352.280-4(a)(5) Negotiated Overhead Rates. (June 1977)
6. 352.280-4(a)(6) Payment. (June 1977)
7. 352.280-4(a)(7) Advance Payment. (June 1977)
8. 352.280-4(a)(8) Examination of Records. (June 1977)
9. 352.280-4(a)(9) Inspection and Reports. (June 1977)
10. 352.280-4(a)(10) Subcontracting. (June 1977)
15. 352.280-4(a)(15) Retrospection. (June 1977)
17. 352.280-4(a)(17) Key Personnel. (June 1977)
18. 352.280-4(a)(18) Litigation and Claims. (June 1977)
19. 352.280-4(a)(19) Indemnity and Insurance. (June 1977)
20. 352.280-4(a)(20) Overtime. (June 1977)
21. 352.280-4(a)(21) Foreign Travel. (June 1977)
22. 352.280-4(a)(22) Questionnaires and Surveys. (June 1977)
23. 352.280-4(a)(23) Printing. (June 1977)
24. 352.280-4(a)(24) Services of Consultants. (June 1977)
29. 352.280-4(a)(29) Indian Preference in Training and Employment. (June 1977)
32. 352.280-4(a)(32) Officials not to Benefit. (June 1977)
33. 352.280-4(a)(33) Buy American Act. (June 1977)
34. 352.280-4(a)(34) Anti-Kickback Act. (June 1977)
35. 352.280-4(a)(35) Use of Indian Business Concerns. (June 1977)
36. 352.280-4(a)(36) Payment of Interest on Contractors' Claims. (June 1977)
37. 352.280-4(a)(37) Fair and Equal Treatment of Indian People. (June 1977)
38. 352.280-4(a)(38) Price Reduction for Defective Cost or Pricing Data. (June 1977)
40. 352.280-4(a)(40) Penalties. (June 1977)
41. 352.280-4(a)(41) Effect on Existing Rights. (June 1977)
42. 352.280-4(a)(42) General Services Administration Supply Sources. (June 1977)

(b) PHSAR Clauses for Fixed-Price Contracts Awarded under the Indian Self-Determination Act.

Number, PHSAR Clause No., and Title and Date of Clause

1. 352.280-4(b)(1) Definitions. (June 1977)
2. 352.280-4(b)(2) Disputes. (June 1977)
5. 352.280-4(b)(5) Convict Labor. (June 1977)
7. 352.280-4(b)(7) Assignment of Claims. (June 1977)
Subpart PHS 380.3—Acquisition of Drugs and Medical Supplies

PHS 380.301 Scope of subpart.
PHS 380.302 Acquisition of drugs.
PHS 380.303 Policy.
PHS 380.303-1 Solicitation and contract requirements.
PHS 380.303-2 Acquisition of controlled drugs.
PHS 380.303-4 Effectiveness of drug products.
PHS 380.304 General.
PHS 380.304-1 Policy.
PHS 380.304-3 Procedures.
PHS 380.304-4 Distribution of information.
PHS 380.305 Maximum allowable cost for drugs.
PHS 380.305-1 General.
PHS 380.305-2 Applicability.
PHS 380.305-3 Responsibilities.
PHS 380.305-4 Solicitation notification.
PHS 380.305-5 Contract requirements.
PHS 380.306 Acquisition of tax free and specially denatured alcohol.

Subpart PHS 380.4—Contracts Under the Indian Self-Determination Act

PHS 380.400 Scope of subpart.
PHS 380.401 Applicability of regulations.
PHS 380.402 Waivers.
PHS 380.403 Negotiating authority.
PHS 380.404 Definitions.
PHS 380.405 Types of contracts.
PHS 380.406 Term of contract.
PHS 380.407 Exemption from bonds.
PHS 380.408 Acquisition of construction and architect-engineering services contracts.
PHS 380.409 Performance of personal services.
PHS 380.410 Special provisions of Indian Self-Determination contract.
PHS 380.411 Contract clauses.

Subpart PHS 380.5—Acquisitions Under the Buy Indian Act

PHS 380.500 Scope of subpart.
PHS 380.501 Policy.
PHS 380.502 Definitions.
PHS 380.502-1 Indian.
PHS 380.502-2 Indian firm.
PHS 380.502-3 Product of Indian industry.
PHS 380.502-4 Buy Indian contract.
PHS 380.502-5 Buy Indian restricted advertising.

PHS 380.503 Requirements.
PHS 380.504 Competition.
PHS 380.505 Responsibility determinations.


Subpart PHS 380.1—Acquisitions Involving Human Subjects

PHS 380.101 Scope of subpart.

This subpart provides policies and procedures to be followed whenever individuals may be at risk as a consequence of participation as a subject in research, development, demonstration, or other activities being conducted under contract.

PHS 380.101 Policy.

It is the policy of the Public Health Service that no contract involving risk to human subjects shall be awarded until acceptable assurance has been given that the project or activity will be subject to initial and continuing review by an appropriate institutional committee(s) as described in Chapter 1–40 PHS Grants Administration Manual.

Except where the prime contractor holds a General Institutional Assurance (see PHS 360.103(b)), a separate Special Assurance will be required of each subcontractor or cooperating institution having immediate responsibility for human subjects involved in performance of the contract. Contracts involving human subjects at risk will not be awarded to an individual unless he/she is affiliated with or sponsored by an institution which can and will assume responsibility for safeguarding the human subjects involved.

PHS 380.103 Applicability.

(a) The policy set forth in PHS 380.102 applies to all contracts which involve activities in which subjects may be at risk. The identification of programs requires the application of sound professional judgment; therefore, the determination should involve professional staff within the component activities of PHS. PHS staff and consultants serving programs shall be responsible for identifying those specific projects or activities which require application of the policy. The Office for Protection from Research Risks (OPRR), Office of the Director, National Institutes of Health, is responsible for negotiation of assurances covering all PHS-supported activities involving human subjects.

(b) Contracting officers shall be guided by recommendations of the OPRR regarding nonaward or termination of a contract due to inadequate assurance or breach of assurance for protection of human subjects. General Institutional Assurances (applicable to all PHS grant and contract activities) previously accepted by the OPRR and listed in its current “Cumulative List of Institutions in Compliance with NIH Policy on Protection of Human Subjects” will be considered acceptable for purposes of this policy. Copies of proposals selected for negotiation and requiring a special assurance shall be forwarded to the Director, OPRR, NIH, Bldg. 31, Rm. 4B09, Bethesda, MD 20205, as early as possible in order that timely action may be taken to secure an assurance.

PHS 380.104 Types of assurances.

Assurances may be one of two types:

(a) General assurance. A general assurance describes the review and
Subpart PHS 380.2—Acquisitions Involving the Use of Laboratory Animals

PHS 380.201 Scope of subpart.

This issuance describes PHS contracts for projects or activities involving animals, and the responsibilities of the PHS agencies and subordinate elements for implementing policies and procedures described herein.

PHS 380.202 Definitions.


(b) Animal. "Animal" means any live, warm-blooded animal (homoiotherm) which is being used, or is intended for use, for research, testing, training, education, experimentation, or demonstration purposes.

(c) Animal facility. "Animal facility" means any building, area, or room used to contain a primary enclosure designed to accommodate an animal or animals to a limited amount of space, such as a room, pen, run, cage, compartment, or hutch.

(d) Institution. Any corporation, institution, organization, agency, or any legally accountable person, other than an individual, located in a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, Wake Island, Johnston Island, the Virgin Islands, the Canal Zone, or the Trust Territory of the Pacific Islands.

(e) Significant numbers of animals. No fixed quantitative definition of this term is offered. Institutions believing that they do not use significant numbers of animals in PHS supported activities and wishing to modify their institutional committee make-up on the basis of their animal inventory as provided for by PHS 380.205(a)(2)(ii) should give inventory information as suggested by the assurance examples in PHS 380.207. Final determination as to the acceptability of such modifications will be made by the PHS.

PHS 380.203 Policy.

It is the policy of PHS that institutions awarded contracts involving animals shall assure PHS in writing that they will evaluate on a continuing basis their animal facilities in regard to the care, use, and treatment of such animals, consistent with the standards established by the Animal Welfare Act, and NIH publication 18-23 "Guide for Care and Use of Laboratory Animals," (reprinted 1980), including the "Principles for Use of Animals." No PHS contract involving the use of animals will be awarded to an institution unless an assurance has been filed with PHS. No contract will be awarded to an individual without affiliation with an institution which has accepted responsibility for administration of the funds awarded and has filed an assurance with PHS.

PHS 380.204 Applicability.

(a) This policy is applicable to the contracts of any PHS activity which involves the use of animals in direct research, testing, training, or other activities to be performed by the contractor institution. While the bulk of such support is offered by a few PHS activities (NIH, FDA), staff of all activities shall be alert to the inclusion of procedures involving animals into proposals received.

(b) Applicability of this policy to contracts for the acquisition of animals or animal materials for use in PHS intramural activities shall be determined by the PHS officials responsible for administering programs which award such contracts.

PHS 380.205 Contractor Implementation.

(a) See PHS 380.207 for examples of acceptable assurance forms. An assurance will identify the evaluation mechanism or mechanisms to be used by the institution, based on one of the following three actions, as appropriate:

(1) Accreditation of all institutional animal facilities by a nationally recognized professional laboratory animal accreditation body. (Registration, licensing, or inspection by the Animal Health Division of the Department of Agriculture or by any State, county, or municipal Government agency, does not serve to satisfy the terms of this policy. Accreditation by the American Association for Accreditation of Laboratory Animal Care does serve to satisfy the terms of this policy.)

(2) Establishment of an institutional committee to evaluate on a continuing basis the care of all animals held or used by or for the contractor institution for use in research, teaching, or other activities supported by PHS contracts.

(i) Where the institution uses significant numbers of animals in PHS supported activities, the committee will consist of at least three members, at least one of whom must be a Doctor of Veterinary Medicine.

(ii) Where the institution does not use significant numbers of animals in PHS supported activities, the committee will consist of at least three members. At least one of the members must be a
scientist with demonstrated expertise in the care and use of laboratory animals. If this expertise is not available, a Doctor of Veterinary Medicine available to the committee on a consultant basis is the permissible alternative.

(2) Accrediting (accreditation and committee). If the accreditation is limited to only a portion of the institution's facilities for the care and use of live animals.

(b) Institutional review of proposals. Contractor institutions are encouraged to review their proposals in the light of the pertinent provisions of the Animal Welfare Act, the standards set by the Institute of Laboratory Animal Resources, National Academy of Sciences, National Research Council (NAS, NRC), and the Principles for Use of Animals, and to familiarize their staff with these provisions, standards, and principles. However, there is no requirement under this policy that institutional committees perform review of individual proposals or regularly provide to PHS summaries or certifications of such committee actions.

(c) Reporting to PHS. No routine reports are required. Assurance requirements are limited to the descriptions, on a one-time basis, of administrative mechanisms for the continuing evaluation of institutional facilities and activities concerned with the care and use of animals. However, significant changes in assurance status or significant problems encountered in implementing this policy shall be promptly reported to the Office for protection from Research Risks, (OPPR) Office of the Director, NIH, PHS.

(1) With respect to an institution, PHS agencies are responsible for implementing the requirements of this policy.

(2) No PHS contract involving the use of animals shall be awarded when the contractor fails to raise questions in the minds of PHS agency staff as to the adequacy of an institution's facilities and activities concerning the care and use of animals. However, significant changes in assurance status or significant problems encountered in implementing this policy shall be promptly reported to the Office for protection from Research Risks, (OPPR) Office of the Director, NIH, PHS.

(d) Maintenance of institutional records. As a part of the continuing evaluation process, PHS awardee institutions shall keep records of committee activities, including recommendations and determinations, and/or records of accrediting body determinations. Institutions shall also keep animal inventory records to establish whether significant numbers of animals are being used. These records shall be available for inspection by the Secretary, HHS, or his/her authorized representatives. They shall be retained for a period of three years after termination of the budget period to which they apply.

PHS 380.206 PHS implementation.

(a) The Office for Protection from Research Risks, (OPPR), Office of the Director, NIH, PHS, will be responsible for general administration and coordination of the implementation of this policy. The OPRR will publish and distribute to all PHS agencies a cumulative list of all institutions which have filed assurances of compliance as specified in PHS 380.205.

(b) Staff, advisory groups, and consultants, in their review of applications for PHS contracts, shall consider the requirements of this policy with special attention to the principles described in the Guide for Care and Use of Laboratory Animals. If a project is disapproved or not awarded as requested, entirely or in part on grounds of incompatibility with this policy or its related principles, PHS program staff shall bring the circumstances to the attention of the OPRR, which will call the matter to the attention of the offeror.

(c) (1) PHS agencies are responsible for implementing the requirements of this policy.

(2) PHS agencies are responsible for implementing the requirements of this policy.

(d) If, in the judgment of the Secretary or his/her authorized representative, an institution has failed in a material manner to comply with the terms of this policy or its related principles, the principal investigator or project director will be contacted by PHS staff and given an opportunity to resolve the questions, within the time period specified. Alternatively, if, in the judgment of PHS staff, the project or activity can properly be restricted so as to eliminate those parts of the design which are incompatible with this policy or its principles, such restricted award may be offered.

(3) Final adverse action shall be taken by PHS only if the principal investigator or project director fails or refuses to satisfactorily resolve the questions within the time period specified. Alternatively, if, in the judgment of PHS staff, the project or activity can properly be restricted so as to eliminate those parts of the design which are incompatible with this policy or its principles, such restricted award may be offered.

(4) PHS shall be promptly notified of this action.

(5) With respect to a particular PHS contract involving the use of animals, require that it be terminated in the manner provided for in applicable acquisition regulations. The contractor shall be promptly notified of this action.

PHS 380.207 Examples of acceptable assurance forms.

Assurances may take any one of several forms depending on circumstances, but should include the information provided by one or more of the examples below, be dated, and be signed by an authorized representative of the institution:

(a) "This institution uses or intends to use significant numbers of warm-blooded animals in activities supported by PHS contracts. We are accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). Our director(s) of laboratory animal care, as listed with AAALAC, is as follows: (insert names[s], degree[s], title[s]). Our accreditation applies to the following facilities and components of this institution:

Records of accrediting body determinations will be available for inspection by the Secretary, HHS, or his authorized representatives."

(b) "This institution uses or intends to use significant numbers of warm-blooded animals in activities supported by PHS contracts. We have established a committee of at least three members, at least one of whom is a Doctor of Veterinary Medicine (insert name), to evaluate the care of all warm-blooded animals housed or used for contracts. The committee will be responsible for animals housed at the following facilities and components of this institution:

The evaluation committee will periodically inspect the animal facilities of this institution and report its findings and recommendations to the
The evaluation committee will periodically inspect the animal facilities of this institution and report its findings and recommendations to the institution’s responsible officials on a schedule the committee determines necessary, but in no case will these reports be issued less than annually. Records will be kept of committee activities and recommendations. These records will be available for inspection by the Secretary, HHS, or his/her authorized representatives.

(d) “This institution uses or intends to use warm-blooded animals in activities supported by HHS contracts, but not in significant numbers (average daily inventory, warm-blooded animals, total inventory, warm-blooded animals, total annual inventory, warm-blooded animals). We have established a committee of at least three members, one of whom is (insert name, highest degree held, field of major interest, years of animal research experience) to evaluate the care of all warm-blooded animals held or used for research, teaching or other activities supported by PHS contracts. The committee will be responsible for animals housed at the following facilities and components of this institution:

The evaluation committee will periodically inspect the animal facilities of this institution and report its findings and recommendations to the institution’s responsible officials on a schedule the committee determines necessary, but in no case will these reports be issued less than annually. Records will be kept of committee activities and recommendations. These records will be available for inspection by the Secretary, HHS, or his/her authorized representatives.

Subpart PHS 380.3—Acquisition of Drugs and Medical Supplies

PHS 380.301 Scope of subpart.
This subpart provides policies and procedures pertaining to the acquisition of drug products and medical supplies by PHS or PHS’s contractors.

PHS 380.302 Acquisition of drugs.

PHS 380.302-1 Policy.
(a) Drugs shall be acquired at the lowest possible price consistent with acceptable standards of identity, strength, quality, purity, safety and effectiveness, and with due regard for the welfare of the patient and the professional judgment of the prescriber.
(b) Contracting activities shall ensure that drugs are acquired by generic name on a competitive basis whenever it is possible to obtain therapeutically effective drugs of established quality. However, the professional judgment of the prescriber to request drugs by brand name or house designation must be recognized when the best interest of the patient requires it. Similarly, scientific investigators have the prerogative to request drugs having end-product characteristics considered necessary for the conduct of research or investigations.
(c) Prior to taking any acquisition action, the contracting officer shall ensure that the requested drug products are not available from mandatory sources such as Federal Supply Schedules. Part 103-28 of the HHS Material Management Manual describes sources of supply for drugs.

PHS 380.302-2 Solicitation and contract requirements.
The contracting officer should consider including statements similar to the following in solicitations and resultant contracts pertaining to drug products:
(a) The offeror (contractor) guarantees that all requirements established by the Food and Drug Administration, HHS, have been met. These requirements include: plant sanitation, manufacturing, packaging, labeling, identification, strength, quality, purity, safety, and effectiveness.

Note.—The contracting officer may want to cite the applicable reference(s) pertaining to the FDA requirements.

(b) The offeror (contractor), by signing this document, guarantees/warrants that any applicable shelf-life requirements have been met and the furnished drugs are free from defects.
(c) The Government reserves the right to inspect the manufacturer’s plant and premises during normal operating hours.

Note.—FDA will normally conduct the inspection when requested, but may request to be reimbursed for the services.

(d) The offeror (contractor) agrees to submit either a comprehensive, certified analysis on each lot of drugs at the time of delivery of the drugs, or a comprehensive list of specifications met by the drugs along with a certificate of analysis, or other suitable documentation, verifying that the drugs meet the appropriate standards.
(e) The offeror (contractor) claims it is not currently listed as a disqualified bidder or offeror for drugs by any Federal agency or department.

(f) The offeror must set forth full, accurate, and complete information as required by this solicitation (including attachments). The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

(g) If the offeror (prime contractor) plans to use (or uses) a subcontractor or secondary manufacturer for the furnishing of any or all the drug products under the resultant contract, the name and address of the subcontractor or secondary manufacturer is to be furnished the contracting officer, along with the drug lots affected. The prime contractor shall ensure that the subcontractor or secondary manufacturer complies with the above stated requirements.

PHS 380.303 Acquisition of controlled drugs.

(a) Controlled drugs include narcotics and dangerous drugs identified by the Drug Enforcement Administration (DEA), Department of Justice, in the regulations implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Title 21 CFR Chapter II).

(b) The DEA issues a Controlled Substances Inventory List which provides general information pertaining to the ordering of controlled drug products and the use of specific order forms. The local DEA regional office should be contacted to receive the list and instructions regarding registering
and ordering forms, as well as other matters concerning the handling and processing of controlled drugs. Sections 103-27.6304(a)(2) and 103-27.6302(b) of the HHS Material Management Manual provide information on issuing, shipping, and safeguarding controlled drugs.

(c) Contracting officers shall ensure that requests for contracts or purchase requests are supported by the required DEA form prior to initiation of any action.

PHS 380.304 Effectiveness of drug products.

PHS 380.304-1 General.

(a) The National Academy of Sciences National Research Council (NAS-NRC) has established effectiveness classifications for the indication of drug products, based upon the following criteria:

1. Factual information that is freely available in scientific literature;
2. Factual information that is available from the Food and Drug Administration, the manufacturer, or other sources; and
3. Experience and informed judgment of the members of NAS-NRC panels.

(b) The indications mentioned in the following categories refer to "the effect the drug purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." That is, the indications are the claims noted in the labeling of a given drug product.

1. Category A—Effective.
   - For the presented indication, the drug is effective on the basis of the criteria cited in PHS 380.304-1(a) above.
2. Category B—Probably Effective.
   - For the indication presented, effectiveness of the drug is probable on the basis of the criteria cited in PHS 380.304-1(a) but additional evidence is required before it can be assigned to Category A.
3. Category C—Possibly Effective.
   - In relation to the indication in question, there is little evidence of effectiveness under any of the criteria cited in PHS 380.304-1(a). The possibility that additional supporting evidence might be developed should not be ruled out, however.
4. Category D—Ineffective.
   - In relation to the indication in question, there is no acceptable evidence under any of the criteria cited in PHS 380.304-1(a) to support a claim of effectiveness.

PHS 380.304-2 Policy.

(a) It is PHS policy to not acquire drug products classified "ineffective" or "possibly effective" for use in its direct care programs. However, there are two exceptions to this policy:

1. Drug products categorized as "ineffective" and "possibly effective" may be acquired for use in the pursuit of approved clinical research products.
2. Drug products categorized as "possibly effective" may be acquired when no alternate means of therapy with drug products in the "probably effective" or "effective" categories are available.

(b) This policy applies to similar drug products marketed by the same or other firms.

PHS 380.304-3 Procedures.

(a) The contracting officer, prior to initiating action on a purchase request or request for contract for drug products, shall ensure that the items are screened against current lists of products identified by the Pharmacy Liaison Officer, Public Health Service, to determine whether acquisition of the items is prohibited, and that the individual actually performing the screening has annotated and initialed the request.

(b) When the request is received for a drug product which is allowable under the exceptions stated in PHS 380.304-2, the contracting officer shall ensure that the appropriate justification is provided, that it is signed by the responsible program official, and that it is included in the contract or purchase request file.

(c) When the request for a restricted drug product cannot be resolved by the substitution of another item, the contracting officer shall consider the request as a deviation and process it in accordance with Subpart 301.4.

PHS 380.304-4 Distribution of information.

(a) The Pharmacy Liaison Officer, Public Health Service, has responsibility for distributing information on the effectiveness of drug products to the principal official responsible for acquisition. The principal official responsible for acquisition will be advised by telephone of drug products classified as "ineffective" or "possibly effective" prior to publication in the Federal Register, and will be provided a monthly list of these drug products following publication in the Federal Register.

(b) The principal official responsible for acquisition shall establish procedures for the distribution of information on the effectiveness of drug products and implement other controls necessary to assure compliance with the policy set forth in PHS 380.304-2.

PHS 380.305 Maximum allowable cost for drugs.

PHS 380.305-1 General.

(a) The regulation entitled "Limitation on Payment or Reimbursement for Drugs," also known as the Maximum Allowable Cost or MAC regulation, is set forth in Part 19 to Subtitle A of Title 45 of the Code of Federal Regulations.

(b) The MAC regulation established departmental policies and procedures for determining allowable drug costs and, where applicable, dispensing fees to be used to establish:
1. Reimbursement to providers and health maintenance organizations under the Medicare program;
2. Reimbursement to States under State administered health, welfare, and social service programs; and
3. Allowable costs under projects for health services.

PHS 380.305-2 Applicability.

(a) This regulation implements the MAC regulation by establishing acquisition procedures consistent with the purpose and intent of the MAC regulation.

(b) This regulation applies to the direct acquisition of drugs by PHS and the acquisition or supply of drugs by PHS contractors.

(c) This regulation does not apply to the acquisition of drugs for research programs made by PHS and its contractors.

PHS 380.305-3 Responsibilities.

(a) The program office which initiates the requirement is responsible for advising the contracting officer as to the applicability of the MAC regulation to the proposed acquisition.

(b) The Pharmacy Liaison Officer, PHS, is responsible for distributing to the principal official responsible for acquisition of the MAC determination or data concerning the acquisition cost of drugs. The MAC determination should be furnished within thirty days after publication as a final rule in the Federal Register. Acquisition cost data should be furnished within thirty days after the effective date.

(c) The principal official responsible for acquisition shall establish procedures for disseminating MAC determinations and acquisition cost data and may initiate other actions necessary to ensure compliance with the requirements of this regulation.

PHS 380.305-4 Solicitation notification.

(a) The contracting officer shall ensure that all requests for proposals and invitations for bids which are subject to the provisions of the MAC...
regulation contain a notice worded substantially as follows:

This acquisition is subject to the Maximum Allowable Cost (MAC) regulation set forth in Part 6 to Subpart A of Title 45 of the Code of Federal Regulations.

(b) The contracting officer shall include the applicable MAC determination or acquisition cost data in the RFP or IFB.

(c) The referenced solicitation notice, or a notice worded similarly to it, is required to be included in all applicable solicitations issued by the contractor or its subcontractors.

**PHS 380.305-5 Contract requirements.**

(a) The contracting officer shall include a clause entitled “Maximum Allowable Cost for Drugs,” reading substantially as the clause cited in PHS 352.280-3, in all contracts subject to the provisions of the MAC regulation.

(b) The contracting officer shall incorporate in all contracts subject to the provisions of the MAC regulation the applicable MAC determination or acquisition cost data furnished in the solicitation.

(c) The clause cited in PHS 352.280-3, or a clause worded substantially as that clause, is required to be included in all applicable contracts awarded by the contractor or its subcontractors.

**PHS 380.306 Acquisition of tax free and specially denatured alcohol.**

(a) All orders for tax free and specially denatured alcohol shall be placed with the HRSA Supply Service Center, Perry Point, MD. Orders shall be placed in accordance with the ordering instructions contained in the HRSA Medical Supply Catalog.

**Subpart PHS 380.4—Contracts under the Indian Self-Determination Act**

**PHS 380.400 Scope of subpart.**

This subpart prescribes procedures for contracting by the Public Health Service (PHS) under the Indian Self-Determination Act (25 U.S.C. 450f).

**PHS 380.401 Applicability of regulations.**

Contracts with tribal organizations resulting from the submission of Indian Self-Determination Contract Proposals as authorized in Public Law 93–638 shall be in accordance with 41 CFR Chapters 1 and 3, except as otherwise provided herein. If this subpart conflicts with any of the other provisions of 41 CFR Chapters 1 or 3, the provisions of this subpart govern.

**PHS 380.402 Waivers.**

(a) The Secretary of Health and Human Services (HHS) waives Federal contract clauses that are normally contained in the General provisions of a contract to the extent that they are omitted from the General provisions prescribed for such contracts in this subpart.

(b) The Secretary may waive for the purpose of a specific contract other provisions of Federal contracting laws or regulations as determined not appropriate in view of, or are inconsistent with, the provisions of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.). Requests for such waivers shall be in accordance with 42 CFR 36.216.

(c) Although it is PHS’s policy to obtain competition whenever possible, any contract award to a tribal organization resulting from the submission of an Indian Self-Determination Contract Proposal will be effected without competition.

(d) Proposed contracts under section 103 of the Indian Self-Determination Act are exempted from the synopsis requirements of 41 CFR 1–1.1003. Although subcontracts are subject under section 7(b) of that act to a preference to Indian organizations and to Indian-owned economic enterprises, opportunities to so subcontract may be publicized by contracting officers as provided for in 41 CFR 1–1.1003–4.

**PHS 380.403 Negotiating authority.**

Contracts entered into pursuant to section 103 of the Indian Self-Determination Act (25 U.S.C. 450g) will cite as the negotiating authority 41 U.S.C. 252(c)(15) and 25 U.S.C. 450g.

**PHS 380.404 Definitions.**

The definitions prescribed in 42 CFR 36.204 are applicable to this subpart.

**PHS 380.405 Types of contracts.**

(a) Cost-reimbursement contracts will be used for all contracts made pursuant to this subpart between PHS and an Indian tribe or tribal organization. In addition to other provisions as the Secretary may from time to time require, the cost-reimbursement contracts shall contain the terms set out in PHS 352.280–4(a).

(b) Fixed-price contracts may be used in only these instances where costs can be precisely established. In addition to other provisions as the Secretary may from time to time require, the fixed-price contracts shall contain the terms set out in PHS 352.280–4(b).

(c) Cost sharing contracts may be used where the tribe contributes to the cost of a program and may specify a percentage of cost or fixed amount to be funded by the Government.

**PHS 380.406 Term of contract.**

(a) The term of contracts awarded under the Act shall not exceed one year except that contracts may be made for a longer term up to three years subject to the availability of appropriations under the following circumstances:

(1) The services provided under the contract can reasonably be expected to be continuing in nature and, as a result, a longer contract term would be advantageous.

(2) The Indian tribe or tribes to be served by the contract request that the term be more than one year. The tribal organizational will indicate the desired term of the contract in the Self-Determination Contract Proposal.

(b) Contract made for a term of more than one year may be renegotiated annually to reflect factors which include, but need not be limited to, cost increases beyond the control of the tribal contractor. Proposed changes in the services provided under the contract which reflect changes in program emphasis may be considered during the annual renegotiation if the changes fall within the general scope of the contract.

**PHS 380.407 Exemption from bonds.**

A tribal organization is not required to furnish performance and payment bonds before carrying out a contract under this subpart for the construction of public buildings or works as required by the Miller Act of August 24, 1935 (49 Stat. 799), as amended. However, the tribal organization shall require each of its subcontractors other than tribal organizations, to furnish both performance and payment bonds as follows:

(a) A performance bond with a surety or sureties satisfactory to the approving official, and in an amount he/she deems adequate, for the protection of the United States.

(b) A payment bond with a surety or sureties satisfactory to the approving official for the protection of all persons supplying labor and material in the prosecution of the work provided for in the contract. Whenever the total amount payable by the terms of the contract is not more than $1,000,000, the payment bond shall be one-half the total amount payable by the terms of the contract. Whenever the total amount payable by the terms of the contract is more than $1,000,000 but not more than $5,000,000, the payment bond shall be 40 percent of the total amount payable by the terms of the contract. Whenever the total amount payable by the terms of the contract is more than $5,000,000, the payment bond shall be $2,500,000.
PHS 380.408 Acquisition of construction and architect-engineering service contract.

(a) This section sets forth procedures and requirements peculiar to construction and architect-engineering service contracts. The determination and conditions of these contracts when negotiated with an Indian tribe or tribal organization pursuant to the Act shall, to the extent applicable, be in accordance with the requirements set forth in 41 CFR Part 1-18 and Subpart 1-4.10. However, if there is a conflict between 41 CFR Part 1-18 and Subpart 1-4.10, and any provision of the Act or 42 CFR Part 38, the Act or 42 CFR Part 36 shall govern. In addition these contracts shall include the special provisions identified in PHS 380.410.

(b) Exceptions.

(1) Subpart 1-18.10 of this title is not applicable.

(2) The contract clauses required by §1-18.703-1 of this title shall be inserted in construction contracts with an Indian tribe or tribal organization which serves as a governmental instrumentality of an Indian tribe, but shall be prefaced by the provision contained in §1-18.702-3 of this title.

(3) In all cases, the contracting officer shall obtain and insert the Wage Determination Decision issued by the Secretary of Labor in the contract prior to award of any contract for construction that falls within the purview of the Davis-Bacon Act. The Wage Determination Decision shall be furnished sufficiently in advance of the contract award date to permit full consideration by the tribal organization and any prospective subcontractors.

PHS 380.409 Performance of personal services.

Any contract made under this subpart may include provisions for the performance of personal services which would otherwise be performed by Federal employees. Such services include, but are not limited to, performing the following functions in connection with the contract and applicable rules and regulations:

(a) Determining the eligibility of applicants for assistance, benefits, or services.

(b) Determining the extent or amount of assistance, benefits, or services to be provided.

(c) Providing such assistance, benefits, or services.

PHS 380.410 Special provisions of Indian Self-Determination contracts.

Contracts entered into pursuant to Section 103 of the Indian Self-Determination Act must incorporate special clauses which are consistent with those prescribed in Subpart I of Part 36 of 42 CFR on the following subjects:

(a) Fair and equal treatment of Indian people.

(b) Use of Indian business concerns.

(c) Indian preference in training and employment.

(d) Indemnity and insurance.

(e) Reports to the Indian people.

(f) Penalties.

(g) Retrocession.

(h) Assumption and reassumption of contract programs.

PHS 380.411 General provisions.

General provisions are published in these regulations (see PHS 352.280-4 for text of clauses) in order to respond to the expressed desire of the Indian people, to have published in one place, all of the terms and conditions applicable to contracts awarded under the Act. These general provisions incorporate the special clauses whose titles are listed in PHS 380.410, above, as well as applicable standard contract clauses.

Subpart PHS 380.5—Acquisitions Under the Buy Indian Act

PHS 380.500 Scope of subpart.

This subpart sets forth the policy on preferential acquisition from Indians under the negotiation authority of the Buy Indian Act. Applicability of this subpart is limited to acquisitions made by or on behalf of the Indian Health Service of the Public Health Service.

PHS 380.501 Policy.

(a) The Indian Health Service will utilize the negotiation authority of the Buy Indian Act to give preference to Indians whenever the use of that authority is authorized and is practicable. The Buy Indian Act was enacted as a proviso to Section 23 of the Act of June 30, 1910, Chapter 431, Pub. L. 313, 61st Congress, 36 Stat. 861, and prescribes the application of the advertising requirements of section 3709 of the Revised Statutes to the acquisition of Indian supplies. As set out in 25 U.S.C. 47, the Buy Indian Act provides as follows:

So far as may be practicable Indian labor shall be employed, and purchases of the products of Indian industry may be made in open market in the discretion of the Secretary of the Interior.

(b) The functions, responsibilities, authorities, and duties of the Secretary of the Interior for maintenance and operation of hospital and health facilities for Indians and for the conservation of the health of Indians were transferred to the Secretary of Health, Education, and Welfare, on July 1, 1955 by Pub. L. 568, 83rd Congress, 42 U.S.C. 2001 et seq. Accordingly, the Secretary of Health and Human Services is authorized to use the Buy Indian Act in the acquisition of products of Indian industry in connection with the maintenance and operation of hospital and health facilities for Indians and for the conservation of the health of Indians. This authority has been delegated exclusively to the Indian Health Service and is not available for use by any other HHS component (unless that component is making an acquisition on behalf of the Indian Health Service).

(c) Use of the Buy Indian Act negotiation authority has been emphasized in subsequent legislation, particularly Pub. L. 94-437 and Pub. L. 96-537.

PHS 380.502 Definitions.

PHS 380.502-1 Indian.

Indian means a member of any tribe, pueblo, band, group, village or community that is recognized by the Secretary of the Interior as being Indian or any individual or group of individuals that is recognized by the Secretary of the Interior or the Secretary of Health and Human Services. The Secretary of Health and Human Services in making such determinations may take into account the determination of the tribe with which affiliation is claimed.

PHS 380.502-2 Indian firm.

Indian firm means a sole enterprise, partnership, corporation, or other type of business organization owned, controlled, and operated by one or more Indians (including, for the purpose of sections 301 and 302 of Pub. L. 94-437, former or currently federally recognized Indian tribes in the State of New York) or by an Indian firm; or a nonprofit firm organized for the benefit of Indians and controlled by Indians (see PHS 380.503(a)).

PHS 380.502-3 Product of Indian industry.

Product of Indian industry means anything produced by Indians through physical labor or by intellectual effort involving the use and application of skills by them.

PHS 380.502-4 Buy Indian contract.

Buy Indian contract means any contract involving activities covered by the Buy Indian Act that is negotiated under the provisions of 41 U.S.C. 252(15) and 25 U.S.C. 47 between an Indian firm and a contracting officer representing the Indian Health Service.
PHS 380.502-5 Buy Indian restricted advertising.

Buy Indian restricted advertising is a special method of negotiated acquisition conducted in the same manner as a formally advertised acquisition, except that competition and award are restricted to Indian firms (see FAR 19.101). Thus, a Buy Indian acquisition may be considered an acquisition set-aside for Indian firms in the manner that some acquisitions are set-aside for small business concerns (see FAR 19.101). Set-aside acquisitions are, technically, negotiated acquisitions but should be conducted as if they were formally advertised acquisitions in instances where the formal advertising method would be used if the set-aside was not in effect.

PHS 380.503 Requirements.

(a) Indian ownership. The degree of ownership that is called for by PHS 380.502-2 shall be 100 percent during the period covered by a Buy Indian contract unless a deviation from that 100 percent requirement is approved on an individual basis by the cognizant Area or Program Office Director of the Indian Health Service. Such a deviation, which may be to not less than 51 percent, must be accompanied by an appropriate justification for the deviation.

(b) Joint ventures. An Indian firm may enter into a joint venture with other entities for specific projects as long as the Indian firm is the managing partner. However, the joint venture must be approved by the contracting officer prior to the award of a contract under the Buy Indian Act.

(c) Bonds. In the case of contracts for the construction, alteration, or repair of public buildings or public works, performance and payment bonds are required by the Miller Act (40 U.S.C. 270a) and Part 28 of the Federal Acquisition Regulation (48 CFR Ch. 1). In the case of contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe, bonds are not required. However, bonds are required when dealing with private business entities which are owned by an Indian tribe or members of an Indian tribe. Bonds may be required of private business entities which are joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe. A bid guarantee or bid bond is required only when a performance or payment bond is required.

(d) Indian preference in employment, training and subcontracting. Contracts awarded under the Buy Indian Act are subject to the requirements of section 7(b) of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638), which requires that preference be given to Indians in employment, training, and subcontracting. Subpart 370.2 and the contract clauses in 352.270–2 and 352.270–3 represent the Department’s implementation of section 7(b). The Indian Preference clause set forth in 352.270–2 shall be included in all Buy Indian solicitations and resultant contracts. The Indian Preference Program clause set forth in 352.270–3 shall be used as specified in 370.222(b). All requirements set forth in Subpart 370.2 which are applicable to the instant Buy Indian acquisition shall be followed by the contracting officer, e.g., sections 370.294 and 370.205.

(e) Subcontracting. Not more than 50 percent of the work to be performed under a prime contract awarded pursuant to the Buy Indian Act shall be subcontracted to other than Indian firms. For this purpose, work to be performed does not include the provision of materials, supplies, or equipment.

(f) Wage rates. A determination of the minimum wage rates by the Secretary of Labor as required by the Davis-Bacon Act (40 U.S.C. 276a–5) shall be included in all contracts awarded under the Buy Indian Act for over $2,000 for construction, alteration, or repair, including painting and decorating, of public buildings and public works, except contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe. The wage rate determination is to be included in contracts with private business entities even if they are owned by an Indian tribe or members of an Indian tribe and in connection with joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe.

PHS 380.504 Competition.

(a) Contracts to be awarded under the Buy Indian Act shall be subject to competition among Indians or Indian concerns to the maximum extent that competition is determined by the contracting officer to be practicable, pursuant to FAR 14.101 and FAR 15.105. When competition is determined not to be practicable, a justification for Noncompetitive Acquisition shall be prepared in accordance with 315.7105 and subsequently retained in the contract file.

(b) Notwithstanding the provisions of Subpart 315.71, a request for approval of noncompetitive acquisitions to be negotiated under the Buy Indian Act may, if $25,000 or less, be approved by the chief of the contracting office or, if over $25,000, by the cognizant Area or Program Office Director. Approval shall be in the form of a justification for Noncompetitive Acquisition.

(c) Solicitations must be synthesized and publicized in the Commerce Business Daily (see FAR 5.2 and Subpart 303.2) and copies of the synopses sent to the tribal office of the Indian tribal government directly concerned with the proposed acquisition as well as to Indian concerns and others having a legitimate interest. The synopsis should state that the acquisition is restricted to Indian firms under the Buy Indian Act.

PHS 380.505 Responsibility determinations.

(a) A contract may be awarded under the Buy Indian Act only if it is first determined that the project or function to be contracted for is likely to be satisfactorily performed under such a contract and that the project or function is likely to be properly completed or maintained under that contract.

(b) The determination called for by paragraph (a), to be made prior to the award of a contract, will be made in writing by the contracting officer reflecting an analysis of the standards set forth in FAR 9.104–1, 306.104–1 of this Chapter and PHS 380.502–2.

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Part V

Department of the Interior

Fish and Wildlife Service

50 CFR Part 20

Regulations; Final Frameworks for Late Season Migratory Bird Hunting; Final Rule and Lead Poisoning in Bald Eagles; Proposed Alternative Conservation Measures; Notice of Intent; Request for Comments
DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
50 CFR Part 20
Migratory Bird Hunting; Final Frameworks for Late Season Migratory Bird Hunting Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This rule prescribes final late season frameworks from which States may select season dates, limits and other options for the 1984-85 migratory bird hunting season. The earliest of these seasons generally commences on or about October 1, 1984, and include most of those for waterfowl.

The frameworks are similar to those in effect last hunting season except restrictive regulations have been developed in the Pacific Flyway for cackling and dusky Canada geese and white-fronted geese, and in the Mississippi Flyway for Mississippi Valley Population Canada geese. In the Atlantic Flyway the option for an experimental permit season for whistling swans will be offered in North Carolina. The Service continues its program of stabilized duck hunting regulations into the 1984-85 hunting season as the fifth year of a 5-year cooperative study with Canada. Restrictions initiated in 1983-84 to reduce the black duck harvest will be continued this year.

The Service responds to the comments received following notice of the National Wildlife Federation petition concerning lead poisoning in bald eagles.

The Service annually prescribes hunting regulations frameworks to the States. The effects of this final rule are to facilitate the selection of hunting seasons by the States and to further the establishment of the late season migratory bird hunting regulations for the 1984-85 season. State selections will be published in the Federal Register as amendments to §§ 20.104 through 20.107 and § 20.109 of Title 50 CFR Part 20.

EFFECTIVE DATE: This rule takes effect on September 14, 1984. Tentative State selections of seasons and other options based on the proposed frameworks were due no later than August 31, 1984.

ADDRESSES: Send State season selections to: Director (FWS/MBMO), U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240. Comments received on the proposed late season frameworks are available for public inspection during normal business hours in Room 536, Matomic Building, 1717 H Street, N.W., Washington, D.C.


SUPPLEMENTARY INFORMATION: The Migratory Bird Treaty Act of July 3, 1918 (40 Stat. 765; 16 U.S.C. 703 et seq.), as amended, authorizes and directs the Secretary of the Interior, having due regard for the zones of temperature and for the distribution, abundance, economic value, breeding habitats, and times and lines of flight of migratory game birds, to determine when, to what extent, and by what means such birds or any part, nest or egg thereof may be taken, hunted, captured, killed, possessed, sold, purchased, shipped, carried, exported or transported.

On March 23, 1984, the U.S. F. and Wildlife Service (hereinafter the Service) published for public comment in the Federal Register (49 FR 11290) proposals to amend 50 CFR Part 20, with comment periods ending June 21, July 16 (later extended to July 18), and August 17 (later extended to August 29), 1984, respectively, for the 1984-85 Alaska, Hawaii, Puerto Rico and the Virgin Islands hunting seasons; other early hunting seasons; and the late hunting seasons frameworks. That document dealt with the establishment of hunting seasons, shooting hours, areas and limits for migratory game birds under §§ 20.101 through 20.107 and 20.109 of Subpart K. A supplemental proposed rulemaking for both the early and late season frameworks appeared in the Federal Register dated June 13, 1984 (49 FR 24417). On July 9, 1984, the Service published for public comment in the Federal Register (49 FR 28026) a third document consisting of a proposed rulemaking dealing specifically with frameworks for early season migratory bird hunting regulations. On July 19, 1984, the Service published in the Federal Register (49 FR 29238) a fourth document containing final frameworks for Alaska, Puerto Rico and the Virgin Islands, and on August 7, 1984 (49 FR 31421) a fifth document containing final frameworks for other early seasons for migratory bird hunting regulations from which State wildlife conservation agency officials selected early season hunting dates, hours, areas and limits for the 1984-85 seasons. On August 20, 1984, the Service published in the Federal Register (49 FR 33090), a sixth document containing proposed frameworks for late season migratory bird hunting regulations. On August 31, 1984, the Service published in the Federal Register (49 FR 34048) a seventh document consisting of a final rule amending Subpart K of Title 50 CFR Part 20 to set hunting seasons, hours, areas and limits for mourning doves, white-winged doves, band-tailed pigeons, rails, woodcock, snipe and gallinules; September teal seasons; sea ducks in certain defined areas of the Atlantic Flyway; ducks in September in Florida, Iowa, Kentucky and Tennessee; sandhill cranes in the Central Flyway and Arizona; sandhill cranes and Canada geese in southwestern Wyoming; migratory game birds in Alaska, Hawaii, Puerto Rico and the Virgin Islands; and special falconry seasons. This document is the eighth in the series and establishes final frameworks for late season migratory bird hunting regulations for the 1984-85 season.

These proposed regulations contain no information collections subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980.

Review of Public Comments and the Service's Response

Written Comments Received

In the Federal Register dated June 13, 1984 (at 49 FR 24418), the Service responded to comments received up to that time on proposed late season frameworks. Eleven statements made at the public hearing on proposed late hunting season frameworks and 597 additional written comments were summarized and responded to in the Federal Register dated August 20, 1984 (at 49 FR 33093). Since then 863 written comments have been received. In several cases, more than one comment was received from the same respondent, and in some others views were offered on more than one regulatory subject. The new comments originated from 19 states, 44 organizations and a number of individuals. They are summarized and responded to according to the regulatory topics identified in the Federal Register dated March 23, 1984 (49 FR 11290). The Service also gave notice in the August 20, 1984 Federal Register (at 49 FR 33091) of receipt of a petition from the National Wildlife Federation (NWF) recommending immediate action to protect bald eagles from lead poisoning. The Service solicited comment on the NWF proposals. The following relates to the petition and the comments:
The Impact of Lead Shot on Bald Eagles—Notice of Alternative Conservation Measures

As discussed in more detail in the pages that follow, one of the most emotional and intensely debated issues arising under the 1984-85 waterfowl season regulations process has been the effect of lead shot on the American bald eagle. Although the Fish and Wildlife Service has been studying this issue for some time, a recent petition on the subject from the National Wildlife Federation (NWF) requesting emergency regulatory action has intensified the Service's assessment of the problem.

Regardless of its cause, lead poisoning in bald eagles is occurring and additional work is needed to provide a better understanding of the ecological relationship and its biological significance of this type of mortality in bald eagles. The ecological relationship between bald eagles and waterfowl also requires strong consideration in assessing bald eagle/lead poisoning. Issues of concern include the species of waterfowl (geese vs ducks) being used as a food base; the number of waterfowl being consumed by bald eagles; the time of year when eagles are feeding on these waterfowl; the length of time of bald eagle-waterfowl interactions at specific sites; and, the use of toxic and non-toxic shot play major roles in influencing the occurrence of lead poisoning in bald eagles.

In order to get a better perspective on this problem, the Service has convened a number of meetings in recent weeks among representatives from its endangered species, research, and migratory bird programs. Wholly apart from the Service's responsibilities towards the bald eagle established under section 7(a)(2) of the Endangered Species Act, the mission of this group of technical and resource experts was to formulate conservation measures which could reasonably be expected to provide credible biological information and long-term solutions to the problem of lead poisoning in bald eagles.

The preliminary conservation recommendations from this ad hoc working group have now been completed. In order to provide the public with an opportunity to comment on these proposed conservation measures, the Service is publishing them in this issue of the Federal Register. All public comments on these measures received within the next 45 days will be taken into account in formulating the Service’s final conservation measures for addressing the problem of lead poisoning in bald eagles.

The National Wildlife Federation petition on lead shot

As noted in the August 20th proposed frameworks publication, the NWF petitioned the Service at the August 1, 1984, public hearing to take emergency action in response to lead poisoning in bald eagles. In particular, the NWF divided 95 counties around the country into so-called “Class I” or “Class II” areas. Class I areas were identified by the NWF as areas where there had been:

- (a) At least one bald eagle death from lead poisoning since 1966;
- (b) a concentration of fifteen or more wintering bald eagles; and (c) at least one documented death of a waterfowl due to lead poisoning or a 5 percent lead shot ingestion rate for waterfowl in the area.

Class II areas were identified as areas where there had been:

- (a) a concentration of fifteen or more wintering bald eagles; and either (b) one or more bald eagles with lead poisoning, regardless of whether the poisoning was lethal or sublethal (included in this category were bald eagles whose lead poisoning had only been preliminarily diagnosed at the time of the August 1st petition); or (c) at least one death of a waterfowl due to lead poisoning or a 5 percent lead shot ingestion rate for waterfowl in the area.

The NWF petitioned the Service to immediately designate non-toxic shot zones for the 1984-85 season, or in the alternative, to exercise on an emergency basis the agency's closure authority under the Migratory Bird Treaty Act and prohibit all waterfowl hunting in those areas for the 1984-85 season. The NWF demanded that the Service immediately propose a regulation for Class II areas which would establish the areas as non-toxic shot zones for the 1985-86 season.

As was noted in the Service's August 20th publication in the Federal Register, the designation of steel shot zones was beyond the scope and intent of the August 1st public hearing and the proposed rule on late season waterfowl frameworks. For reasons set forth in more detail later in this document, the Fish and Wildlife Service has historically bifurcated the regulatory process establishing waterfowl frameworks (e.g., seasons and bag limits) from the regulatory process establishing non-toxic shot zones. Thus, that part of the NWF petition regarding the emergency establishment of steel shot zones for Class I areas was not germane to the regulatory process at hand.

Instead, the Service intended to solicit public comment on the NWF's steel shot request in conjunction with a mid-September publication of steel shot zone modifications proposed for the 1985-86 season.

Summary of Major Comments

In response to the August 20th publication, twenty-one comments were received on the NWF petition. Letters from the NWF, the Sierra Club Legal Defense Fund, Inc., National Audubon Society, The Wildlife Society, Center for Environmental Education, The Izaak Walton League of America, Natural Resources Defense Council, Inc., and World Wildlife Fund-U.S. were in support of the petition submitted by the NWF. Letters from The Sportsmen's Clubs of Texas, Inc., South Carolina Wildlife Federation, and six individuals were also in support of the NWF petition.

The National Rifle Association (NRA) submitted comments which questioned the emergency nature of the NWF petition and the validity of some of the county designations by the NWF. The NRA requested the economic impacts of the NWF petition be carefully analyzed and adequate time for public comment be permitted by the Service before final decisions are made.

The Arizona Game and Fish Department questioned the need for emergency action. They stated that action taken without adequate warning to hunters and ammunition suppliers tends to cause unnecessary resentment.

In addition, a resident in Holt County, Missouri, a Class I area in the NWF analysis, objected to the NWF petition. He questioned the adequacy of steel shot as a replacement for lead shot and expressed concern over the negative economic impacts of the actions outlined in the NWF petition.

Finally, the Federal Cartridge Corporation commented that the ammunition industry needs 12 to 14 months notice when changes in steel shot zones are made. This period allows time to remove lead shot inventories and produce and distribute steel shot ammunition. For these reasons the Federal Cartridge Corporation requested that the implementation of steel shot in additional areas be delayed until 1985.

None of the comments identified above presented the Service with new technical data or information which the Service did not already have.

The NWF submitted the most extensive comments on the issue. The Federation objected to the fact that the Service formally submitted for public comment only that part of its petition dealing with the emergency closure of its Class I areas to the hunting of waterfowl. The Federation also...
contended that the Service failed to justify this procedure. In addition, the NWF criticized the Service for what it characterized as a failure to respond in a timely fashion to a known problem involving lead poisoning in bald eagles. It objected to a statement in the August 20th publication implying that a revised Biological Opinion on the subject stemming from reinitiated Section 7 consultation had been signed on the 15th of August when it actually had been signed on the 27th of that month. The NWF also indicated that a failure to respond be made to its-petition by September 14, the anticipated publication date of the late season final frameworks. Finally, the NWF demanded that a final report be helpful in summarizing its biological methodologies and assumptions which served as the basis for the NWF petition and report.

A. Summary of Literature on Lead Poisoning of Bald Eagles

Recognition of lead poisoning as a cause of mortality among bald eagles is of recent origin (Mulhern et al., 1970). An increasing number of diagnosed cases of this disease are being reported to the National Wildlife Health Laboratory. However, far less is known about lead poisoning in bald eagles than in waterfowl because of the limited number of experimental studies carried out on this species.

There is one experimental study involving lead dosing of bald eagles. In this study, four out of five bald eagles that received lead died (Pattee et al., 1981), and the fifth became blind and was sacrificed after 133 days. The span of time from ingestion to death after initial dosing of the four eagles that died was 10, 12, 20 and 125 days (Hoffman et al., 1981). These birds were given an initial dosage of 10 number 4 lead shot. Regurgitation of shot required redosing and resulted in actual numbers of shot fed varying from 10 to 155. The number of shot recovered at necropsy varied from 1 to 10, and the number of shot recovered as a result of being expelled by the eagles is from 5 to 145.

The study by Pattee et al. (1981), demonstrates that ingestion of lead shot can result in bald eagle mortality, provided shot is retained long enough for lead absorption to occur. It did not determine what causes retention of lead pellets. However, it appears that once pellets have been retained in bald eagles for more than 24 hours, there is a tendency for continued retention of the shot for a prolonged period (Redig, 1976). Lead concentrations in liver tissue of the four birds that died in Pattee’s study ranged between 11.5 and 27.0 ppm (wet weight basis). Those findings are consistent with experimental data from lead studies in waterfowl and are supportive of diagnostic evaluations of eagle mortality made by the NWHL and other laboratories.

There are two differences between the cause of lead poisoning in bald eagles and in waterfowl. These are methods of lead ingestion and time of ingestion until death. Ingestion of lead shot as a result of feeding activities occurs for both eagles and waterfowl. However, for waterfowl the principal source of exposure is spent lead shot deposited in waterfowl hunting areas. The major source of lead exposure for bald eagles is thought to be shot lodged in the tissue of food animals (Redig, 1976; Pattee and Hennes, 1983).

The second important difference is the lead intoxication process. Data on bald eagles and other raptors indicate that lead intoxication is a slower process in raptors than in waterfowl. The time involved between exposure and death may span more than a month in bald eagles (Redig, 1979), while waterfowl typically succumb or recover within 3 weeks. It also appears that the period of debilitation prior to death is more prolonged in waterfowl than in bald eagles. The result is that waterfowl with acute lead poisoning are less mobile than bald eagles with acute lead poisoning. It is this greater mobility of the eagles during this period that makes it more difficult to indentify areas containing high concentrations of lead shot that serve as the source of lead in bald eagle deaths.

B. Critique of National Wildlife Federation Class I and II Selection Criteria

The methods used by the NWF to identify bald eagle/lead poisoning problem areas require the use of non-toxic shot. Attention is focused on the following:

(1) Utilization of waterfowl/lead poisoning problem areas as a criterion for identifying bald eagle problem areas. The Service believes the primary cause of lead poisoning in bald eagles is from the ingestion of shot embedded in the tissues of birds hit, but not retrieved by hunters, rather than consumption of lead poisoned waterfowl. Therefore, the basis for using waterfowl lead poisoning problem areas to define bald eagle problem areas is questionable.

Furthermore, the definition of waterfowl/lead poisoning areas based on duck or goose gizzard collections with a 5 percent incidence of ingested shot, represents an arbitrary designation. It cannot be assumed that a 5 percent incidence of shot in gizzards will result in lead poisoning. Finally, NWF’s use of a single case of lead poisoning in waterfowl within a county during the past 10 years to define a waterfowl/lead poisoning area is questionable. Differences in opinion about what constitutes a lead poisoning area, and the significance of lead poisoning as a mortality factor in waterfowl, continue to be the most difficult and controversial aspects of dealing with the lead poisoning issue.

The petition and report do not indicate what criteria were used to verify the occurrence of lead poisoning in waterfowl (page 8, section A 1). In view of the weight being given to a single case of documented lead poisoning, a rigorous examination is needed to determine what constitutes verification.

(2) Identification of lead poisoning in bald eagles as a criterion for identifying lead poisoning problem areas. Lead poisoning as a cause of death in bald eagles cannot be defined solely on the basis of a lead liver concentration of 10 ppm or greater (NWF report, p. 11-12) because toxicology is only one part of the diagnostic process used in assessing the cause of bald eagle mortality.

Experimental values of lead in soft tissues of bald eagles are available from five eagles, four of which died (Pattee et al., 1981). This small sample is an inadequate one on which to base rigid judgments regarding lead concentrations in soft tissues. Enough exceptions have been observed in lead concentrations in the soft tissues of birds to question seriously the validity of assessments of lead poisoning, based solely on tissue concentrations of lead.

The National Wildlife Federation cites an exception to the 10 ppm criterion by selecting 6ppm with associated clinical signs as being diagnostic of lead poisoning.
poisoning in bald eagles. Using such a criterion is invalid because differences in response of individual birds to lead can result in higher concentrations of lead being present without a diagnosis of lead poisoning being issued. Conversely, a difference in response can result in lead concentrations in liver tissue below 10 ppm also being diagnosed as lead poisoning.

The petition does not indicate whether the NWF used the diagnoses of pathologists reporting cases they reviewed, or whether they reevaluated those cases based on the criteria stated on page 12 of their report. If changes were made, the biological validity of any alterations in the diagnoses needed to be assessed. This is especially true if clinical signs were used as criteria. It is not clear whether NWF used the term clinical signs to include postmortem findings. Other signs are associated with live birds and are not specific for lead poisoning. Pathology at necropsy and histopathological evaluations are better indicators of lead poisoning than are clinical signs.

Evaluation of sublethal levels in body tissues of bald eagles is subject to opinion. Although a great deal of support is possible, a strong biological basis is lacking to support the many hypotheses regarding effects of these tissues on lead concentrations. Sublethal levels of lead in body tissues clearly demonstrate exposure to lead. Enzyme assays clearly demonstrate some disruptive effects of lead on certain biological functions. However, extrapolation of these and other findings to an assessment of bald eagle survival and reproduction, following exposure to sublethal levels of lead, is questionable.

FWS Response to Public Comments on the NWF Petition

Having employed the above analysis in measuring the scientific validity of the NWF's petition and its assessment of an emergency, the Service will now respond to the major public comments received on the NWF petition: A. The failure to request expressly public comment on that part of the NWF petition regarding emergency steel shot designations. All twenty-one of the public comments received addressed the steel shot portion of the Federation's petition. Regardless of that fact, the Service believes that that part of the NWF petition dealing with emergency designation of steel shot zones was beyond the scope and subject matter of the August 20th proposed rule. That proposed rule was intended to cover the establishment of late season frameworks and not the designation of steel shot zones. The latter issue has been historically addressed in a separate series of rulemakings that follow an entirely different timetable than that utilized for regulations involving hunting seasons and bag limits.

This bifurcation of the migratory bird hunting regulatory process has been employed for a number of reasons. Final administrative decisions on the content of migratory bird frameworks must necessarily be made at the end of summer after the last breeding ground surveys have been completed and an assessment of the fall flight is developed. Although time is of the essence at that point, generally the States are able to complete their own administrative review procedures on the selection of seasons and bag limits before the start of the fall hunting season.

On the other hand, the designation of new steel shot zones requires substantially more lead time for the implementation of final administrative decisions. One of the primary reasons for this has been that every year since 1978, the Service has had a rider attached to its appropriation bill which bars it from spending funds to implement and enforce final steel shot regulations without the approval of the affected States. As a matter of law, this appropriations limitation precludes the very sort of unilateral Federal designation of steel shot zones that the NWF petition demanded for its Class I areas for the 1984-85 season. And, it is important to note, the appropriation act's limitation on Service action is controlling even in the face of other substantive agency obligations under statutes like the Endangered Species Act.

Given the appropriations rider, and local controversies which can surround each new steel shot zonal designation, sufficient lead time must be built into the regulatory process to allow for extensive consultation with the affected States. As a general matter, the Service attempts to finalize steel shot designations one year in advance of the actual affected season. In the case of the 1984-85 season, for example, the last Federal Register publication on steel shot occurred in June of 1983 (48 FR 26457).

Often one of the crucial factors for gaining State approval is the availability of non-toxic shot in the wholesale and retail markets. Orders for ammunition are received by late spring, and not all major ammunition manufacturers have regional distribution centers capable of rapidly reallocating limited supplies of steel shot, an unexpected conversion to steel shot in August or September would for all practical purposes close down the fall hunt. The Service and the States are aware of this potential effect which is one of the reasons why they try to avoid the sort of precipitous regulatory action advocated by the NWF for Class I areas.

Moreover, since so much lead time on the designation of steel shot zones is built into the Federal rulemaking process, many States print up and distribute their hunter informational materials on lead and steel requirements well in advance of the establishment of final State seasons and bag limits. A last minute conversion to steel shot would in most instances hopelessly confuse the hunting public and make the successful enforcement of a new steel shot requirement virtually impossible.

In summary, both as a matter of law and as a matter of policy, the Service was not being arbitrary and capricious, nor acting in violation of Federal law, by deferring public consideration of the NWF steel shot proposal until the next scheduled publication of steel shot proposals for the 1985-86 season which is currently set for mid-September. The appropriations rider precludes the Service from unilaterally converting the Class I areas into 1984-85 steel shot zones. Since there was no practical or legally authorized opportunity for the Service to implement the 1984-85 Class I proposal, the Service intends to solicit public comment formally in the mid-September publication on NWF petition in the context of a proposal to designate Class I and Class II areas as non-toxic shot zones for 1985-86. Although submitting it for public comment, the Service would not be endorsing it as a proposed rule.

B. Lead poisoning in bald eagles. The NWF and others criticized the Service for not having acted sooner in dealing with lead poisoning problem in bald eagles. To date, most research on lead poisoning has focused on waterfowl and even this effort has produced tentative conclusions. Moreover, as noted in the August 27th Biological Opinion written by the Endangered Species Office, not only is lead poisoning not jeopardizing continued existence of the bald eagle nationwide, the eagle is in fact continuing its recovery and is increasing in number. In fact, the National Wildlife Federation's own recent national population survey of bald eagles showed an increase of over 500 eagles from last year. Because the resources available for the endangered species recovery program are not inexhaustible, the Service felt it was justified in concentrating its research efforts on more critically endangered species like
the whooping crane or the California condor.

Given the increase, however, in both the public's concern over this matter and the number of eagles recently diagnosed as having died of lead poisoning, the Service recognizes the need to intensify its efforts to resolve this problem. The Service believes the preliminary conservation measures set forth in this issue of the Federal Register is a positive step and responds to the criticism of the NWF and others.

C. NWF demand for FWS to publish by September 14 both a response to its steel shot petition for Class I Areas and a proposed rule for the Class II Areas for 1985-86. The Service believes that the detailed discussion of the NWF petition for Class I Areas in the preceding page adequately addresses the first part of the Federation's demand. As for the immediate issuance of a steel shot proposed rule for the NWF's Class II Areas, the Service has made a commitment to solicit public comment on this request in its next regularly scheduled publication of its 1985-86 steel shot proposals. Moreover, the Service is proposing its own alternative conservation measures in the general public notice section of this Federal Register and has set mid-December as the target date for making a decision on the proposed designation of steel shot zones for a number of the Federation's Class II Areas.

D. The use of the Service's emergency closure authority under the Migratory Bird Treaty Act. Many of the commenters in favor of the NWF petition supported its alternative request that the Service close down waterfowl hunting in Class I Areas on an emergency basis if steel shot zones were not designated for those areas this fall. After a careful review of all relevant information on this matter, the Service has decided against exercising its emergency closure powers as requested. To begin with, the Service is not convinced that it is confronted with an emergency. As noted in the August 27 Biological Opinion on the NWF petition, the bald eagle is steadily continuing its recovery and has not had its continued existence jeopardized by lead poisoning. As noted previously, this is substantiated by the fact that the Federation's own recently announced population count for bald eagles showed an increase of over 900 bald eagles since last year. Moreover, the Service's biological critique of the Federation's methodology and criteria has shown that many of the petition's assumptions and conclusions are speculative. Given the stringent standards the courts have devised for assessing the legality of emergency rules, the Service is not convinced that such precipitous action as an emergency closure is either authorized or warranted at this time. The Service admits that more must be done to study the effects of lead poisoning of eagles, but it feels that there is no crisis facing the eagle, nor is there likely to be one with the implementation of carefully devised conservation measure like those set forth in today's general public notice. By accelerating its analysis of the problem in an orderly and logical fashion, the Service believes that it will be in a much better position by mid-December to launch a comprehensive program for addressing lead poisoning in bald eagles.

2. Framework dates for ducks and geese in the continental United States. Two comments were received regarding frameworks for ducks and geese. The National Wildlife Federation and the Wildlife Legislative Fund of America (by letters of August 8 and August 22, 1984, respectively) endorsed the proposed late season regulations. Both organizations supported the Service's proposal to continue the stabilized duck hunting regulations study through the 1984-85 season. The National Wildlife Federation also urged the Service to present the evaluation of the stabilized regulations program as soon as practicable, but before seasons are established for 1985-86.

Response. The support of the National Wildlife Federation and the Wildlife Legislative Fund of America for the proposed frameworks and continuation of the stabilized regulations study is acknowledged. The Service notes the interest of the Federation in an expedited review of the 5-year stabilized regulations study and a presentation of the evaluation prior to the 1985-86 waterfowl seasons. In response to similar comments in the June 20, 1984, Federal Register (at 49 FR 33082), the Service indicated an intensive review will be initiated to determine what management measures should be implemented in 1985, including harvest reductions as they may be appropriate, to improve the status of duck populations, particularly mallards and pintails, in the prairie breeding grounds of Canada. The Service's review and development of management programs will be a cooperative effort with the Flyway Councils, the Canadian Wildlife Service, and other appropriate Canadian jurisdictions.

3. Black ducks. The National Wildlife Federation (by letter of August 8, 1984) endorsed the Service's proposal to continue the black duck harvest restrictions of 1983-84 in 1984-1985 and 1985-86 in order to insure that the Service can evaluate what impact restrictive regulations have on black duck populations.

Response. The Service acknowledges the request of the National Wildlife Federation for the proposed black duck hunting frameworks and the continuation of those frameworks through the 1985-86 waterfowl season.

4. Wood ducks. Wisconsin (by letter of August 14, 1984) expressed the view that the proposed early wood duck season option offered the Mississippi Flyway States of Arkansas, Louisiana, Mississippi, and Alabama (August 20, 1984, Federal Register, at 49 FR 33101) violates the concept of the stabilized duck hunting regulations study and has the potential to reduce the nesting wood ducks. They stated that because the affected States have never pursued this option it should be withdrawn and possibly offered Flyway-wide when the wood duck population can sustain such a season.

Response. The early wood duck season option was first offered to the above States by the Service in 1977 in an effort to provide for additional harvest of southeastern wood ducks, yet not increase the harvest of northern nesting wood ducks. The option, offered every year since 1977, allows the additional harvest of wood ducks for up to 9 days during the period October 1-15 provided that the days taken are a part of the regular waterfowl season days of participating States. The Service does not view the option as being a violation of the stabilized duck hunting regulations program because it has been offered each of the previous 4 years of the 5-year study. Although the eligible States have not exercised their option for an early wood duck season, the Service believes it should continue to be offered in 1984. The Service does not believe the early wood duck season option should be offered Flyway-wide since northern wood ducks are already harvested at a relatively high rate.

12. Canvasback and redheads. In the August 20, 1984, Federal Register the Service accepted a change in the boundary for the experimental canvasback area in Maryland and indicated it was "incorporated in the proposed late season framework * * *". Through error the requested change was not made in the August 20 Federal Register but it is corrected in these final late season frameworks for migratory birds.
13. **Zoning.** In the June 13, 1984, Federal Register [at 49 FR 24421] the Service proposed to apply Central Flyway duck season length and Mississippi Flyway bag limits to the West zone in Louisiana beginning in the 1985-86 hunting season. The Service has received 25 comments on the Louisiana proposal: 8 (1 State and 2 individuals) in support and 17 (18 States, 2 organizations and 2 individuals) in opposition. The comments in opposition identify the following problems:

1. The Service has inadequately considered the adverse impacts that implementation of this proposal could have on Central and Mississippi Flyway duck resources.

2. The proposal is inconsistent with the concept of Federal-State cooperative waterfowl management in that it was developed by Louisiana and the Service without consultation with or participation by other concerned States.

3. The proposal narrowly addresses the relationship between the Mississippi and Central Flyways only with respect to Louisiana. It ignores this relationship with respect to other States in the Mississippi Flyway and fails to address the potential impact on the entire boundary between the two Flyways.

4. The potential for further modifying the distribution of the harvest among States in the Mississippi and Central Flyways, which is already heavily weighted in favor of Louisiana has not been given adequate consideration.

5. Conclusions drawn from study, on which the proposal is based, are strongly influenced by questionable assumptions regarding differences in harvest rates between the Mississippi and Central Flyways.

6. It is inappropriate at this time, when mallard and other duck populations are depressed as a result of drought, to initiate changes in frameworks that may increase duck harvest, especially mallards.

7. The proposal should not be considered until after the current experiment involving stabilized duck hunting regulations has been completed, analyzed, and evaluated.

By letter of August 16, 1984, Michigan indicated that the boundary description of their Southeastern duck hunting zone as described in the August 20, 1984, Federal Register [at 49 FR 33102] was inadequate and provided a more detailed description of the zone.

**Response.** In view of the source and nature of comments received on the proposal for zoning Louisiana the Service has concluded that further action should be deferred pending additional consultation particularly with the Central and Mississippi Flyway Councils.

With respect to the comment from Michigan, the final frameworks set forth in this document reflect a more detailed description of the Southeastern zone in Michigan.

14. **Goose and Brant Seasons.** For State wildlife agencies (Wisconsin, Michigan, Kentucky and Indiana), 3 organizations and 21 individuals commented on the harvest regulations proposed in the August 20, 1984, Federal Register for Mississippi Valley Population (MVP) Canada Geese.

Wisconsin noted that the seasonal bag limit for Canada geese in the Theresa portion of the Horicon Zone should be 4 birds, rather than 2 as proposed, and that no mention was made of the late season for giant Canada geese normally offered in the Mississippi River Zone. Wisconsin also commented about Canada goose season lengths and bag limits in other States, including Missouri and Indiana, and observed that they appeared to be inconsistent with efforts to reduce the kill of MVP geese.

Michigan objected to the proposed regulations as being more restrictive than necessary, particularly in areas where Tennessee Valley Population (TVP) Canada geese intermingle with MVP Canada geese. They recommended a 40-day season Statewide, except in 10 western counties of the Upper Peninsula where the season would be 25 days. Bag limits could be 2 birds daily Statewide, except in the Allegan County Goose Management Area where a 1-bird daily bag limit would apply. State-imposed quotas would be established in the Seney Zone (500 birds), Allegan County Goose Management Area (4000 birds, 6000 in 1983), and Saginaw County Goose Management Area (5000 birds).

Kentucky proposed that the 7000 Canada goose quota assigned to the West Kentucky Zone be increased by 500 birds in recognition of harvest of TVP geese in the Union-Henderson County area.

Indiana proposed that a 40-day Canada goose season be established in Posey County with a quota of 1000 birds assigned to the Hovey Lake area. When the quota is reached, the Canada goose season in Posey County would be closed. Indiana also proposed that the Canada goose season length Statewide, except for Posey County, be 50 days.

Six individuals and 1 hunting club in Michigan believed that the season length and bag limits for Canada geese were too restrictive, especially as they affected hunting for TVP and giant Canadas.

Three Indiana goose hunters believed the proposed regulations for Canada geese in Posey County were too restrictive and that Indian was being treated unfairly compared with other States in the MVP range.

An Illinois hunting group indicated that it was unfair to apply restrictions outside the Canada goose quota zones, questioned the accuracy of harvest estimates, and recommended a framework closing date of December 31 in Illinois.

Eleven individuals and 1 organization in Tennessee believed the 1500-bird quota for Canada geese in the Northwest Zone should be larger and compared the small Tennessee quota with the larger quotas of other States. Two of the individuals suggested that quotas elsewhere be reduced to allow a larger quota in Tennessee. One of the individuals recommended a 2-bird daily bag limit for Canada geese, and another noted that restrictive regulations would result in economic loss because of reduced tourism.

**Response.** The Service will correct in the final frameworks the bag limits in the Horicon Zone to provide for a season bag limit of 4 birds instead of 2 birds. The late season for giant Canada geese, from November 25 to December 9 in the Mississippi Flyway Zone, is included in the final frameworks. Bag limits of 2 daily and 4 in possession will be continued as in previous years. In regard to Wisconsin's comments about Canada goose hunting regulations in other States where MVP geese are harvested the Service is of the view that the proposed season lengths and bag limits will be effective in lowering the kill as recommended by the MVP Committee of the Mississippi Flyway Council. Michigan's concern that restrictions on the harvest of MVP geese in that State will have the additional effect of reducing the harvest of TVP geese is noted and the Service concurs that this is likely to be the case in Michigan as well as some other States in the MVP range. However, in those areas where both MVP and TVP geese are present at the same time there appears to be no practical way to avoid this situation and still provide the needed reduction in MVP harvests. The MVP Committee of the Mississippi Flyway Council has unanimously recommended that the 1984 harvest be reduced by 50 percent from that of 1983 to help reverse the 7-year downward trend. They recommended that the season length throughout the MVP range be no more than 25 days. The Committee believes that this is
necessary in order to achieve progress toward the unanimously accepted 500,000 bird population goal, and the Service concurs. The Service believes the proposed Canada goose regulations for Michigan are necessary under the circumstances. The Service is of the view that the proposal by Michigan for a 25-day season in the 10 western counties of the Upper Peninsula and 40 days elsewhere in the State, a daily bag limit of 2 geese in most areas, and a reduction of 2000 birds in the harvest quota for the Allegheny County Goose Management Area is inadequate to achieve a 50 percent Statewide reduction in harvest of MVP geese.

In Kentucky, as in Michigan, there is no clear line dividing the ranges of MVP and TVP Canada geese. Some TVP geese occur in the range occupied by MVP geese, and vice versa. Thus, the proposal to increase the Kentucky harvest objective by 800 geese to allow for kill of TVP geese within the MVP control zone is considered inappropriate because no allowance is made for harvest of MVP geese that occurs in the range assigned to TVP geese.

The Indiana proposal appears to have merit and deserves technical consideration by the MVP Committee of the Mississippi Flyway Council for future consideration. The main question concerns the degree to which harvest at Hovey Lake is related to the County-wide harvest in Posey County. The 40-day season length proposed by Indiana is inconsistent with guidelines of the MVP Committee that season length not exceed 25 days.

The comments by individuals and organizations are generally dealt with above. The Service has proposed restrictive regulations for MVP Canada geese within guidelines provided by the MVP Committee. It is difficult to apply restrictions evenly, and some inequities may occur. However, the Service believes that a significant effort is necessary to reduce the harvest of these geese and make progress toward achieving a 500,000 bird population.

15. Whistling swan. In the August 20, 1984, Federal Register (at 49 FR 33101) the Service proposed a limited experimental swan hunt in North Carolina beginning in the 1984–85 hunting season. In that document the Service addressed the comments received through August 7th. Since August 7, an additional 812 written comments have been received, 212 in opposition and 600 in support of a swan season. Those opposed to swan hunting continue to express the belief swans are too special to be hunted, that if hunted, many will be crippled and lost, and that any agricultural or shellfish losses could be alleviated by means other than hunting. Those favoring a season believe swans are numerous enough to sustain hunting and are a proper game species, that swans do cause agricultural damage and do compete with other wildlife for food resources.

Response. The additional comments received in opposition or support since August 7 are similar in content to those responded to in the August 20, 1984, Federal Register (49 FR 33099). The recent comments offer no new evidence that a limited experimental swan season would be detrimental to the eastern population of whistling swans. The Service recognizes that strong opposition, on other than biological grounds, exists to the hunting of swans. The Service notes, however, that swans have been harvested for sport and for the Pacific Flyway since 1982. The sum of that experience indicates that swans are an appropriate game bird and that permit hunts represent a safe and cautious approach to the proper management of the resource. Therefore, a swan season, with the constraints previously noted, is authorized for North Carolina in 1984–85.


By letter of August 22, 1984, The Wildlife Legislative Fund of America expressed concern over the impact of illegal taking of cackling Canada geese, white-fronted geese, emperor geese and black brant in Alaska, whether for subsistence or other purposes. They strongly urged the Service to take action to control the spring harvest of these species before it worsens because it is having serious adverse impacts on the species and it is contrary to the laws and treaties regarding protection of migratory game birds.

Response. The Service acknowledges the concerns expressed by The Wildlife Legislative Fund of America. In the August 20, 1984 Federal Register (at 49 FR 33002) the Service responded to similar concerns expressed by two speakers at the August 1, 1984, Public Hearing on late waterfowl hunting season regulations. Harvest restrictions on several species of geese that nest in the Yukon-Kuskokwim Delta of Alaska have been proposed for 1984–85. In addition, the Association of Village Council Presidents, working in cooperation with the above agencies on behalf of the residents of the Yukon-Kuskokwim Delta have agreed to follow the same guidelines in curtailing the harvest of these geese in the Delta where they traditionally contribute an important source of food in spring and early summer. This curtailment was initiated in the spring of 1984. The Service is of the view that the development and implementation of this agreement represents an important step toward conservation of these geese and merits continuation until results of the agreement can be measured.

Nontoxic Shot Regulations

On August 13, 1981, the Service published in the Federal Register (46 FR 40879) final rules describing nontoxic shot zones for waterfowl hunting. When eaten by waterfowl, spent lead pellets may have a toxic effect. Nontoxic shot zones reduce availability of lead pellets in selected waterfowl feeding areas. Steel shot is the only non-toxic shot type available at this time.

Amendments to these regulations were published in the Federal Register (47 FR 32546; July 28, 1982 and 48 FR 26457; June 8, 1983). These amendments relate to changes in Indiana, Maine, Massachusetts, Nebraska, Michigan, Illinois, Florida, and Texas. Some States have State regulations requiring steel shot for waterfowl hunting in areas not included in the Federal regulations published in the Federal Register on August 13, 1981 (46 FR 40879) and as amended.

Some national wildlife refuges require use of steel shot on hunting areas within their boundaries, and these rules are published with other regulations regarding public use of the refuges (Title 50 CFR Part 32.12—Hunting). Waterfowl hunters are advised to consult State and local regulations regarding the use of nontoxic shot for waterfowl hunting.

NEPA Consideration

The “Final Environmental Statement for the Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (FES 75–54)” was filed with the Council of Environmental Quality on June 6, 1975, and notice of availability was published in the Federal Register on June 13, 1975 (40 FR 25241). In addition, several environmental assessments have been prepared on specific matters which serve to supplement the material in the Final Environmental Statement. A recent supplement to the Final Environmental Statement is the environmental assessment entitled “Proposed Hunting Regulations on Eastern Population of Whistling [Tundra] Swans, 1984” and dated September 1984. Copies of the environmental assessments are available from the Service.

Endangered Species Act Consideration

Section 7 of the Endangered Species Act provides that, “The Secretary shall
regulations were not likely to jeopardize the continued existence of the listed bald eagle. In a supplemental biological opinion dated September 6, 1984, the OES considered actions proposed to be taken by the Service in regard to its authorities for the conservation of listed species under section 7(a)(1) of the Endangered Species Act. The OES believed the measures proposed were timely and appropriate. A second revised supplemental opinion was issued by OES on September 10, 1984, which concluded that the proposed migratory bird regulations were not likely to jeopardize, even on a regional basis, the continued existence of the listed bald eagle.

As in the past, hunting regulations this year are designed, among other things, to remove or alleviate chances of conflict between seasons for migratory game birds and the protection and conservation of endangered and threatened species.

The Service’s biological opinion resulting from its consultation under Section 7 is considered a public document and is available for public inspection in or available from the Office of Endangered Species and the Office of Migratory Bird Management, Department of the Interior, Washington, D.C.

Regulatory Flexibility Act and Executive Order 12291

In the Federal Register dated March 23, 1984 (at 49 FR 11124), the Service reported measures it had undertaken to comply with requirements of the Regulatory Flexibility Act and the Executive Order. These included preparing a Determination of Effects and an updated Final Regulatory Impact Analysis, and publication of a summary of the latter. These regulations have been determined to be major under Executive Order 12291 and they have a significant economic impact on substantial numbers of small entities under the Regulatory Flexibility Act. This determination is detailed in the aforementioned documents which are available upon request from the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240.

Memorandum of Law

The Service published its Memorandum of Law, required by section 4 of Executive Order 12291, in the Federal Register dated July 19, 1984 (at 49 FR 29239).

Authorship

The primary author of this final rule is Morton M. Smith, Office of Migratory Bird Management, working under the direction of Rollin D. Sparrowe, Chief.

Regulations Promulgation

The rulemaking process for migratory bird hunting must, by its nature, operate under severe time constraints. However, the Service is of the view that every attempt should be made to give the public the greatest possible opportunity to comment on the regulations. Thus, when the proposed late hunting season rulemakings were published on March 23, June 15, and August 20, the Service established what it believed were the longest periods possible for public comment. In doing this, the Service recognized that at the close of each period time would be of the essence. That is, if there were a delay in the effective date of these regulations after this final rulemaking, the Service is of the opinion that the States would have insufficient time to select season dates, shooting hours and limits; to communicate those selections to the Service; and to establish and publicize the necessary regulations and procedures that implement their decisions.

Therefore, the Service under authority of the Migratory Bird Treaty Act of July 3, 1916, as amended (40 Stat. 755; 16 U.S.C. 701–711), prescribes final frameworks setting forth the species to be hunted, the daily bag and possession limits, the shooting hours, the season lengths, the earliest opening and latest closing season dates, and hunting areas, from which State conservation agency officials may select hunting season dates and other options. Upon receipt of season and option selections from State officials, the Service will publish in the Federal Register final rulemaking amending 50 CFR Part 20 (§§ 20.104 through 20.107 and § 20.109) to reflect seasons, limits and shooting hours for the contiguous United States for the 1984–85 season.

The Service therefore finds that “good cause” exists, within the terms of 5 U.S.C. 553(d)(3) of the Administrative Procedure Act, and these frameworks will, therefore, take effect immediately upon publication.

List of Subjects in 50 CFR Part 20


The rules that eventually will be promulgated for the 1984–85 hunting season are authorized under the Migratory Bird Treaty Act of July 3, 1918 (40 Stat. 755; 16 U.S.C. 703 et seq.), as amended.
Final Regulations Frameworks for 1984-85 Late Hunting Seasons on Certain Migratory Game Birds

Pursuant to the Migratory Bird Treaty Act, the Secretary of the Interior has approved final frameworks for season lengths, shooting hours, bag and possession limits, and outside dates within which States may select seasons for hunting waterfowl, coots and gallinules; sandhill cranes in Arizona; and common snipe in the Pacific Flyway. Frameworks are summarized below. States may be more restrictive in selecting season regulations, but may not exceed the framework provisions.

GENERAL

Split Season: States in all Flyways may split their season for ducks, geese or brant into two segments. States in the Atlantic and Central Flyways may, in lieu of zoning, split their season for ducks or geese into three segments. Exceptions are noted in appropriate sections.

Shooting Hours: From one-half hour before sunrise to sunset daily, for all species and seasons, including falconry seasons.

Extra Blue-winged Teal: States in the Mississippi and Central Flyways selecting neither a teal or early duck season in September nor the point system may select an extra daily bag and possession limit of two 4 blue-winged teal, respectively, for 9 consecutive days designated during the regular duck season. These extra limits are in addition to the regular duck bag and possession limits.

Extra teal: States in the Atlantic Flyway (except Florida) not selecting the point system may select an extra teal limit of no more than 2 blue-winged teal or 2 green-winged teal or 1 of each daily and no more than 4 singly or in the aggregate in possession for 9 consecutive days during the regular duck season.

Special Scaup-only Season: States in the Atlantic, Mississippi and Central Flyways may select a special scaup-only hunting season not to exceed 16 consecutive days, with daily bag and possession limits of 5 and 10, respectively, subject to the following conditions:
1. The season must fall between October 1, 1984, and January 31, 1985, all dates inclusive.
2. The season must fall outside the open season for any other ducks except sea ducks.
3. The season must be limited to areas mutually agreed upon by the State and the Service prior to August 31, 1984.
4. These areas must be described and delineated in State hunting regulations.

OR

Extra Scaup: As an alternative, States in the Atlantic, Mississippi and Central Flyways, except those selecting the point system, may select an extra daily bag and possession limit of 2 and 4 scaup, respectively, during the regular duck hunting season, subject to conditions 3 and 4 listed above. These extra limits are in addition to the regular duck limits and apply during the entire regular duck season.

Point System: Selection of the point system for any State entirely within a flyway must be on a statewide basis, except if New York selects the point system, conventional regulations may be retained for the Long Island Area. New York may not select the point system within the Upstate zoning option, and Massachusetts, Connecticut and Pennsylvania may not select the point system pending completion of zoning studies.

Deferred Season Selections: States that did not select rail, woodcock, snipe, sandhill crane, gallinule and sea duck seasons in July should do so at the time they make their waterfowl selections.

Frameworks for open seasons and season lengths, bag and possession limit options, and other special provisions are listed below by Flyway.

ATLANTIC FLYWAY


Ducks, Coots and Mergansers


Hunting Season: 50 days.

Daily Bag and Possession Limits (including restrictions on black ducks): (a) basic daily bag and possession limits of 4 and 8 ducks, respectively, of which no more than 2 in the daily bag and 4 in possession may be black ducks; or (b) basic daily bag and possession limits of 5 and 10 ducks, respectively, of which no more than 1 in the daily bag and 2 in possession may be black ducks. In addition, the following restrictions of black duck harvest are listed by State.

Connecticut: During the first segment of the split season in both the coastal and inland zones, no black ducks are permitted; during the second segment of the season, 1 black duck is permitted per day and 2 in possession.

Delaware: No hunting of black ducks is permitted on the following dates of the duck hunting season: October 1-3 and October 29-November 3. On other days of the duck hunting season 1 black duck in the daily bag and 2 in possession is permitted.

Maine: North Zone: 1 black duck is permitted per day and 2 in possession. South Zone during the first segment of a split season, no black ducks are permitted. During the second segment of a split season, 2 black ducks are permitted per day and 4 in possession.

Maryland: Inland Zone: The season is closed on black ducks during the first segment of a split season (no less than 3 hunting days); during the remainder of the season the black duck will have a point value of 100. Coastal Zones: The season is closed on black ducks during the first 6 days of the duck season; during the remainder of the season the black duck will have a point value of 100.

Massachusetts: Western Zone: 1 black duck is permitted per day and 2 in possession, and the season will open no earlier than October 14. Central Zone: 1 black duck is permitted per day and 2 in possession, the season opening will coincide with the duck season opening in the Zone opening in the Central Zone and the pheasant hunting season. Coastal Zones: The season opening will coincide with the pheasant hunting season. During periods when black ducks may be hunted, 2 black ducks are permitted per day and 4 in possession. No hunting of black ducks is permitted during a 10-day period in the second segment of a split season, and no hunting of black ducks is permitted after January 1 in this zone.

New Hampshire: Inland Zone: 1 black duck is permitted per day and 2 in possession. Coastal Zones: during the first part of a split season no hunting of black ducks is permitted; during the second part of the split season 2 black ducks are permitted per day and 4 in possession.

New Jersey: For black duck restrictions see point system option for Atlantic Flyway.

New York: Long Island Zone: 1 black duck is permitted per day and 2 in possession throughout the season. Western Zone: during the first part of a split season, 1 black duck is permitted per day and 2 in possession; during the second part of the split season no hunting of black ducks is permitted. Northeastern Zone: during the first part of a split season, 1 black duck is permitted per day and 2 in possession; during the second part of the split season no hunting of black ducks is permitted. Southeastern Zone: during the first 25 days of the duck hunting season 1 black duck is permitted per day and 2 in possession and during the last 25 days of the duck hunting season no hunting of black ducks is permitted.

North Carolina: The season for black ducks is closed during that part of the duck season prior to December 17; thereafter 1 black duck per day and 2 in possession is permitted.

Pennsylvania: Lake Erie Zone: 1 black duck is permitted per day and 2 in possession during the October 21 to December 3 portion of the duck season; on all other duck hunting days no black ducks are permitted. Northeast Zone: 1 black duck is permitted in the daily bag and 2 in possession during the October 24 to December 3 portion of the duck season; on all other duck hunting days no black ducks are permitted. North Zone: 1 black duck will be permitted per day and 2 in possession during the October 20 to November 18 portion of the duck season; on all other duck hunting days no black ducks are permitted. South Zone: 1 black duck will be permitted per day and 2 in possession during the November 7 to December 3 portion of the duck season; on all other duck hunting days no black ducks are permitted.

Rhode Island: The daily bag limit of black ducks is 1 and the possession limit is 2.
**South Carolina**: During the November 21 to November 24 portion of the duck season no black ducks are permitted in the daily bag. On all other duck hunting days the daily bag limit of black ducks is 1 and the possession limit is 2; however, there will be no open season on black ducks in Georgetown, Charleston, Colleton, and Beaufort Counties.

**Vermont**: No black ducks are permitted in the daily bag during the first 5-7 days of the hunting season; 1 black duck per day and 2 in possession is permitted during the remainder of the duck hunting season.

**Virginia**: During the period November 20-December 1 (excluding no less than 10 duck hunting days), no black ducks are permitted in the daily bag.

**West Virginia**: The daily bag limit of black ducks is 1 and the possession limit is 2.

**Canvasbacks and Redheads**: Except in closed areas, the limit of canvasbacks is 1 daily and 1 in possession. The limit of redheads throughout the flyway is 2 daily, except that in areas open to canvasback harvest the daily bag limit is 2 redheads, or 1 redhead and 1 canvasback. The possession limit of redheads is twice the daily bag limit under conventional regulations. The possession limit of canvasbacks is equal to the daily bag limit. Under the point system, canvasbacks (except in closed areas) count 100 points each and redheads flywaywide count 70 points each.

Areas closed to canvasback hunting are:

- **New York**: Upper Niagara River between the Peace Bridge at Buffalo, New York, and the Niagara Falls. All waters of Lake Cayuga.
- **New Jersey**: Those portions of Monmouth County and Ocean County lying east of the Garden State Parkway.
- **Maryland, Virginia, and North Carolina**: Those portions of each State lying east of U.S. Highway 1.

In addition, areas or portions of areas as specified below, otherwise closed to taking of canvasbacks, may be opened to hunting of canvasbacks during an experimental season. The experimental season must occur during the last 11 days of the regular season in New York, New Jersey and North Carolina and the last 6 days of the regular duck season in Maryland and Virginia. The daily bag under conventional regulations may include no more than 4 canvasbacks, not more than 1 of which may be a female. Under the point system male canvasbacks are 25 points and females 100 points. Possession limits are twice daily bag limits. The areas eligible for this experimental season are:

- **New York**: Upper Niagara River between the Peace Bridge at Buffalo, New York, and the Niagara Falls, and all waters of Lake Cayuga.
- **New Jersey**: (1) east of the Garden State Parkway from Route 440, south to Route 36 (Raritan and Sandy Hook Bays, Navesink and Shrewsbury Rivers); (2) east of the Garden State Parkway from Route 88 south to Route 12 (Barnegat, Silver and Manahawkin Bays, Metedeconk River); (3) west of the Garden State Parkway from Route 72 south to Route 1 (Toms River). The waters of Chesapeake Bay and its tributaries to the first upstream bridge, except on the Patuxent River the boundary is the second upstream bridge (Maryland Route 221 bridge near Benedict, MD); including Potomac River and its tributaries upstream to U.S. Route 301 bridge.
- **Maryland**: The waters of Chesapeake Bay and its tributaries to the first upstream bridge, except on the Patuxent River the boundary is the second upstream bridge (Maryland Route 221 bridge near Benedict, MD); including Potomac River and its tributaries upstream to U.S. Route 301 bridge.
- **Virginia**: Starting at the Virginia-Maryland line (301 birdies) those lands and waters enclosed in the area bounded by: U.S. Highway 301 south to Route 207 and continuing to the junction of U.S. Route 1, south on Route 1 to Route 460, then southeast on 460 to Route 13, then east and north on Route 13 to the Maryland line, then westward on the Maryland-Virginia line to Route 301.
- **North Carolina**: That portion of Pamlico Sound and its tributaries designated as coastal fishing waters within two miles of the mainland, extending from Long Shoal Point on north side of Pamlico Sound to the point of marsh near New Bern on north side of Broad Creek known as Piney Point and upstream in Pamlico River to the Aurora-Selawkey ferry crossing.

The remaining portions of areas in each of the five participating States presently closed to the taking of canvasback will remain closed.

**Early Wood Duck Season Option**: Virginia, North Carolina, South Carolina and Georgia may split their regular hunting season so that a hunting season not to exceed 6 consecutive days occurs between October 1 and October 15. During this period under conventional regulations, no special restrictions will be established for the flyway and possession limits for the flyway shall apply to wood ducks. Under the point system, wood ducks shall be 25 points. For other ducks, daily bag and possession limits shall be the same as established for the flyway under conventional or point system regulations. For those States using conventional regulations, the extra test option may be selected concurrent with the early wood duck season option. This exception to the daily bag and possession limits of wood ducks shall not apply to that portion of the duck hunting season that occurs after October 15.

**Restrictions on Wood Ducks**: Under conventional and point system options, the daily bag and possession limits may not include more than 2 and 4 wood ducks, respectively.

**Restriction on Mottled Ducks**: The season is closed to taking of mottled ducks in South Carolina.

**Merganser Limits**: The daily bag limit of mergansers is 5, only 1 of which may be a hooded merganser. The possession limit is 10, only 2 of which may be hooded mergansers.

**Coot Limits**: The daily bag and possession limits of coots are 15 and 30, respectively.

**Lake Champlain Area, New York Follows Vermont**: The Lake Champlain Area of New York must follow the waterfowl seasons, daily bag and possession limits, and shooting hours selected by Vermont. This area includes that part of New York lying east and north of a boundary running south from the Canadian border along U.S. Highway 9 to New York Route 22 south of Keesville, along New York Route 22 to South Bay, along and around the shoreline of South Bay to New York Route 22, along New York Route 22 to U.S. Highway 4 at Whitehall, and along U.S. Highway 4 to the Vermont border.

**Special Scaup and Goldeneye Season**: In lieu of a special scaup season, Vermont may, for the Lake Champlain Area, select a special scaup and goldeneye season not to exceed 16 consecutive days, with a daily bag limit of 3 scaup or 3 goldeneyes or 3 in the aggregate, and possession limit of 6 scaup or 6 goldeneyes or 6 in the aggregate, subject to the same provisions that apply to the special season elsewhere.

**Zoning**:

**Long Island**: New York may, for Long Island, select season dates and daily bag and possession limits which differ from those in the remainder of the State.

**Upstate New York**: Upstate New York (excluding the Lake Champlain area) may be divided into three zones (West, North, South) for the purpose of setting separate duck, coot, and merganser seasons. Option (a) or (b) for seasons and bag limits (see Daily Bag and Possession Limits) is applicable to the zones in the Upstate area within the flyway framework; only conventional regulations may be selected. Each zone will be permitted the number of days offered under options (a) or (b). In addition, a 2-segment split season may be selected in each zone. The basic daily bag limit on ducks in each zone and the restrictions applicable to options (a) and (b) of the regular season for the flyway also apply. The daily bag and possession limits may not include more than 2 and 4 wood ducks, respectively. The 16-day special scaup season will not be allowed.

**New York Zone Definitions**: The zones are defined as follows:

- **The West Zone** is that portion of Upstate New York lying west of a line commencing at the north shore of the Salmon River and its junction with Lake Ontario and extending easterly along the north shore of the Salmon River to its intersection with Interstate Highway 81, then southerly along Interstate Highway 81 to the Pennsylvania border.
- **The North Zone** is that portion of Upstate New York lying north of the Salmon River and its junction with Lake Ontario and extending easterly along the north shore of the Salmon River to its intersection with Interstate Highway 81, then southerly along Interstate Highway 81 to the Pennsylvania border.
- **The South Zone** is that portion of Upstate New York lying south of the Salmon River and its junction with Lake Ontario and extending easterly along the north shore of the Salmon River to its intersection with Interstate Highway 81, then southerly along Interstate Highway 81 to the Pennsylvania border.
Connecticut may be divided into two zones as follows:

a. North Zone - That portion of State north of Interstate 95.

b. South Zone - That portion of State south of Interstate 95.

Maine may be divided into two zones as follows:

a. North Zone - Game Management Zones 1 through 5.

b. South Zone - Game Management Zones 6 through 8.

New Hampshire

Coastal Zone - That portion of the State east of a boundary formed by Interstate Highway 4 beginning at the Maine-New Hampshire line in Rollinsford west to the city of Dover, south to the intersection of State Highway 108, south along State Highway 108 through Madbury, Durham, and Newmarket to the junction of State Highway 85 in Newfields, south to State Highway 85 in Exeter, east to State Highway 61 (Exeter-Hampton Expressway), east to Interstate 95 (New Hampshire Turnpike) in Hampton, and south along Interstate 95 to the Massachusetts line.

Inland Zone - That portion of the State north and west of the above boundary.

West Virginia may be divided into two zones as follows:

a. Allegheny Mountain Upland Zone - The eastern boundary extends south along U.S. Route 220 through Keyser, West Virginia, to the intersection of U.S. Route 50; follows U.S. Route 50 to the intersection with State Route 93; follows State Route 93 south to the intersection with State Route 42 and continues south on State Route 42 to Petersburg; follows State Route 28 south to Minehaha Springs; then follows State Route 39 west to U.S. Route 219; and follows U.S. 219 south to the intersection of Interstate 64. The southern boundary follows I-64 west to the intersection with U.S. Route 60, and follows Route 60 west to the intersection of U.S. Route 19. The western boundary follows Route 19 north to the intersection of I-79, and follows I-79 north to the intersection of U.S. Route 48. The northern boundary follows U.S. Route 48 east to the Maryland State line and the State line to the point of beginning.

b. Remainder of the State - That portion outside the above boundaries.

Maryland, Massachusetts, New Jersey and Pennsylvania, may continue zoning experiments now in progress as shown in the sections that follow. Maryland may be divided into two zones, Maryland and New Jersey may be divided into Three Zones, and Pennsylvania into four zones all on an experimental basis for the purpose of setting separate duck, coot and merganser seasons. Option (a) or (b) for seasons and bag limits (see Daily Bag and Possession Limits) is applicable to all of the zones within the Flyway framework. Only conventional regulations may be selected in Massachusetts, Connecticut, West Virginia and Pennsylvania. New Jersey and Maryland must select the point system. Each zone will be permitted the full number of days offered under options (a) or (b). In addition, a two-segment split season without penalty may be selected. The basic daily bag limit of ducks in each zone and the restrictions applicable to options (a) and (b) of the regular season for the Flyway also apply. Teal and scaup bonus bird options, and the 16-day special season shall be allowed.

Zone Definitions:

Maryland

Inland Zone - That portion of the State north and west of U.S. Route 1 from its junction with the Maryland-Pennsylvania border south to its junction with I-95 north of Washington, D.C. and east and south along I-95 to the Maryland-Virginia border.

Coastal Zone - That portion of the State south and east of the above described highway boundaries.

Massachusetts

Western Zone - That portion of the State west of a line extending from the Vermont line at Interstate 91, south to Route 9, west on Route 9 to Route 16, south on Route 16 to Route 202, south on Route 202 to the Connecticut line.
Canada Geese

Outside Dates, Season Lengths, and Limits: Between October 1, 1984, and January 30, 1985, in all States, except that the framework opening date is September 22 in Iowa, and the framework closing date is January 31 in Mississippi.

MISSISSIPPI FLYWAY

The Mississippi Flyway includes Alabama, Arkansas, Illinois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Ohio, Tennessee and Wisconsin.

Ducks, Coots and Mergansers

Outside Dates: Between September 28, 1984, and January 20, 1985, in all States, except that the framework opening date is September 22 in Iowa, and the framework closing date is January 31 in Mississippi.

Bunting Season: Not more than 50 days.

Limits: The daily bag limit of ducks is 5, and may include no more than 3 mallards (no more than 2 of which may be females), 1 black duck and 3 wood ducks (except as noted below). The possession limit is 10, including no more than 6 mallards (no more than 4 of which may be females), 2 black ducks and 4 wood ducks (except as noted below). Except in closed areas, the limits of canvasbacks and redheads are 1 daily and 2 in possession for each species.

Closed Areas for Canvasback Hunting:

Mississippi River - (1) Entire river, both sides, from Lock and Dam 9 upstream to the confluence of the Chippewa River. (2) Pool 19 bordering Iowa and Illinois.

Michigan - Macomb and St. Clair Counties, including the adjacent Great Lakes waters and interconnecting waterways under the jurisdiction of the State of Michigan.

Wisconsin - in the Mississippi River Zone, all that part of Wisconsin west of the Burlington-Northern Railroad from Lock and Dam 9 north to the center-line of the Chippewa River.

Merganser Limits: The daily bag limit of mergansers is 5, only 1 of which may be a hooded merganser. The possession limit is 10, only 2 of which may be hooded mergansers.

Coot Limits: The daily bag and possession limits of coots are 15 and 30, respectively.

Point System Option: As an alternative to conventional bag limits for ducks, a 50-day season with point-system bag and possession limits may be selected within the framework dates prescribed. Point value for species and sexes taken is as follows: in closed areas, the canvasback and black duck count 100 points each; the redhead, female mallard, wood duck (except as noted below) and hooded merganser count 70 points each; the pintail, blue-winged teal, cinnamon teal, wigeon, gadwall, shoveler, soyup, green-winged teal, and mergansers (except hooded mergansers) count 40 points each; the male mallard and all other species of ducks count 25 points each. The daily bag limit is reached when the point value of the last bird taken, added to the sum of the point value of the other birds already taken during that day, reaches or exceeds 100 points. The possession limit is the maximum number of birds that legally could have been taken in 2 days.

Coot Limits—Point System: Coots have a point value of zero, but the daily bag and possession limits are 15 and 30, respectively, under the conventional limits.

Early Wood Duck Season Option: Arkansas, Louisiana, Mississippi and Alabama may select their regular duck hunting seasons in such a way that a hunting season not to exceed 9 consecutive days may occur between September 29 and October 15. During this period, under conventional regulations, no special restrictions within the regular daily bag and possession limits established for the Flyway shall apply to wood ducks, and under the point system, the point value of wood ducks shall be 35 points. For other species of ducks, daily bag and possession limits shall be the same as established for the Flyway under conventional or point system regulations. In addition, the extra blue-winged teal option available to States in this Flyway that select conventional regulations and do not have a September teal season may be selected during this period. This exception to the daily bag and possession limits for wood ducks shall not apply to that portion of the duck hunting season that occurs after October 15.

Western Louisiana: In that portion of Louisiana west of a boundary beginning at the Arkansas-Louisiana border on Louisiana Highway 3; then south along Louisiana Highway 3 to Bossier City; then east along Interstate 20 to Minden; then south along Louisiana Highway 9 to Jonesboro; then south along U.S. Highway 167 to Lafayette; then southeast along U.S. Highway 90 to Houma; then south along the Houma Navigation Channel to the Gulf of Mexico through Cat Island Pass—the season for ducks, coots and mergansers may extend 5 additional days. If the 5-day extension is selected, and if point-system regulations are selected for the State, point values will be the same as for the rest of the State.

Pymatuning Reservoir Area, Ohio: The waterfowl seasons, limits and shooting hours in the Pymatuning Reservoir area of Ohio will be the same as those selected by Pennsylvania. The area includes Pymatuning Reservoir and that part of Ohio bounded on the north by Conne Road 306 known as Woodward Road, on the west by Pymatuning Lake Road, and on the south by U.S. Highway 322.

Zoning: Alabama, Illinois, Indiana, Iowa, Michigan, Missouri, Ohio, Tennessee and Wisconsin may select hunting seasons for ducks, coots and mergansers by zones described as follows:

Alabama: South Zone - Mobile and Baldwin Counties. North Zone - The remainder of Alabama. The season in the South Zone may be split.

Indiana: North Zone - That portion of the State north of State Highway 18. Ohio River Zone - That portion of Indiana south of Interstate Highway 64. South Zone - That portion of the State between the North and Ohio River Zone boundaries. The season in each zone may be split into two segments.

Iowa: North Zone - That portion of Iowa north of Interstate 80. South Zone - The remainder of the State.

Michigan: North Zone - The Upper Peninsula. Southeast Zone - That portion of the Lower Peninsula lying south and east of a line running north from the Michigan–Ohio border along U.S. Highway 127 to U.S. Highway 27, north along U.S. Highway 27 to South County Line Road in Gratiot County, east along South County Line Road to McClelland Road, north along McClelland Road to M-57, west along M-57 to U.S. Highway 27, north along U.S. Highway 27 to M-10, east along M-10 to M-14, north along M-14 to U.S. Highway 27, north along US-27 to Shore Road in Arenac County, east along Shore Road to the tip of Point Lookout, then due east ten miles into Saginaw Bay, and from that point along a northeast line to the Ontario border. Middle Zone - The remainder of the State. Michigan may split its season in each zone into two segments.

Missouri: North Zone - That portion of Missouri north of a line running east from the Missouri border along U.S. Highway 40 to State Highway 32, east along State Highway 32 to State Highway 72, east along State Highway 72 to State Highway 34, then east along State Highway 34 to the Missouri border. South Zone - The remainder of Missouri. Missouri may split its season in each zone into two segments.

Ohio: North Zone - The counties of Darke, Miami, Clark, Champaign, Union, Delaware, Licking, Muskingum, Guernsey, Harrison and Jefferson and all counties north thereof. In addition, the North Zone also includes that portion of the Buckeye Lake area in Fairfield and Perry Counties bounded on the west by State Highway 31, on the south by State Highway 204, and on the east by State Highway 15. Ohio River Zone - The counties of Hamilton, Clermont, Brown, Adams, Scioto, Lawrence, Gallia and Meigs. South Zone - That portion of the State between the North and Ohio River Zone boundaries. Ohio may split its season in each zone into two segments.

Tennessee: Reelfoot Zone - Lake and Obion Counties, or a designated portion of that area. State Zone - The remainder of Tennessee. Seasons may be split into two segments in each zone.

Wisconsin: North Zone - That portion of the State north of a line extending northerly from the Minnesota border along U.S. Highway 65, south along U.S. Highway 65 to State Highway 32, east along State Highway 32 to State Highway 72, east along State Highway 72 to State Highway 34, then east along State Highway 34 to the Wisconsin border. South Zone - The remainder of Wisconsin. The season in the South Zone may be split into two segments.

Within each State: (1) the same bag limit option must be selected for all zones; and (2) if a special season is selected for a zone, it shall not begin until after the regular season closing date in that zone.

Geese

Definition: For the purpose of hunting regulations listed below, the term “geese” also includes brant.

Outside Dates, Season Lengths and Limits: Between September 29, 1984, and January 20, 1985, seasons may be selected for the states (including blue) and white-fronted geese by zones established for duck hunting seasons, with daily bag and possession limits as described above.

Minnesota. In the:

(a) Lac Qui Parle Zone (described in State regulations)—the season for Canada geese closes after 50 days or when 4,500 birds have been harvested, whichever occurs first. The daily bag limit is 1 Canada goose and the possession limit is 2.

(b) Southeastern Zone (described in State regulation)—the season for Canada geese may extend for 70 consecutive days. The daily bag limit is 2 Canada geese and the possession limit is 4.

(c) Remainder of the State—the season for Canada geese will be concurrent with the duck season. The daily bag limit is 1 Canada goose and the possession limit is 2.

Iowa: The season may extend for 70 consecutive days. The daily bag limit is 2 Canada geese and the possession limit is 4.

Missouri: In the:

(a) Swan Lake Zone (described in State regulations)—the season for Canada geese closes after 25 days when 16,000 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4.

(b) Southeast Zone (east of U.S. Highway 67 and south of Crystal City)— A 50-day season on Canada geese may be selected between December 1, 1984, and January 20, 1985, with a daily bag limit of 1 Canada goose and a possession limit of 2.

(c) Remainder of the State—the season for Canada geese will be concurrent with the duck season in the respective duck hunting zones. The daily bag limit is 1 Canada goose, and the possession limit is 2.

Wisconsin: In the:

(a) Horizon and Central Zones (Columbia, Dodge, Fond Du Lac, Green Lake, Marquette and Winnebago Counties, and the northwest portion of Washington County north of State Highway 33 and west of U.S. Highway 45) - the harvest of Canada geese is limited to 15,000 birds. The season may not exceed 25 days, and bag limits may not exceed 2 birds per day and 4 birds per season.

(b) Mississippi River Zone (that portion of the State west of the Burlington-Northern Railroad in Grant, Crawford, Vernon, LaCrosse, Trempealeau, Buffalo, Pepin and Pierce Counties)—the season for Canada geese may not exceed 20 days. The daily bag limit is 1 Canada goose and the possession limit is 2. A special late season harvest of giant Canada geese may be held during November 22 to December 9. The daily bag and possession limits during this special season are 2 and 4, respectively.

(c) Northeast Zone (that portion of the North Hunting Zone which includes the Counties of Vilas, Oneida, Lincoln, Marathon, a portion of Wood County, and all counties or portions of counties eastward). The season for Canada geese may not exceed 20 days. The daily bag limit is 1 Canada goose and the possession limit is 2. In Brown County, a special late season to control local populations of giant Canada geese may be held during December 1-31. The daily bag and possession limits during this special season are 2 and 4 birds, respectively.
Illinois: In the:

(a) Southern Illinois Quota Zone (described in State regulations) - The season for Canada goose will close after 25 days or when 17,500 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada goose and the possession limit is 4.

(b) Tri-County Area (all of Knox County; the townships of Buckhart, Canton, Cass, Deerfield, Fairview, Farmington, Joshua, Orion, Putnam and that portion of Banner Township bounded on the north by Illinois Route 9 and on the east by U.S. 24 in Fulton County; the township of Alba, Annawan, Atkinson and Cornwall in Henry County) - The season for Canada goose may not exceed 20 days. The daily bag limit is 1 Canada goose and the possession limit is 4.

(c) Remainder of State - Seasons for Canada geese up to 20 days may be selected by zones established for duck hunting seasons, except that in the South Zone the season will close no later than December 15. The daily bag limit is 1 Canada goose and the possession limit is 4.

Michigan: In the:

(a) Counties of Baraga, Dickinson, Delta, Gogebic, Houghton, Iron, Keweenaw, Marquette, Menominee, and Ontonagon—the season for Canada goose may extend for 20 days, with a framework opening date for all geese of September 26. The daily bag limit is 1 Canada goose and the possession limit is 2.

(b) Southern Michigan Goose Management Area (described in State regulations)—The season for Canada geese may not exceed 35 days between September 29, 1984, and December 20, 1984. During this period, the daily bag limit is 1 Canada goose and the possession limit is 2. A late season of up to 37 days may be held between December 22, 1984, and February 16, 1985 to control local populations of giant Canada geese. During the late season, the daily bag limit is 3 Canada geese and the possession limit is 6.

(c) Remainder of the State:

(1) West of a boundary described as follows: North from the Indiana border along U.S. Highway 141 to U.S. Highway 31, then north along U.S. Highway 31 to I-75, then north along I-75 to the Ontario border - The season for Canada geese may not exceed 20 days. The daily bag limit is 1 Canada goose and the possession limit is 2.

(2) East of the boundary described in (1) above - The season for Canada geese may not exceed 35 days. The daily bag limit is 1 Canada goose and the possession limit is 2.

Ohio: The daily bag limit is 2 Canada goose and the possession limit is 4, except that in the counties of Ashtabula, Trumbull, Marion, Wyandot, Lucas, Ottawa, Erie, Sandusky, Mercer and Auglaize, the daily bag limit is 1 Canada goose and the possession limit is 2.

Indiana: The season for Canada goose may extend for 70 days, except in Posey County where the season may not exceed 20 days. The daily bag limit is 2 Canada goose and the possession limit is 4, except in Posey County, where the daily bag and possession limits are 1 and 2, respectively. The goose season may be set by zones established for duck hunting.

Kentucky: In the:

(a) West Kentucky Zone (that portion of the State west of a line beginning at the Kentucky-Tennessee border at Fulton, Kentucky, extending northerly along the Purchase Parkway to I-24, east on I-24 to U.S. 641; northerly on U.S. 641 to U.S. 60; northeasterly on U.S. 60 to U.S. 41; and then northeasterly on U.S. 41 to the Kentucky-Indiana border) - The State may select one of the following options for Canada geese:

(1) A season not to exceed 20 days, with a daily bag limit of 1 Canada goose and a possession limit of 2.

(2) A season not to exceed 25 days, with a daily bag limit of 2 Canada geese and a possession limit of 4. If this option is selected, the progression of the harvest will be monitored and the season will close after 25 days or when 7,000 birds have been harvested, whichever occurs first.

Under both options, the season may extend to January 31, 1985.

(b) Remainder of the State - The season may extend for 70 days. The daily bag limit is 2 Canada goose and the possession limit is 4.

Tennessee: In the:

(a) Northwest Zone (Lake, Obion, Weakley and Carroll Counties, and those portions of Gibson and Dyer Counties not included in the Southwest Zone) - The State may select one of the following options for Canada geese:

(1) A season not to exceed 20 days, with a daily bag limit of 1 Canada goose and a possession limit of 2.

(b) Southwest Zone (that portion of the State bounded on the north by State Highways 20 and 104, and on the east by U.S. Highways 45W and 45) - The season for Canada goose may extend for 15 days, with a framework closing date of January 31, 1985. The daily bag limit is 1 Canada goose and the possession limit is 2.

(c) Remainder of the State - The season for Canada geese may extend for 70 days. The daily bag limit is 1 Canada goose and the possession limit is 2, except in that portion west of State Highway 13, where the daily bag and possession limits are 2 and 4, respectively.

Arkansas and Louisiana: The season for Canada goose is closed.

Mississippi: In the:

(a) Sardis Zone (described in State regulations) - The season for Canada goose may extend for 30 days, 10 days of which must occur before December 15, 1984. The daily bag limit is 1 Canada goose and possession limit is 2.

(b) Remainder of the State - The season for Canada goose may not exceed 15 days. The daily bag limit is 1 Canada goose and the possession limit is 2.

In both areas, the framework closing date is January 31, 1985.

Alabama: The season is closed for all geese in the counties of Henry, Russell and Barbour. Elsewhere in Alabama, the daily bag limit is 2 Canada goose and the possession limit is 4.
Missouri, Illinois, Kentucky and Tennessee Quota Zone Closures: When it has been determined that the quota of Canada geese alloted to the Southern Illinois Zone, the Swan Lake Zone in Missouri, and, if applicable, the West Kentucky Zone and the Northwest Zone in Tennessee will have been filled, the season for taking Canada geese in the respective area will be closed by the Director upon giving public notice through local information media at least 48 hours in advance of the time and date of closing or by the State through State regulations with such notice and time (not in excess of 48 hours) as they deem necessary.

Shipping Restrictions: In Illinois and Missouri and in the Kentucky counties of Ballard, Hickman, Fulton and Carlisle, geese may not be transported, shipped or delivered for transportation or shipment by common carrier, the Postal Service, or by any person except as the personal baggage of licensed waterfowl hunters, provided that no hunter shall possess or transport more than the legally-prescribed possession limit of geese. Geese possessed or transported by persons other than the taker must be labeled with the name and address of the taker and the date taken.

**CENTRAL FLYWAY**

The Central Flyway includes Colorado (east of the Continental Divide), Kansas, Montera (Blaine, Carbon, Fergus, Judith Basin, Stillwater, Sweetgrass, Wheatland and all counties east thereof), Nebraska, New Mexico (east of the Continental Divide except that the entire Jicarilla Apache Indian Reservation is in the Pacific Flyway), North Dakota, Oklahoma, South Dakota, Texas and Wyoming (east of the Continental Divide).

Ducks (including mergansers) and Coots

**Outside Dates:** September 29, 1984, through January 20, 1985.

**Hunting Season:** The season in the Low Plains Unit may include no more than 60 days. The season in the High Plains Mallard Management Unit may include no more than 83 days provided that the last 23 days of such season must begin on or after December 8, 1984. The High Plains Unit, roughly defined as that portion of the Central Flyway which lies west of the 100th meridian, shall be described in State regulations.

States may split their seasons into 2 or, in lieu of zoning, 3 segments.

**Daily Bag and Possession Limits:** Conventional limits for ducks are 5 daily, including no more than 1 canvasback, 1 redhead, 1 female mallard, 1 hooded merganser and 2 wood ducks; and 10 in possession, including no more than 1 canvasback, 2 redheads, 2 female mallards, 1 hooded mergansers and 4 wood ducks.

As an alternative to conventional bag and possession limits for ducks, States may select point system regulations. Under this system, the daily bag limit is reached when the point value of the last bird taken, added to the sum of the point values of other birds already taken during that day, reaches or exceeds 100 points. The point values are: canvasbacks, 100 points each; female mallards, Mexican-like ducks, mottled ducks (Texas only), wood ducks, redheads and hooded mergansers, 70 points each; blue-winged teal, green-winged teal, cinnamon teal, scaup, pintails, gadwalls, wigeon, shoveler and mergansers (except the hooded merganser), 10 points each; all other species and sexes of ducks, 30 points each. The possession limit is the maximum number of birds which legally could have been taken in 2 days.

**The daily bag and possession limits of coots are 15 and 30, respectively.**

**Zoning:** Montana, Nebraska, New Mexico, South Dakota, Oklahoma and Wyoming may select hunting seasons for ducks (including mergansers) and coots either statewide or by zones desigated as follows:

- **Montana:** Two experimental zones in the Central Flyway portion as follows:
  - Zone 2. The counties of Carter, Custer, Dawson, Fallon, Powder River, Prairie, Rosebud, Treasure and Wibaux.

- **Nebraska:** Four zones within the Low Plains portion as follows:
  - Zone 1. Keya Paha County east of U.S. Highway 183 and all of Boyd County including the adjacent waters of the Niobrara River.
  - Zone 2. The area bounded by designated highways and political boundaries starting on U.S. 73 at the State Line near Falls City; north to N-67; north through Nemaha to U.S. 73-75; north to U.S. 34; west to the Alvo Road; north to U.S. 6; northeast to N-63; north and west to U.S. 77; north to N-92; west to U.S. 81; south to N-66; west to N-14; south to I-80; west to U.S. 24; east to N-10; south to the State Line; west to U.S. 283; north to N-23; west to N-47; north to U.S. 30; east to N-14; north to N-52; northwesterly to N-91; west to U.S. 281; north to Wheeler County and including all of Wheeler and Garfield Counties and Loup County east of U.S. 183; east on N-70 from Wheeler County to N-14; south to N-29; northeast to N-47; east to U.S. 81; southeast to U.S. 30; east to U.S. 73; north to N-51; east to the State Line; and south and west along the State Line to the point of beginning.
  - Zone 3. The area, excluding Zone 1, north of Zone 2.
  - Zone 4. The area south of Zone 2.

- **New Mexico:** Two experimental zones as follows:
  - Zone 1. The Central Flyway portion of New Mexico north of Interstate Highway 40 and U.S. Highway 54.
  - Zone 2. The remainder of the Central Flyway portion of New Mexico.

- **Oklahoma:** Two experimental zones in the Low Plains portion as follows:
  - Zone 1. That portion of northwestern Oklahoma, except the Panhandle, bounded by the following highways: starting at the Texas-Oklahoma border, OK 33 to OK 47; OK 47 to U.S. 183; U.S. 183 to I-40; I-40 to U.S. 177, U.S. 177 to OK 51, OK 51 to I-35, I-35 to U.S. 60, U.S. 60 to U.S. 64, U.S. 64 to OK 132, and OK 132 to the Oklahoma-Kansas state line.
  - Zone 2. The remainder of the Low Plains portion.
as noted, with a daily bag limit of 2 geese except as follows:

and that portion of Texas east of U.S. Highway 81 may select management units for dark geese of no more than 72 days, except in Nebraska and South Dakota.

period September 29, 1984, through January 20, 1985; and for light geese, no more than 93 days than 86 days with a daily bag limits of 5 geese.

Within Dates: September 29, 1984, through October 28, 1984, for dark geese and September 29, 1984, through February 28, 1985, for light geese.

Definitions: In the Central Flyway, "geese" includes all species of geese and brant, "dark geese" includes Canada and white-fronted geese and black brant, and "light geese" include all other species.

Outside Dates: September 29, 1984, through January 20, 1985, for dark geese and September 29, 1984 through February 17, 1985 for light geese, except as noted for New Mexico.

Possession Limits: Goose possession limits are twice the daily bag limits.

West Tier States. States in this tier may select seasons either statewide or in designated management units as follows:

Montana: No more than 93 days daily bag limits are 2 geese in Sheridan County and 3 geese in the remainder of the Central Flyway portion.

Wyoming: No more than 93 days with daily bag limits of 2 geese for each of four Goose Management Units which coincide with management zones for ducks.

Colorado: No more than 93 days with a daily bag limit of 2 geese.

New Mexico: For dark geese, no more than 93 days with a daily bag limit of 2 during the period September 29, 1984, through January 20, 1985; and for light geese, no more than 83 days with a daily bag limit of 5 during the period September 29, 1984, through February 28, 1985.

Texas (west of U.S. 81): No more than 93 days with a daily bag limit of 5 geese which may include no more than 2 dark geese.

East Tier States - Light geese. North Dakota, South Dakota, Nebraska, Kansas, Oklahoma and that portion of Texas east of U.S. Highway 81 may select a season for light geese of no more than 86 days with a daily bag limits of 5 geese.

East Tier States - Dark geese. States may select seasons statewide or in designated management units for dark geese of no more than 72 days, except in Nebraska and South Dakota as noted, with a daily bag limit of 2 geese except as follows:

North Dakota: The daily bag limit may include no more than 1 Canada goose and 1 white-fronted goose or 2 white-fronted geese through October 26 and no more than 2 Canada goose or 2 white-fronted geese or 1 of each during the remainder of the season.

South Dakota: In Bon Homme, Brule, Buffalo, Campbell, Charles Mix, Corson (east of SD Highway 65), Dewey, Gregory, Hankon (north of Kirley Road and east of Plum Creek), Highway, Hyde, Lyman, Potter, Stanley, Sully, Tripp (east of U.S. Highway 183), Walworth and Yankton (west of U.S. Highway 81) Counties, the season length may not exceed 79 days and the daily bag limit may include no more than 1 Canada goose and 1 white-fronted goose through November 9, and no more than 2 Canada goose or 1 Canada goose and 1 white-fronted goose for the remainder of the season. In the remainder of the season, the daily limit may include no more than 1 Canada goose and 1 white-fronted goose.

Nebraska: In Goose Management Unit I comprised of Boyd, Cedar (west of U.S. Highway 81), Keys Paha (east of U.S. Highway 183) and Knox Counties, the season length may be no more than 79 days and the daily bag limit may include no more than 1 Canada goose and 1 white-fronted goose or 2 white-fronted gooses through September 29, 1984, and no more than 2 Canada geese or 1 Canada goose and 1 white-fronted goose for the remainder of the season.

Kans: The daily bag limit may include no more than 2 Canada geese or 1 Canada goose and 1 white-fronted goose through November 25 and no more than 1 Canada goose and 1 white-fronted goose during the remainder of the season.

Oklahoma: In Goose Management Unit 1 (that portion of western and southern Oklahoma bounded by the following highways: starting at the Kansas-Oklahoma line, U.S. 77 to U.S. 177, U.S. 177 to OK 53, OK 53 to U.S. 75, U.S. 75 to Indian Nation Turnpike, Indian Nation Turnpike to U.S. 271, and U.S. 271 to the Oklahoma-Texas line) and in Goose Management Unit 3, the daily bag limit may include no more than 2 Canada geese or 1 Canada goose and 1 white-fronted goose through November 9 and no more than 2 Canada geese or 1 Canada goose and 1 white-fronted goose during the remainder of the season.

Texas: In that portion east of U.S. Highway 81, the bag limit may include no more than 1 Canada goose and 1 white-fronted goose daily.

Whistling Swans

The following States may issue permits authorizing each permittee to take no more than one whistling swan, subject to guidelines in a current, approved management plan and general conditions that each State determine hunter participation and harvests, and specified conditions as follows:

Montana (Central Flyway portion): no more than 500 permits with the season dates concurrent with the season for taking geese.

North Dakota: no more than 1,000 permits with the season dates concurrent with the season for taking ducks.

South Dakota: no more than 500 permits with the season dates concurrent with the season for taking ducks.
PACIFIC FLYWAY

The Pacific Flyway includes Arizona, California, Colorado (west of the Continental Divide), Idaho, Montana (including and to the west of Hill, Chouteau, Cascade, Meagher and Park Counties), Nevada, New Mexico (the Jicarilla Apache Indian Reservation and west of the Continental Divide), Oregon, Utah, Washington and Wyoming (west of the Continental Divide including the Great Divide Basin).

Ducks (including Mergansers), Coots, Gallinules and Common Snipe


Hunting Seasons: Concurrent 93-day seasons on ducks, coots, gallinules and common snipe may be selected except as subsequently noted.

Duck Limits: Basic daily bag and possession limits for ducks are 7 and 14, respectively. No more than 2 redhead or 2 canvasbacks or 1 of each may be taken daily and no more than 4 singly or in the aggregate may be possessed.

Coot and Gallinule Limits: The daily bag and possession limit of coots and gallinules is 25 singly or in the aggregate.

Common Snipe Limits: The daily bag and possession limit of common snipe is 8 and 16, respectively.

California—Waterfowl Zones: Season dates for the Colorado River Zone of California must coincide with season dates selected by Arizona. Season dates for the Northeastern and Southern Zones of California may differ from those in the remainder of the State.

Nevada—Clark County Waterfowl Zone: Season dates for Clark County may differ from those in the remainder of Nevada.

*Columbia Basin* Portions of Washington, Oregon, and Idaho: In the Idaho counties of Ada, Benewah, Blaine, Bonner, Boundary, Cimes, Canyon, Cassia, Elmore, Gem, Gooding, Jerome, Kootenai, Latah, Lewis, Lincoln, Minidoka, Nez Perce, Owyhee, Payette, Power, Shoshone, Twin Falls, Washington and that portion of Bingham County lying outside the Blackfoot Reservation drainage; the Oregon counties of Baker, Gilliam, Malheur, Morrow, Sherman, Umatilla, Union, Wallowa and Wasco; and in Washington all areas lying east of the summit of the Cascade Mountains and east of the Big White Salmon River in Klickitat County, the seasons may be 100 days and must run concurrently.

Colorado, Montana, New Mexico and Wyoming — Common Snipe: For States partially within the Flyway a 93-day season for common snipe may be selected to occur between September 1, 1984, and February 28, 1985, and need not be concurrent with the duck season.

Geese (including Brant)

Outside dates, season lengths and limits on geese (including brant): Between September 29, 1984, and January 20, 1985, a 93-day season on geese (except brant in Washington, Oregon and California) may be selected except as subsequently noted. The basic daily bag and possession limit is 6, provided that the daily bag limit includes no more than 3 white geese (snow, including blue, and Ross' geese) and 3 dark geese (all other species of geese). The basic daily bag and possession limits are proportionately reduced in those areas where special restrictions apply to Canada geese. In Washington and Idaho, the daily bag and possession limits are 3 and 6 geese, respectively. Between October 20 and November 30, 1984, Washington, Oregon and California may select an open season for brant with daily bag and possession limits of 2 and 4 brant, respectively.

Alæutian Canada goose closure: The season is closed on the Alæutian Canada goose. Emergency closures may be invoked for all Canada geese should Alæutian Canada goose distribution patterns or other circumstances justify such actions.

Cackling Canada goose closure: The season is closed on the cackling Canada goose in California, Oregon and Washington.

Canada goose closures in California: Three areas in California, described as follows, are restricted in the hunting of Canada geese:

1. In the counties of Del Norte and Humboldt there will be no open season for Canada geese.

2. In the Sacramento Valley in that area bounded by a line beginning at Willows in Glenn County proceeding south on Interstate Highway 5 to the junction with Hahn Road north of Arbuckle in Colusa County; then easterly on Hahn Road and the Grimes-Aruckle Road to Grimes on the Sacramento River; then southerly on the Sacramento River to the Tisdale Bypass; then easterly on the Tisdale Bypass to where it meets O'Shanon Road; then easterly on O'Shanon Road to State Highway 89; then northerly on State Highway 89 to its junction with the Gridley-Colusa Highway in Gridley in Butte County; then westerly on the Gridley-Colusa Highway to its junction with the River Road; then northerly on the River Road to the Princeton Ferry; then westerly across the Sacramento River to State Highway 45; then northerly on State Highway 45 to its junction with State Highway 162; then continuing northerly on State Highway 45-162 to Glenn; then westerly on State Highway 162 to the point of beginning in Willows, the hunting season for Canada geese will not open before December 15 and may continue to the end of the waterfowl hunting season.

3. In the San Joaquin Valley in that area bounded by a line beginning at Modesto in Stanislaus County proceeding west on State Highway 132 to the junction of Interstate Highway 5; then southerly on Interstate Highway 5 to the junction of State Highway 152 in Merced County; then easterly on State Highway 152 to the junction of State Highway 59; then northerly on State Highway 59 to the junction of State Highway 89 at Merced; then northerly and westerly on State Highway 99 to the point of beginning; the hunting season for Canada geese will close no later than November 23.

Western Oregon: Those portions of Coos and Curry Counties lying west of U.S. Highway 101 and that portion of Tillamook County lying south of an east-west line passing through the most westerly point of Cape Lookout shall be closed to the hunting of Canada geese. The season on Canada geese in the remainder of Western Oregon shall extend from November 17 through December 16, with bag and possession limits of 1 goose. On State management areas and National Wildlife Refuges having controlled hunts within this area, the bag and possession limits may be increased to 3 geese, of which only 1 may be a dusky Canada goose. A method of validating geese harvested on these areas is a condition of the optionally larger limits.

*Columbia Basin* Portions of Washington and Oregon—geese: In the Washington counties of Adams, Benton, Douglas, Franklin, Grant, Kittitas, Kittiscott, Lincoln, Walla Walla and Yakima, and in the Oregon counties of Gilliam, Morrow, Sherman, Umatilla, Union, Wallowa and Wasco, the goose season may be of 100 days duration and must run concurrently with the duck season.

Oregon (Lake and Klamath Counties) — geese: In the Oregon counties of Lake and Klamath the season on dark geese will not open until two weeks after the opening date of the white goose season and be two weeks less than the white goose season.
California (Northeastern Zone) — geese: In the Northeastern Zone of California the season may be from October 13 to January 13, except that white-fronted geese may be taken only during October 13 to November 4. Limits will be 3 geese per day and 3 in possession, of which not more than 1 may be a dark goose in the daily bag, or 2 dark geese in possession. The daily bag limit on dark geese may be expanded to 3, provided both are Canada geese.

California (Balance of the State Zone) — geese: In the Balance of the State Zone the season may be from November 3 through January 20, except that white-fronted geese may be taken only during November 3 to January 6. Limits shall be 3 geese per day and 3 in possession, of which not more than 1 may be a dark goose. The daily bag limit on dark geese may be expanded to 3, provided both are Canada geese.

Pacific Population of Canada geese—Idaho, Oregon and Montana: In that portion of Idaho lying west of the line formed by U.S. Highway 93 north from the Nevada border to Shoshone, thence northerly on Idaho State Highway 75 (formerly U.S. Highway 93) to Challis, thence northerly on U.S. Highway 93 to the Montana border (except Boundary, Bonner, Kootenai, Benewah, Shoshone, Latah, Nez Perce, Lewis, Clearwater and Idaho Counties); in the Oregon counties of Baker and Malheur; and in Montana (Pacific Flyway portion west of the Continental Divide), the daily bag and possession limits are 2 Canada geese and the season for Canada geese may not extend beyond January 6, 1985.


Idaho, Colorado and Utah: In that portion of Idaho lying east of the line formed by U.S. Highway 93 north from the Nevada border to Shoshone, thence northerly on Idaho State Highway 75 (formerly U.S. Highway 93) to Challis, thence northerly on U.S. Highway 93 to the Montana border; in Colorado; and in Utah, except Washington County, the daily and possession limits are 2 and 4 Canada geese, respectively, and the season for Canada geese may be no more than 86 days and may not extend beyond January 6, 1985.

Nevada: Nevada may designate season dates on geese in Clark County and in Elko County and that portion of White Pine County within Ruby Lake National Wildlife Refuge differing from those in the remainder of the State. In Clark County the season on Canada geese may be no more than 86 days. The daily bag and possession limit is 2 Canada geese throughout the State.

Arizona, California, Utah and New Mexico: In California, the Colorado River Zone where the season must be the same as that selected by Arizona and the Southern Zone; in New Mexico; and in Washington County, Utah; the season for Canada geese may be no more than 86 days. The daily bag and possession limit is 2 Canada geese except in that portion of California Department of Fish and Game District 22 within the Southern Zone (i.e., Imperial Valley) where the daily bag and possession limits for Canada geese are 3 and 6, respectively.

Western Washington: In the Washington counties of Island, Skagit, Snohomish and Whatcom, the season for snow geese may not extend beyond January 1, 1985. In Clark and Cowlitz counties the season on Canada geese shall extend from November 17 through December 16, with bag and possession limits of 1 goose. On State management areas and National Wildlife Refuges having controlled hunts within these two counties, the bag and possession limits may be increased to 3 geese, of which only 1 may be a dusky Canada goose. A method of validating geese harvested in these areas is a condition of the optionally larger limits.

Whistling Swans

In Utah, Nevada and Montana, an open season for whistling swans may be selected subject to the following conditions: (a) the season must run concurrently with the duck season; (b) the appropriate State agency must issue permits and obtain harvest and hunter participation data; (c) in Utah, no more than 2,500 permits may be issued, authorizing each permittee to take 1 whistling swan; (d) in Nevada, no more than 650 permits may be issued, authorizing each permittee to take 1 whistling swan in either Churchill, Lyon, or Pershing Counties; (e) in Montana, no more than 500 permits may be issued authorizing each permittee to take 1 whistling swan in either Teton or Cascade Counties.

Sandhill Cranes

Arizona may select an experimental sandhill crane season subject to the conditions specified in the frameworks for early seasons.

SPECIAL FALCONRY FRAMEWORKS

Extended Seasons: Falconry is a permitted means of taking migratory game birds in any State meeting Federal falconry standards in 50 CFR 21.29(k). These States may select an extended season for taking migratory game birds in accordance with the following:

- **Framework Dates:** Seasons must fall within the regular and any special season framework dates.
- **Daily Bag and Possession Limits:** Daily bag and possession limits for all permitted migratory game birds shall not exceed 3 and 6 birds, respectively, singly or in the aggregate, during both regular hunting seasons and extended falconry seasons.
- **Regulations Publication:** Each State selecting the special season must inform the Service of the season dates and publish said regulations.

Regular Seasons: General hunting regulations, including seasons, hours, and limits, apply to falconry in each State listed in 50 CFR 21.29(k) which does not select an extended falconry season.

**NOTE:** In no instance shall the total number of days in any combination of duck seasons (regular duck season, special duck season, September teal season, special season, special goose season or falconry season) exceed 197 days for a species in one geographical area.


G. Ray Arnett,
Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 84-24488 Filed 9-13-84; 8:45 am]
BILLING CODE 4310-55-C
DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
50 CFR Part 20

Lead Poisoning in Bald Eagles; Proposed Alternative Conservation Measures

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent; request for comments.

SUMMARY: The United States Fish and Wildlife Service is announcing that it has developed a series of proposed alternative conservation measures designed to address lead poisoning in bald eagles. These conservation measures range from a commitment to do additional scientific research to a recognition of the potential need to designate additional steel shot zones for the hunting of migratory waterfowl in the 1985–86 hunting season. Comments and information on the biological and economic impacts of these proposed conservation measures are solicited. Such information and comments will be used in revising these conservation measures, as necessary, and in preparing any required environmental and economic impact analyses under the National Environmental Policy Act, the Regulatory Flexibility Act and Executive Order 12291.

DATE: The comment period for this notice will end on October 29, 1984.

ADDRESS: All comments and information should be submitted to: Director (FWS/MBMO), U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240. Comments and information received in response to this notice will be available for public inspection during normal business hours in Room 595, Matomie Building, 1717 H Street NW., Washington, D.C.


SUPPLEMENTARY INFORMATION:

Introduction

The American bald eagle, our national symbol, is afforded greater protection than any other species. Protective provisions found in the Bald and Golden Eagle Protection Act, the Endangered Species Act and the Migratory Bird Treaty Act collectively impose unique conservation responsibilities for the bald eagle upon the Secretary of the Interior. After a period of substantial decline, the last few years have witnessed a dramatic increase in the population levels of bald eagles. Nonetheless, the species is not yet fully recovered and some eagles continue to die from lead poisoning.

Mindful of his conservation responsibilities, the Secretary of the Interior through the United States Fish and Wildlife Service is asking the public to participate in the development of comprehensive conservation measures designed to resolve the issue of lead poisoning in bald eagles. To achieve this goal, the Service has developed a plan of action that is progressive yet scientifically responsible. It recognizes both the existence of considerable scientific uncertainty about the relationship between lead shot and bald eagle mortality and the Secretary’s conservation responsibilities. First, the Service has tentatively established a priority listing of areas where there is substantive evidence showing that bald eagles have either died from lead poisoning or could potentially be affected by lead poisoning. For those areas of greatest concern, the Service is announcing its current intention to propose regulations by mid-December that would ban the use of lead shot for the 1985–86 season unless study and public comment during the interim period show that regulations would not be appropriate. Similar regulatory measures could be proposed for other areas by mid-December depending on the results of further analysis of data and public comments. Second, the Service is preparing a comprehensive research strategy comprised of short- and long-term research proposals to be implemented over the next three years. Public comment is also being sought in connection with this element of the Service’s conservation program. Finally, the Service requests assistance in the development of an objective public education program on the issue of lead poisoning of eagles.

The Service fully recognizes the crucial role that the States must play in developing a comprehensive and effective response to the lead poisoning issue and welcomes their participation. The Service also recognizes that elements of this program could produce temporary hardships on some members of the hunting community. The Service therefore intends this public notice to provide all persons with an early opportunity to comment on the Service’s conservation measures. Nevertheless, given the Secretary’s unique conservation responsibilities for the American bald eagle, the Service must weigh the degree of scientific uncertainty against the risk to the well-being of this nation’s symbol—a matter of interest and concern to all Americans.

General Background

After a period of significant decline in population, due in large measure to the effects of certain pesticides, the bald eagle is increasing in number in all parts of the country. For example, the National Wildlife Federation recently announced that their annual eagle population survey showed an increase of over 900 bald eagles from the year before. The most important factor contributing to this long-term recovery was the steps taken by the Federal Government to restrict the use of pesticides.

As the effects of pesticides on eagles continue to decline, attention has shifted to other causes of eagle mortality. Most recently, the debate has focused upon the effect and causes of lead poisoning in eagles. The Fish and Wildlife Service has been aware of this issue and has been studying it for some time. Formulating definitive solutions to the problem of lead poisoning in eagles is very difficult. Most of the research in recent years regarding the environmental effects of lead shot has focused on waterfowl, not raptors. Moreover, the biological conclusions developed for lead poisoning in waterfowl are not readily transferable to bald eagles.

The Fish and Wildlife Service acknowledges that an increased number of dead bald eagles recovered in recent years have died of lead poisoning. To date, the exact cause of this increase is unknown. The Service believes, however, that it may be related to increased testing for lead poisoning; greater consumption of waterfowl by bald eagles as a primary winter food source; habitat losses resulting in increased concentrations of eagles and waterfowl for longer periods during the year; and an increased effort to recover dead bald eagles.

Regardless of the reasons, lead poisoning in bald eagles is occurring and additional work is needed to provide a better understanding of the ecological relationship and biological significance of this type of mortality in bald eagles. The ecological relationship between bald eagles and waterfowl also requires that strong consideration be given to various factors that could be relevant in identifying bald eagle/lead poisoning problem areas: The species of waterfowl (geese vs. ducks) used as a food base, the numbers of waterfowl being consumed by bald eagles, the time of year when eagles are feeding on these waterfowl, the use of toxic and non-
confirmed that each of those counties had a wintering population of fifteen or more bald eagles. Finally, the Service noted for each county whether or not there had been a documented death of a bald eagle that was attributed by the Service to lead poisoning. In addition to a high level of lead within the soft tissues of a bald eagle, the Service relied upon pathology at necropsy and histopathological evaluations as a basis for concluding that lead poisoning was the cause of death.

Using this priority ranking approach, the Service has divided the counties under consideration into three different categories. Category I includes those counties of most concern to the Service. The classification indicators used to place areas into Category I were the following: (1) An annual average harvest of 25,000 or more waterfowl; and (2) at least one documented bald eagle death attributed by the Service to lead poisoning. Apply these indicators to the list of counties previously established, the Service identified 5 counties in three states to be included in Category I.

These counties are:

<table>
<thead>
<tr>
<th>Name of county</th>
<th>Number of harvested waterfowl</th>
<th>Number of dead bald eagles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skagit (WA)</td>
<td>22,000</td>
<td>3</td>
</tr>
<tr>
<td>Moclips (OR)</td>
<td>27,200</td>
<td>1</td>
</tr>
<tr>
<td>Jackson (OR)</td>
<td>56,200</td>
<td>0</td>
</tr>
<tr>
<td>Holt (MO)</td>
<td>25,000</td>
<td>1</td>
</tr>
</tbody>
</table>

The four listed counties in California and Oregon constitute the Klamath Basin area and were treated as an ecological habitat unit because the same waterfowl and eagle populations must range over this entire area. Thus Klamath County in Oregon was included within Category I despite the fact that no recorded eagle deaths occurred there.

The top three counties of the Klamath Basin alone generate an annual average waterfowl harvest of over 163,000 birds and have a wintering population of well over a hundred bald eagles. As a related matter, a recent monitoring study of two national wildlife refuges within this Basin indicated a significant lead poisoning problem in waterfowl on those refuges. Based on these findings, the Service has requested that the State of California designate those two refuges as steel shot zones for the 1985-86 season. Therefore, this earlier agency decision, which was limited to wildlife refuges and waterfowl, should not be confused with this current proposal involving bald eagles.

The fifth county in Category I, Holt County, Missouri, was included because of the size of its waterfowl harvest (25,000) and the presence of a confirmed bald eagle death due to lead poisoning. Moreover, a significant percentage of Holt County’s annual harvest is of geese, not ducks, and there is a large concentration of wintering bald eagles.

For these five counties in Category I, the Service has tentatively concluded that available evidence indicates that there is a substantial likelihood of a problem involving lead poisoning in both eagles.

Category II areas were selected on the basis of less restrictive indicators. These indicators were: (1) An average annual harvest of 25,000 or more waterfowl and no eagle deaths attributable to lead poisoning; or (2) an average annual harvest of less than 25,000 waterfowl and one documented bald eagle death due to lead poisoning. Applying these indicators to the list of counties previously established, the Service has identified fourteen counties in eleven states to be included in Category II. These counties are:

For these fourteen counties in Category II, the Service has tentatively concluded that available information suggests that there may be a problem in these areas involving lead poisoning in eagles.

Category III areas were selected on the basis of a classification indicator that was less restrictive than those utilized for Category II. This indicator was: An average annual harvest of between 10,000 and 25,000 waterfowl but no documented bald eagle deaths due to lead poisoning. Applying this indicator to the list of counties previously established, the Service has identified ten counties in seven states to be included in Category III. These counties are:

<table>
<thead>
<tr>
<th>Name of county</th>
<th>Number of harvested waterfowl</th>
<th>Number of dead bald eagles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whatcom (WA)</td>
<td>10,200</td>
<td>0</td>
</tr>
<tr>
<td>Pierce (WA)</td>
<td>11,000</td>
<td>0</td>
</tr>
<tr>
<td>Spokane (WA)</td>
<td>16,400</td>
<td>0</td>
</tr>
<tr>
<td>Duchesne (UT)</td>
<td>10,800</td>
<td>0</td>
</tr>
<tr>
<td>Mississippi (AR)</td>
<td>11,200</td>
<td>0</td>
</tr>
</tbody>
</table>
For these ten counties in Category III, the Service has tentatively concluded that available information suggests that there is the potential for a problem of unknown magnitude involving the lead poisoning of bald eagles.

In developing the various classification indicators for Categories I through III the Service has arrived at certain tentative conclusions. First, based on currently available data, the Service believes there is more likely to be a causal connection between the use of lead shot and lead poisoning in bald eagles for Category I areas, than there is for the other two Categories. Second, as the Service's degree of confidence in its assumptions increases from Category III to Category I, the agency's ability to initiate effective, remedial conservation measures increases as well. For these reasons, the Service's proposed plan of action for addressing lead poisoning in eagles becomes progressively more specific and aggressive as one moves away from Category III and into the other Categories.

**Proposed Plan of Action**

Based on the above assumptions, priority rankings and conservation obligations, the Service is actively considering the following. First, for Category I counties, the Service has under active consideration a proposal to designate these counties as non-toxic shot zones for the 1985-86 season. Moreover, after compliance with other aspects of procedural administrative law, the Service is prepared to issue a proposed regulation to that effect by December 15, 1984, unless either further study by the Service, or public comments received in response to this notice, presents evidence that: (1) The proposal will not contribute to the conservation of the bald eagle; or (2) factual assumptions underlying the Category I designations are erroneous. Moreover, in recognition of current Appropriations Act restrictions on the Service's authority to promulgate steel shot regulations without the approval of the affected states, the Service will consult actively with affected states and seek their approval should such a rule ultimately be published for Category I areas.

As for the Category II counties, the Service believes that an intensive review of available data, and the accelerated acquisition of additional information, may provide further evidence of a causal connection between the use of lead shot and lead poisoning in bald eagles. Currently available information, however, is not sufficient for the Service to announce any particular regulatory intentions at this time. The Service recognizes the distinct possibility of having eventually to add some of the Category II areas to the Category I level of concern. Therefore, the Service is interested in receiving public comments on whether an adequate data base exists that would warrant the designation of any Category II area as a non-toxic shot zone for the 1985-86 season. The Service also requests that all relevant data be provided regarding a causal connection between the use of lead shot and lead poisoning in eagles in these areas. The Service's proposed decision regarding further action on Category II areas prior to the publication of any Category I proposed rule.

Finally, for Category III areas, the Service again believes that an intensive review of available data and the accelerated acquisition of additional information may provide further guidance as to what administrative actions, if any, the Service should take. Although it is conceivable that proposed steel shot regulations may ultimately be required for some of the Category III areas as information both about these areas and the effects of lead poisoning of eagles increases, the Service is not prepared to say that this is the case at this time. Instead, the Service will review what additional data becomes available within the next two months and will reassess its decision to focus on research instead of immediate regulatory action for Category III areas. The Service actively solicits public comment on this approach for Category III areas.

In summary, the public is being asked to comment on an array of regulatory strategies that are tailored to the incidence of lead poisoning in bald eagles. During the public comment period, the Service will continue to evaluate its assumptions and indicators and will refine them when deemed appropriate. There may be, for example, situations where smaller ecological units like river basins more accurately reflect the areas of lead poisoning concern than do artificial political boundaries like county lines. Thus, the Service is not locked in to the approach of using counties as the basis for further regulatory action where a smaller, descriptive unit would more accurately address lead poisoning. The public is urged to suggest similar refinements if warranted to suggest other areas that should be added to Categories I, II or III. In addition to providing ecological data and information, the Service also requests the public to submit information on anticipated economic impacts that could result from the implementation of the various regulatory strategies.

**Research and Planning**

In addition to the above action plan regarding the designation of steel shot zones, the Service has also begun to develop a research strategy for providing additional scientific data on lead poisoning in bald eagles. The goal of this research program will be to maximize the acquisition of meaningful data in a cost effective and timely manner. The Service's research strategy is to be divided into two categories, consisting of short term proposals, capable of being completed by the first of December, and long term proposals, capable of being completed within three years. Individual proposals would be ranked in priority order within each category based on the availability of funds and the usefulness of the anticipated data.

The Service is especially interested in receiving public comment on potential long term research proposals. Potential subject areas the Service is considering include food habit studies of wintering concentrations of bald eagles; time sequential approaches for taking blood samples at breeding and wintering areas; additional analysis of plumbism in bald eagles; accelerated pathological analysis of retrieved dead bald eagles with a priority for analysis of eagles from Category I, II and III areas; and the expansion of current banding efforts. The Service has set September 21st and November 1st respectively as the target dates for designating its research matters will be taken into account in developing the agency's forthcoming research proposals.

The Service also notes that the bald eagle is one of 54 National Species of Special Emphasis (NSSE) designated by the Service to be addressed in FWS Regional Resource Planning (RRP). The RRP process, a key component of the Service's overall planning effort, follows a seven step process from an analysis phase to a specific operations or action plan phase. Endangered Species Recovery Plans are also integrated into this process along with data and information from other sources.
including the public. The first cycle of RRP documents were completed in the fall of 1983 and are currently being revised. As more data become available to the Service regarding lead poisoning in bald eagles, it will be incorporated into the Bald Eagle Recovery Plans and RRP's as appropriate.

In addition, the service is in the process of developing an overall report on the bald eagle that would summarize information and data regarding the status of the species. The report will also specify management actions that should be implemented to address the conservation needs of the species. The format of the report will now be revised to address lead poisoning in an expanded fashion. The report should be completed in the early spring of 1985.

Education

Finally, the Service intends to develop an objective public education program on the issue. Public comments on the scope and content of such an education program are solicited and will be taken into account by the Service as it begins to formulate its plans.


Rolf L. Wallenstrom,
Acting Director, U.S. Fish and Wildlife Service.
Part VI

Federal Maritime Commission

46 CFR Part 510
Licensing of Ocean Freight Forwarders; Final Rule
46 CFR Parts 515, 520, 525, 530, and 540
The Shipping Act of 1984; Marine Terminal Operations and Passenger Vessels; Final Rules
The Association, although generally forwarders, consider that with a revised rule, as recommended, the industry could realize a saving of three million dollars. The significant saving, it is suggested, would result from elimination of the need both for forwarders to submit the huge volume of certifications to carriers and for carriers to process and retain this paperwork in order to generate appropriate compensation checks. Payment of compensation, it is believed, could better be automated, thus less enmeshed in clerical procedures.

In view of the comments regarding the certification requirements contained in the forwarder regulations, the Final Rules will allow forwarders to provide the required certification on one copy of the bill of lading, or on a forwarder’s summary statement, or on a forwarder’s invoice for compensation, or as an endorsement on the back of a carrier’s compensation check. Carriers will still be required to retain a copy of the forwarder’s certification. Forwarders will only be required to retain in their shipment files evidence that the required services were performed on the particular shipments.

It is our belief that this change is consistent with the language of the 1984 Act, and it will afford the industry an opportunity to streamline procedures for the payment of ocean freight compensation to the benefit of all concerned. Moreover, under the Final Rule, forwarders will no longer be required to check specific services performed on each shipment as the certification language is broad enough to cover any shipment. Appropriate amendments to the pertinent sections of the Final Rules have been made accordingly.

The National Customs Brokers and Forwarders Association of America, Inc. (the Association) submitted comments on a number of areas of the Interim Rules. The Association favors the shipper-affiliations notice requirement contained in section 510.31(b) of the Interim Rules. However, it believes that it does not go far enough to protect exporters in the United States. It believes that the requirement should be extended beyond affiliations with exporters from foreign countries. It sees the potential for harm to U.S. exporters if forwarders affiliated with foreign exporters release information about their U.S. principals to their foreign affiliates which the foreign affiliate could use to attract business away from the U.S. exporter.

We see merit in the Association’s suggestion and we have adopted the recommended language offered by the Association as part of the Final Rules. The Association, although generally supporting the changes in the invoicing rule, does not feel the notice that is to
The Interim Rules, we are not disposed to change this rule and it will be adopted as the rule currently reads.

The issue raised by the “8900” Lines, et al. will be the subject of a separate proceeding on the issue is necessary at this time.

Having addressed the comments submitted to our Interim Rules, we turn now to two areas which we wish to further amend for clarification purposes. Under §510.31(e), Arrangements with unauthorized persons, we have amended the last sentence by adding the word “also” after “licensure shall.” This change is to make it clear that when a third party is involved in a forwarding transaction, the licensee shall, in addition to providing the third party with an invoice, provide a copy of its invoice to the shipper. Thus, the last sentence is to read, in pertinent part:

• • • the licensee shall also transmit to the person paying the forwarding charges a copy of its invoice for services rendered.

Under §510.33(a), Disclosure of principal, we have added language specifying that the identity of the shipper must be shown “in the shipper identification box on the bill of lading” as opposed to just “on the bill of lading” as the rule currently reads.

The Interim Rules deleted several sections from the rules in effect prior to June 18, 1984 (prior rules). For the sake of clarity, we have redesignated a number of sections. The Interim Rules deleted paragraph (a) of §510.32, Forwarder and principal fees.

Therefore, we have redesignated the remaining paragraphs, (b) through (k), as paragraphs (a) through (j) in the Final Rules.

Paragraphs (a) and (b) of §510.35, Reports required to be filed, have been deleted and all that remains is paragraph (c). Thus, we have entitled §510.35 as Anti-rebate certification, and deleted the paragraph designation.

The Interim Rules also deleted §§510.12 and 510.21 from the prior rules. In view of this, we have redesignated §§510.13 through 510.20 as §§510.12 through 510.19 in the Final Rules.

Similarly, §§510.31 through 510.35 have been redesignated as §§510.21 through 510.25 in the Final Rules. Conforming amendments to cross references that appear throughout the Final Rules have been made accordingly.

To correct an oversight regarding the appropriate OMB control numbers appearing in §510.91, we have amended that section to reflect the correct OMB control number as 3072-0018 for all the sections indicated in the table appearing in the section.

Pursuant to 5 U.S.C. 601 et seq., the Chairman of the Commission certifies that the Final Rules published herein will not have a significant economic impact on a substantial number of small entities. The Final Rules are intended to bring the Commission’s regulations in line with new legislation. Further, they tend to lessen the regulatory burden upon the forwarding industry and they should have a cost-saving impact on the operations of forwarders.

List of Subjects in 46 CFR Part 510

Exports, Freight forwarders, Maritime carriers, Rates, Reports and record-keeping requirements, Surety bonds.

Therefore, pursuant to 5 U.S.C. 553 and sections 3, 8, 10, 11, 13, 15, 17, and 19 of the Shipping Act of 1984 (46 U.S.C. app. 1702, 1707, 1709, 1710, 1712, 1714, 1716 and 1718), the Commission revises 46 CFR Part 510 to read as follows:

PART 510—LICENSING OF OCEAN FREIGHT FORWARDERS

Subpart A—General

Sec. 510.1 Scope.
510.2 Definitions.
510.3 License, when required.
510.4 License, when not required.

Subpart B—Eligibility and Procedure for Licensing; Bond Requirements

510.11 Basic Requirements for licensing; eligibility.
510.12 Application for license.
Subpart A—General

§ 510.1 Scope.

(a) This part sets forth regulations providing for the licensing as ocean freight forwarders of persons, including individuals, corporations and partnerships, who wish to carry on the business of freight forwarding. This part also prescribes the bonding requirements and the duties and responsibilities of ocean freight forwarders; regulations concerning practices of freight forwarders and common carriers, and the grounds and procedures for revocation and suspension of licenses.

(b) Information obtained under this part is used to determine the qualifications of freight forwarders and their compliance with shipping statutes and regulations. Failure to follow the provisions of this part may result in denial, revocation or suspension of a freight forwarder license. Persons operating without the proper license may be subject to civil penalties not to exceed $5,000 for each such violation unless the violation is willfully and knowingly committed, in which case the amount of the civil penalty may not exceed $25,000 for each violation; for other violations of the provisions of this part, the civil penalties range from $5,000 to $25,000 for each violation (46 U.S.C. app. 1712). Each day of a continuing violation shall constitute a separate violation.

§ 510.2 Definitions

The terms used in this part are defined as follows:


(b) "Beneficial interest" includes a lien or interest in or right to use, enjoy, profit, benefit, or receive any advantage, either proprietary or financial, from the whole or any part of a shipment of cargo where such interest arises from the financing of the shipment or by operation of law, or by agreement, express or implied. The term "beneficial interest" shall not include any obligation or liability existing solely by reason of the advance of out-of-pocket expenses incurred in dispatching a shipment.

(c) "Branch office" means any office established by or maintained by or under the control of a licensee for the purpose of rendering freight forwarding services, which office is located at an address different from that of the licensee's designated home office. This term does not include a separately incorporated entity.

(d) "Brokerage" refers to payment by a common carrier to an ocean freight broker for the performance of services as specified in paragraph (m) of this section.

(e) "Common carrier" means any person holding itself out to the general public to provide transportation by water of passengers or cargo between the United States and a foreign country for compensation that:

(1) Assumes responsibility for the transportation from the port or point of receipt to the port or point of destination, and

(2) Utilizes, for all or part of that transportation, a vessel operating on the high seas or the Great Lakes between a port in the United States and a foreign country.

(f) "Compensation" means payment by a common carrier to a freight forwarder for the performance of services as specified in § 510.23(c) of this part.

(g) "Freight forwarding fee" means charges billed by a freight forwarder to a shipper, consignee, seller, purchaser, or any agent thereof, for the performance of freight forwarding services.

(h) "Freight forwarding services" refers to the dispatching of shipments on behalf of others, in order to facilitate shipment by a common carrier, which may include, but is not limited to, the following:

(1) Ordering cargo to port;

(2) Preparing and/or processing export declarations;

(3) Booking arranging for or confirming cargo space;

(4) Preparing or processing delivery orders or dock receipts;

(5) Preparing and/or processing ocean bills of lading;

(6) Preparing or processing consular documents or arranging for their certification;

(7) Arranging for warehouse storage;

(8) Arranging for cargo insurance;

(9) Clearing shipments in accordance with United States Government export regulations;

(10) Preparing and/or sending advance notifications of shipments or other documents to banks, shippers, or consignees, as required;

(11) Handling freight or other monies advanced by shippers, or remitting or advancing freight or other monies or credit in connection with the dispatching of shipments;

(12) Coordinating the movement of shipments from origin to vessel; and

(13) Giving expert advice to exporters concerning letters of credit, documents, licenses or inspections, or on problems germane to the cargo's dispatch.

(i) "From the United States" means oceanborne export commerce from the United States, its Territories, or possessions to foreign countries.

(j) "Licensee" is any person licensed by the Federal Maritime Commission as an ocean freight forwarder.

(k) "Ocean common carrier" means a common carrier that does not operate the vessels by which the ocean transportation is provided, and is a shipper in its relationship with an ocean common carrier.

(l) "Ocean common carrier" means a vessel-operating common carrier but the term does not include one engaged in ocean transportation by ferry boat or ocean tramp.

(m) "Ocean freight broker" is an entity which is engaged by a carrier to secure cargo for such carrier and/or to sell or offer for sale ocean transportation services and which holds itself out to the public as one who negotiates between shipper or consignee and carrier for the purchase, sale, conditions and terms of transportation.

(n) "Ocean freight forwarder" means a person in the United States that:

(1) Dispatches shipments from the United States via common carriers and books or otherwise arranges space for those shipments on behalf of shippers; and

(2) Processes the documentation or performs related activities incident to those shipments.

(o) "Principal," except as used in Surety Bond Form FMC 59, Rev., refers to the shipper, consignee, seller, or purchaser of property, and to anyone acting on behalf of such shipper, consignee, seller, or purchaser of property, who employs the services of a
licensee to facilitate the ocean transportation of such property.

(p) “Reduced forwarding fees” means charges to a principal for forwarding services that are below the licensee’s usual charges for such services.

(q) “Shipment” means all of the cargo carried under the terms of a single bill of lading.

(r) “Shipper” means an owner or person for whose account the ocean transportation of cargo is provided or to the person to whom delivery is to be made.

(s) “Small shipment” refers to a single shipment sent by one consignor to one consignee on one bill of lading which does not exceed the underlying common carrier’s minimum charge rule.

(t) “Special contract” is a contract for freight forwarding services which provides for a periodic lump sum fee.

(a) “United States” includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, and all other United States territories and possessions.

§ 510.3 License; when required.

Except as otherwise provided in this part, a person must hold a valid ocean freight forwarded license in order to perform freight forwarding services, except as provided in § 510.4 of this part, no person shall perform, or hold out to perform, such services unless such person holds a valid license issued by the Commission to engage in such business. A separate license is required for each branch office that is separately incorporated.

§ 510.4 License; when not required.

A license is not required in the following circumstances:

(a) Shipper. Any person whose primary business is the sale of merchandise may, without a license, dispatch and perform freight forwarding services on behalf of its own shipments, or on behalf of shippers or consolidated shipments of a parent, subsidiary, affiliate, or associated company. Such person shall not receive compensation from the common carrier for any services rendered in connection with such shipments.

(b) Employee or branch office of licensed forwarder. An individual employee or unincorporated branch office of a licensed ocean freight forwarder is not required to be licensed in order to act solely for such licensee, but each licensed ocean freight forwarder will be held strictly responsible hereunder for the acts or omissions of any of its employees rendered in connection with the conduct of the business.

(c) Common carrier. A common carrier, or agent thereof, may perform ocean freight forwarding services without a license only with respect to cargo carried under such carrier’s own bill of lading. Charges for such forwarding services shall be assessed in conformance with the carrier’s published tariffs on file with the Commission.

(d) Ocean freight brokers. An ocean freight broker is not required to be licensed to perform those services specified in § 510.2(m).

Subpart B—Eligibility and Procedure for Licensing; Bond Requirements

§ 510.11 Basic Requirements for licensing; eligibility.

(a) Necessary qualifications. To be eligible for an ocean freight forwarder’s license, the applicant must demonstrate to the Commission that:

1) It possesses the necessary experience, that is, its qualifying individual has a minimum of three (3) years experience in ocean freight forwarding duties in the United States, and the necessary character to render forwarding services; and

2) It has obtained and filed with the Commission a valid surety bond in conformance with § 510.4

(b) Qualifying individual. The following individuals must qualify the applicant for a license:

1) Sole proprietorship—The applicant sole proprietor.

2) Partnership—At least one of the active managing partners, but all partners must execute the application.

3) Corporation—At least one of the active corporate officers.

(c) Affiliates of forwarders. An independently owned applicant may be granted a separate license to carry on the business of forwarding even though it is associated with, under common control with, or otherwise related to another ocean freight forwarder through stock ownership or common directors or officers, if such applicant submits:

1) A separate application and fee, and

2) A valid surety bond in the form and amount prescribed under § 510.14 of this part.

(d) Common carrier. A common carrier or agent thereof which meets the requirements of this part may be licensed to dispatch shipments moving on other than such carrier’s own bill of lading subject to the provisions of § 510.25(g) of this part.

§ 510.12 Application for license.

(a) Application and forms. Any person who wishes to obtain a license to carry on the business of forwarding shall submit, in duplicate, to the Director of the Commission’s Bureau of Tariffs, a completed application Form FMC–16 Rev. (“Application for a License as an Ocean Freight Forwarder”) and a completed antirebate certification in the format prescribed under § 510.25 of this part. Copies of Form FMC–18 Rev. may be obtained from the Director, Bureau of Tariffs, Federal Maritime Commission, Washington, D.C. 20573, or from any of the Commission’s offices at other locations. Notice of filing of such application shall be published in the Federal Register and shall state the name and address of the applicant. If the applicant is a corporation or partnership, the names of the officers or partners thereof shall be published.

(b) Fee. The application shall be accompanied by a money order, certified check or cashier’s check in the amount of $350 made payable to the “Federal Maritime Commission.”

(c) Rejection. Any application which appears upon its face to be incomplete or to indicate that the applicant fails to meet the licensing requirements of the Shipping Act of 1984, or the Commission’s regulations, shall be returned by certified U.S. mail to the applicant without further processing, together with an explanation of the reason(s) for rejection, and the application fee shall be refunded in full.

All other applications will be assigned an application number, and each applicant will be notified of the number assigned to its application. Persons who have had their applications returned may reapply for a license at any time thereafter by submitting a new application, together with the full application fee.

(d) Investigation. Each applicant shall be investigated in accordance with § 510.13 of this part.

(e) Changes in fact. Each applicant and each licensee shall submit to the Commission, in duplicate, an amended Form FMC–16 Rev. advising of any changes in the facts submitted in the original application, within thirty (30) days after such change(s) occur. In the case of an application for a license, any unreported change may delay the processing and investigation of the application and may result in rejection or denial of the application. No fee is required when reporting changes to an
§ 510.13 Investigation of applicants.
The Commission shall conduct an investigation of the applicant's qualifications for a license. Such investigations may address:
(a) The accuracy of the information submitted in the application;
(b) The integrity and financial responsibility of the applicant;
(c) The character of the applicant and its qualifying individual; and
(d) The length and nature of the qualifying individual's experience in handling freight forwarding duties.

§ 510.14 Surety bond requirements.
(a) Form and amount. No license shall be issued to an applicant who does not have a valid surety bond (FMC-59 Rev.) on file with the Commission in the amount of $30,000. The amount of such bond shall be increased by $10,000 for each of the applicant's unincorporated branch offices. Bonds must be issued by a surety company found acceptable by the Secretary of the Treasury. Surety Bond Form FMC-59 Rev. can be obtained in the same manner as Form FMC-18 Rev. under § 510.12(a) of this part.
(b) Filing of bond. Upon notification by the Commission to the agent of U.S. mail that the applicant has been approved for licensing, the applicant shall file with the Director of the Commission's Bureau of Tariffs, a surety bond in the form and amount prescribed in § 510.14(a) of this part. No license will be issued until the Commission is in receipt of a valid surety bond from the applicant. If more than six (6) months elapse between issuance of the notification of qualification and receipt of the surety bond, the Commission shall, at its discretion, undertake a supplementary investigation to determine the applicant's continued qualification. The fee for such supplementary investigation shall be $100 payable by money order, certified check, or cashier's check to the "Federal Maritime Commission." Should the applicant not file the requisite surety bond within two years of notification, the Commission will consider the application to be invalid.
(c) Branch offices. A new surety bond, or rider to the existing bond, increasing the amount of the bond in accordance with § 510.14(a) of this part, shall be filed with the Commission prior to the date the licensee commences operation of any branch office. Failure to adhere to this requirement may result in revocation of the license.
(d) Termination of bond. No license shall remain in effect unless a valid surety bond is maintained on file with the Commission. Upon receipt of notice of termination of a surety bond, the Commission shall notify the concerned licensed company by certified mail at its last known address, that the Commission shall, without hearing or other proceeding, revoke the license as of the termination date of the bond unless the licensee shall have submitted a valid replacement surety bond before such termination date. Replacement surety bonds must bear an effective date no later than the termination date of the expiring bond.

§ 510.15 Denial of license.
If the Commission determines, as a result of its investigation, that the applicant:
(a) Does not possess the necessary experience or character to render forwarding services;
(b) Has failed to respond to any lawful inquiry of the Commission; or
(c) Has made any willfully false or misleading statement to the Commission in connection with its application, a letter of intent to deny the application shall be sent to the applicant by certified U.S. mail, stating the reason(s) why the Commission intends to deny the application. If the applicant submits a written request for hearing on the proposed denial within twenty (20) days after receipt of notice, such hearing shall be granted by the Commission pursuant to its Rules of Practice and Procedure contained in Part 502 of this chapter. Otherwise, denial of the application will become effective and the applicant shall be so notified by certified U.S. mail. Civil penalties for violations of the Act or any Commission order, rule or regulation may be assessed in accordance with Part 505 of this chapter, in connection with an application for a license or its continuance in effect;
(4) Where the Commission determines that the licensee is not qualified to render freight forwarding services; or
(5) Failure to honor the licensee's financial obligations to the Commission, such as for civil penalties assessed or agreed to in a settlement agreement under Part 505 of this chapter.

§ 510.16 Revocation or suspension of license.
(a) Grounds for revocation. Except for the automatic revocation for termination of a surety bond under § 510.14(d) of this part, or as provided in § 510.14(c) of this part, a license may be revoked or suspended after notice and hearing for any of the following reasons:
(1) Violation of any provision of the Act, or any other statute or Commission order or regulation related to carrying on the business of forwarding;
(2) Failure to respond to any lawful order or inquiry by the Commission; or
(3) Making a willfully false or misleading statement to the Commission in connection with an application for a license or its continuance in effect;
(b) Civil penalties. As provided for in Part 505 of this chapter, civil penalties for violations of the Act or any Commission order, rule, or regulation may be assessed in any proceeding to revoke or suspend a license and may be compromised when such a proceeding has not been instituted.
(c) Notice of Revocation. The Commission shall publish in the Federal Register a notice of each revocation.

§ 510.17 Application after revocation or denial.
Whenever a license has been revoked or an application has been denied because the Commission has found the licensee or applicant to be not qualified to render forwarding services, any further application within 3 years of the date of the most recent conduct on which the Commission's notice of revocation or denial was based, made by such former licensee or applicant or by another applicant employing the same qualifying individual or controlled by persons on whose conduct the Commission based its determination for revocation or denial, shall be reviewed directly by the Commission.

§ 510.18 Issuance and use of license.
(a) Qualification necessary for issuance. The Commission will issue a license if it determines, as a result of its investigation, that the applicant possesses the necessary experience and character to render forwarding services and has filed the required surety bond.
(b) To whom issued. The Commission will issue a license only in the name of the applicant, whether the applicant be a sole proprietorship, a partnership, or a corporation, and the license will be issued to only one legal entity. A license issued to a sole proprietor doing business under a trade name shall be in the name of the sole proprietor, indicating the trade name under which the licensee will be conducting business. Only one license shall be issued to any applicant regardless of the number of names under which such applicant may be doing business.
(c) Use limited to named licensee. Except as otherwise provided in this part, such license is limited exclusively to use by the named licensee and shall
requirements set forth in § 510.11(a) of this part. The licensee may continue to operate as an ocean freight forwarder while the Commission investigates the qualifications of the newly designated partner or officer.

(d) Incorporation of branch office. In the event a licensee's validly operating branch office undergoes incorporation as a separate entity, the licensee may continue to operate such office pending receipt of a separate license, provided that:

(1) The separately incorporated entity applies to the Commission for its own license within ten (10) days after incorporation, and

(2) The continued operation of the office is carried on as a bona fide branch office of the licensee, under its full control and responsibility, and not as an operation of the separately incorporated entity.

(e) Application form and fee. Applications for Commission approval of status changes or for license transfers under § 510.19(a) of this part shall be filed in duplicate with the Director, Bureau of Tariffs, Federal Maritime Commission, on Form FMC-18, Rev., together with a processing fee of $100, made payable by money order, certified check, or cashier's check to the "Federal Maritime Commission."

Subpart C—Duties and Responsibilities of Freight Forwarders; Forwarding Charges; Reports to Commission

§ 510.21 General duties.

(a) License; name and number. Each licensee shall carry on the business of forwarding only under the name in which its license is issued and only under its license number as assigned by the Commission. Wherever the licensee's name appears on shipping documents, its FMC license number shall also be included.

(b) Stationery and billing forms; notice of shipper affiliation.

(1) The name and license number of each licensee shall be permanently imprinted on the licensee's office stationery and billing forms. The Commission may temporarily waive this requirement for good cause shown if the licensee rubber stamps or types its name and FMC license number on all papers and invoices concerned with any forwarding transaction.

(2) When a licensee is a shipper or seller of goods in international commerce or affiliated with such an entity, the licensee shall have the option of:

(i) Identifying itself as such and/or, where applicable, listing its affiliates on its office stationery and billing forms, or

(ii) including the following notice on such items:

This company is a shipper or seller of goods in international commerce or is affiliated with such an entity. Upon request, a general statement of its business activities and those of its affiliates, along with a written list of the names of such affiliates, will be provided.

(c) Use of license by others; prohibition. No licensee shall permit its license or name to be used by any person who is not a bona fide individual employee of the licensee.

Unincorporated branch offices of the licensee may use the license number and name of the licensee if such branch offices:

(1) Have been reported to the Commission in writing; and

(2) are covered by an increased bond in accordance with § 510.14(c) of this part.

(d) Arrangements with forwarders whose licenses have been revoked. Unless prior written approval from the Commission has been obtained, no licensee shall, directly or indirectly:

(1) Agree to perform forwarding services on export shipments as an associate, correspondent, officer, employee, agent, or sub-agent of any person whose license has been revoked or suspended pursuant to § 510.16 of this part;

(2) assist in the furtherance of any forwarding business of such person;

(3) share forwarding fees or freight compensation with any such person; or

(4) permit any such person directly or indirectly to participate, through ownership or otherwise, in the control or direction of the freight forwarding business of the licensee. 

(e) Arrangements with unauthorized persons. No licensee shall enter into an agreement or other arrangement (excluding sales agency arrangements not prohibited by law or this part) with an unlicensed person so that any resulting fee, compensation, or other benefit inures to the benefit of the unlicensed person. When a licensee is employed for the transaction of forwarding business by a person who is not the person responsible for paying the forwarding charges, the licensee shall also transmit to the person paying the forwarding charges a copy of its invoice for service rendered.

(f) False or fraudulent claims, false information. No licensee shall prepare or file or assist in the preparation or filing of any claim, affidavit, letter of indemnity, or other paper or document concerning a forwarding transaction which it has reason to believe is false or fraudulent, nor shall any such licensee knowingly impart to a principal, common carrier or other person, false
information relative to any forwarding transaction.

(g) Response to requests of Commissioner. Upon the request of any authorized representative of the Commission, a licensee shall make available promptly for inspection or reproduction all records and books of account in connection with its forwarding business, and shall respond promptly to any lawful inquiries by such representative.

(h) Policy against rebates. The following declaration shall appear on all invoices submitted to principals:

(Name of firm) has a policy against payment, solicitation, or receipt of any rebate, directly or indirectly, which would be unlawful under the United States Shipping Act of 1984.

§ 510.22 Forwarder and principal; fees.

(a) Compensation or fee sharing. No licensee shall share, directly or indirectly, any compensation or freight forwarding fee with a shipper, consignee, seller, or purchaser, or an agent, affiliate, or employee thereof; nor with any person advancing the purchase price of the property or guaranteeing payment therefor; nor with any person having a beneficial interest in the shipment.

(b) Withholding information. No licensee shall withhold any information concerning a forwarding transaction from its principal.

(c) Due diligence. Each licensee shall exercise due diligence to ascertain the accuracy of any information it imparts to a principal concerning any forwarding transaction.

(d) Errors and omissions. Each licensee shall comply with the laws of the United States and any involved State, Territory, or possession thereof, and shall assure that to the best of its knowledge there exists no error, misrepresentation in, or omission from, any export declaration, bill of lading, affidavit, or other document which the licensee executes in connection with a shipment. A licensee who has reason to believe that its principal has not, with respect to a shipment to be handled by such licensee, complied with the laws of the United States or any State, Commonwealth or Territory thereof, or has made any error or misrepresentation in, or omission from, any export declaration, bill of lading, affidavit, or other paper which the principal executes in connection with such shipment, shall advise its principal promptly of the suspected noncompliance, error, misrepresentation or omission, and shall decline to participate in any transaction involving such document until the matter is properly and lawfully resolved.

(e) Express written authority. No licensee shall endorse or negotiate any draft, check, or warrant drawn to the order of its principal without the express written authority of such principal.

(f) Receipt for cargo. Each receipt issued for cargo by a licensee shall be clearly identified as "Receipt for Cargo" and be readily distinguishable from a bill of lading.

(g) Invoices: documents available upon request. A licensee may charge its principal for services rendered. Upon request of its principal, each licensee shall provide a complete breakout of the components of its charges and a true copy of any underlying document or bill of charges pertaining to the licensee’s invoice. The following notice shall appear on each invoice to a principal:

Upon request, we shall provide a detailed breakout of the components of all charges assessed and a true copy of each pertinent document relating to these charges.

(h) Special contracts. To the extent that special arrangements or contracts are entered into by the licensee, the licensee shall not deny equal terms to other shippers similarly situated.

(i) Reduced forwarding fees. No licensee shall render, or offer to render, any freight forwarding service free of charge or at a reduced fee in consideration of receiving compensation from a common carrier or for any other reason. Exception: A licensee may perform freight forwarding services for recognized relief agencies or charitable organizations, which are designated as such in the tariff of the common carrier, free of charge or at reduced fees.

(j) Accounting to principal. Each licensee shall account to its principal(s) for overpayments, adjustments of charges, reductions in rates, insurance refunds, surplus monies received for claims, proceeds of c.o.d. shipments, drafts, letters of credit, and any other sums due such principal(s).

§ 510.23 Forwarder and carrier; compensation.

(a) Disclosure of principal. The identity of the shipper must always be disclosed in the shipper identification box on the bill of lading. The licensee’s name may appear after the name of the shipper, but the licensee must be identified as the shipper’s agent.

(b) Certification required for compensation. A common carrier may pay compensation to a licensee only pursuant to such common carrier’s tariff provisions. Where a common carrier’s tariff provides for the payment of compensation, such compensation shall be paid on any shipment forwarded on behalf of others where the licensee has provided a written certification as prescribed in § 510.23(c) of this part and the shipper has been disclosed on the bill of lading as provided for in § 510.23(a) of this part. A common carrier shall be entitled to rely on such certification unless it knows that the certification is incorrect. The common carrier shall retain such certification for a period of five (5) years.

(c) Form of certification. Where a licensee is entitled to compensation, the common carrier shall provide the common carrier with a signed certification which indicates that the licensee has performed the required services that entitle it to compensation. The certification shall read as follows:

The undersigned hereby certifies that neither it nor any holding company, subsidiary, affiliate, officer, director, agent or executive of the undersigned has a beneficial interest in this shipment; that it is the holder of valid FMC License No. ———, issued by the Federal Maritime Commission and has performed the following services:

1. Engaged, booked, secured, reserved, or contracted directly with the carrier or its agent for space aboard a vessel or confirmed the availability of that space; and

2. Prepared and processed the ocean bill of lading, dock receipt, or other similar document with respect to the shipment.

The required certification may be placed on one copy of the relevant bill of lading, a summary statement from the licensee, the licensee’s compensation invoice, or as an endorsement on the carrier’s compensation check. Each licensee shall retain evidence in its shipment files that the licensee, in fact, has performed the required services enumerated on the certification.

(d) Compensation pursuant to tariff provisions. No licensee, or employee thereof, shall accept compensation from a common carrier which is different than that specifically provided for in the carrier’s effective tariff(s) lawfully on file with the Commission. No conference or group of common carriers shall deny in the export commerce of the United States compensation to an ocean freight forwarder or limit that compensation to less than a reasonable amount.

(e) Compensation; services performed by underlying carrier; exceptions. No licensee shall charge or collect compensation in the event the underlying common carrier, or its agent, has, at the request of such licensee, performed any of the forwarding services set forth in § 510.2(h) unless such carrier or agent is also a licensee, or unless no other licensee is willing and able to perform such services.

(f) Duplicative compensation. A common carrier shall not pay compensation for the services described
in § 510.23(c) more than once on the same shipment.

(a) Licensed non-vessel-operating common carrier; compensation.

(1) A non-vessel-operating common carrier or person related thereto licensed under this part may collect compensation when, and only when, the following certification is made together with the certification required under paragraph (c) of this section:

The undersigned certifies that neither it nor any related person has issued a bill of lading or otherwise undertaken common carrier responsibility as a non-vessel-operating common carrier for the ocean transportation of the shipment covered by this bill of lading.

(2) Whenever a person acts in the capacity of a non-vessel-operating common carrier as to any shipment, such person shall not collect compensation, nor shall any underlying ocean common carrier pay compensation to such person for such shipment.

(b) A freight forwarder may not receive compensation from a common carrier with respect to any shipment in which the forwarder has a beneficial interest or with respect to any shipment in which any holding company, subsidiary, affiliate, officer, director, agent, or executive of such forwarder has a beneficial interest.

§ 510.24 Records required to be kept.

Each licensee shall maintain in an orderly and systematic manner, and keep current and correct, all records and books of account in connection with its business of forwarding. These records must be kept in the United States in such manner as to enable authorized Commission personnel to readily determine the licensee’s cash position, accounts receivable and accounts payable. The licensee must maintain the following records for a period of five years:

(a) General financial data. A current running account of all receipts and disbursements, accounts receivable and payable, and daily cash balances, supported by appropriate books of account, bank deposit slips, cancelled checks, and monthly reconciliation of bank statements.

(b) Types of services by shipment. A separate file shall be maintained for each shipment. Each file shall include a copy of each document prepared, processed, or obtained by the licensee, including each invoice for any service arranged by the licensee and performed by others, with respect to such shipment.

(c) Receipts and disbursements by shipment. A record of all sums received and/or disbursed by the licensee for services rendered and out-of-pocket expenses advanced in connection with each shipment, including specific dates and amounts.

(d) Special contracts. A true copy, or if oral, a true and complete memorandum, of every special arrangement or contract with a principal, or modification or cancellation thereof, to which it may be a party. Authorized Commission personnel and bona fide shippers shall have access to such records upon reasonable request.

§ 510.25 Anti-rebate certifications.

By March 1st of each year, the Chief Executive Officer of every licensee shall certify that it has a policy against rebates, that it has promulgated such policy and that it will cooperate with the Commission in any investigation of suspected rebates. This certification shall be in accordance with the following format:

(Name of Filing Firm)

Certification of Policies and Efforts to Combat Rebating in the Foreign Commerce of the United States

Pursuant to the provisions of section 15(b) of the Shipping Act of 1984, and Federal Maritime Commission regulations promulgated pursuant thereto, 46 CFR Parts 510 and 582,

1. , Chief Executive Officer of (name of firm), holder of valid ocean freight forwarder license # , state under oath that:

   1. It is the policy of (name of firm) to prohibit the participation of any freight forwarder in the payment, solicitation, or receipt of any rebate, directly or indirectly, to or by any carrier shipper, which is unlawful under the provisions of the Shipping Act of 1984.

   2. Each owner, officer, employee and agent of (name and firm) was notified or reminded of this policy on or before of the present year.

   3. (Set forth the details of measures instituted within the filing firm or otherwise to prohibit participation in the payment of illegal rebates in the foreign commerce of the United States.)

4. (Name of firm) affirms that it will fully cooperate with the Commission in its investigation of suspected rebating in United States foreign trades.

Signature

Subscribed to and sworn before me this day of , 19.

Notary Public

$ § 510.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

This section displays the control numbers assigned to information collection requirements of the Commission in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511. The Commission intends that this part comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which requires that agencies display a current control number assigned by the Director of the Office of Management and Budget (OMB) for each agency information collection requirement:

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<th>Section</th>
<th>Current OMB control No.</th>
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<tbody>
<tr>
<td>510.12 (Form FMC-18)</td>
<td>3072-0018</td>
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<tr>
<td>510.14</td>
<td>3072-0018</td>
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<tr>
<td>510.15</td>
<td>3072-0018</td>
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<tr>
<td>510.19 (Form FMC-18)</td>
<td>3072-0018</td>
</tr>
<tr>
<td>510.21 through 510.25</td>
<td>3072-0018</td>
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By the Commission.

Francis C. Hanvey, Secretary.

[FR Doc. 84-35122 Filed 9-13-84; 8:45 am]
BILLING CODE 6730-01-M

46 CFR Parts 515, 520, 525, 530, and 540

[Docket No. 84–18]

The Shipping Act of 1984; Final Rules for Marine Terminal Operations and Passenger Vessels

AGENCY: Federal Maritime Commission.

ACTION: Final rules.

SUMMARY: On March 20, 1984, the President signed the Shipping Act of 1984, which became effective on June 18, 1984. The Commission hereby issues final rules to supersede previously issued interim rules to implement the Shipping Act of 1984. In addition, minor style and technical changes have been made. The parts which are included in this rulemaking are: Part 515 (filing of tariffs by marine terminal operators—old part 533); Part 520 (filing of tariffs by terminal barge operators in Pacific Slope States—old part 550); Part 525 (free time and demurrage—old part 536); Part 530 (truck detention at New York—old part 551); and Part 540 (security for the protection of the public on passenger vessels). Along with the final rule on Part 510 (Ocean Freight Forwarders), published separately, all of Subchapter B is now final.

The Interim Rules published on May 3, 1984, generated only two comments: one from the Maryland Port Administration which endorsed the language modifications to Part 515, “Filing of Tariffs by Terminal Operators”; and the other from the National Maritime Council which had no further comment other than recognizing that the Interim Rules were required for technical compliance with the 1984 Act. The Commission, therefore, sees no need to make any substantive changes in any of the Interim Rules, and is publishing them as final, superseding rules in this proceeding in their entirety.

In preparing the various parts for publication, certain other non-substantive changes suggested themselves. Most of such minor changes made here involve style (e.g., for OMB Control Numbers or exemptions under the Paperwork Reduction Act; changing “provided, however” to “except”; elimination of gender specific references, etc.); grammatical corrections, puncturing, correction of typographical errors, and removal of superfluous verbiage—all without affecting substance.

In addition, we are restoring to the “Authority Citation” in old Part 550 (new Part 520), reference to Sec. 3 of the Shipping Act, 1916 (46 U.S.C. app. 804); we are deleting obsolete, effective-date provisions appearing in (old) §§ 553.4 and 540.4(b); a new map of the New York Port District is being provided for (new) Part 530, and we think a more descriptive nomenclature is “Marine Terminal Operators” instead of merely “Terminal Operators.”

The Federal Maritime Commission has determined that this rule is not a "major rule" as defined in Executive Order 12291 dated February 17, 1981, because it will not result in:

(1) An annual effect on the economy of $100 million or more;
(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
(3) Significant adverse effects on competition, employment, investment, productivity, innovations, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Chairman of the Federal Maritime Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities, including small businesses, small organizational units and small governmental jurisdictions.

List of Subjects
46 CFR Parts 515, 520, 525, and 530
Barges, Cargo, Cargo vessels, Harbors, Imports, Maritime carriers, Motor carriers, Ports, Rates and fares, Reporting and recordkeeping requirements, Trucks, Water carriers, Waterfront facilities, Water transportation.

46 CFR Part 540
Rates and fares, Passenger vessels, Reporting and recordkeeping requirements, Surety bonds.

Corrections
These final rules are subject to review and editing of form before publication in the Code of Federal Regulations. Users are requested to notify the Commission of any omissions and typographical-type errors in order that corrections can be made before the Commission’s CFR book goes to press in January, 1985.


1. The Title to Subchapter B is revised to read as follows:

SUBCHAPTER B—REGULATIONS AFFECTING OCEAN FREIGHT FORWARDERS, MARINE TERMINAL OPERATIONS AND PASSENGER VESSELS

2. Title 46 Code of Federal Regulations, Parts 515, 520, 525, 530, and 540 are revised to read as follows:

PART 515—FILING OF TARIFFS BY MARINE TERMINAL OPERATORS

Sec. 515.1 Scope.
515.2 Purpose.
515.3 Persons who must file.
515.4 Filing of tariffs and tariff changes.
515.5 Compliance with this part and other terminal tariff filing requirements.
515.6 Definitions.

§ 515.1 Scope.

This part sets forth rules and regulations for the filing of terminal tariffs by persons engaged in carrying on the business of furnishing wharfage, dock, warehouse or other terminal facilities within the United States or a
commonwealth, territory, or possession thereof, in connection with a common carrier by water in the foreign or domestic offshore commerce of the United States.

§ 515.2 Purpose.
The purpose of this part is to enable the Commission to discharge its responsibilities under section 17 of the Shipping Act, 1916 and section 10 of the Shipping Act of 1984, by keeping the public informed of practices, rates and charges related thereto, instituted and to be instituted by marine terminals, and by keeping the public informed of such practices. Compliance is mandatory and failure to file the required tariffs may result in a penalty of not more than $5,000 for each day such violation continues. Additionally, if willful and knowing, the Shipping Act of 1984 provides a civil penalty of not more than $25,000 for each day a violation continues.

§ 515.3 Persons who must file.
Except with regard to bulk cargo, forest products, recycled metal scrap, waste paper, and paper waste, every person other than the Department of Defense (including the military department and all agencies of the Department of Defense), carrying on the business of furnishing wharfage, dock, warehouse, or other terminal facilities as described in § 515.1, including, but not limited to terminals owned or operated by States and their political subdivisions; railroads who perform port terminal services not covered by their line haul rates; common carriers who perform port terminal services; and warehousemen who operate port terminal facilities, shall file in duplicate with the Bureau of Tariffs, Federal Maritime Commission, and shall keep open for inspection at all its places of business, a schedule or tariff showing all its rates, charges, rules, and regulations relating to or connected with the receiving, handling, storing, and/or delivering of property at its terminal facilities, except that rates and charges for terminal services performed for water carriers pursuant to negotiated contracts, and for storage of cargo and services incidental thereto by public warehousemen pursuant to storage agreements covered by issued warehouse receipts need not be filed for purposes of this part.

§ 515.4 Filing of tariffs and tariff changes.
Every tariff or tariff change shall be filed on or before its effective date, except as required by Commission Order or by agreements approved pursuant to section 15 of the Shipping Act, 1916 and/or effective under section 6 of the Shipping Act of 1984, and be kept open for public inspection as provided in § 515.3.

§ 515.5 Compliance with this part and other terminal tariff filing requirements.
Persons who file tariffs pursuant to requirements of Commission Orders or agreements, approved under section 15 of the Shipping Act, 1916 and/or effective under section 6 of the Shipping Act of 1984, shall not be relieved of such requirements by this part. Marine Terminal Operators who file tariffs with the Interstate Commerce Commission pursuant to statute or rule of that Commission may satisfy the requirements of this part of filing with the Federal Maritime Commission a copy of any such tariff filed with the Interstate Commerce Commission.

§ 515.6 Definitions.
(a) The definitions of terminal services set forth in paragraph (d) of this section shall be set forth in tariffs filed pursuant to this part except that other definitions of terminal services may be used if they are correlated by footnote or other appropriate method to the definitions set forth herein. Any additional services which are offered shall be listed and charges therefor shall be shown in terminal tariffs.

(b) These definitions shall apply to “port terminal facilities” which are defined as one or more structures comprising a terminal unit, and include, but are not limited to wharves, warehouses, covered and/or open storage spaces, cold storage plants, grain elevators and/or bulk cargo loading and/or unloading structures, landings, and receiving stations, used for the transmission, care and convenience of cargo and/or passengers in the interchange of same between land and water carriers or between two water carriers.

(c) For the purpose of this section, “point of rest” means that area on the terminal property between any place on the terminal and railroad cars, trucks, lighters or barges or any other means of conveyance to or from the terminal facility.

(d) Definitions of terminal services—
(1) Dockage means the charge assessed against a vessel for berthing at a wharf, pier, bulkhead structure, or bank or for mooring to a vessel so berthed.
(2) Wharfage means a charge assessed against the cargo or vessel on all cargo passing or conveyed over, onto, or under wharves or between vessels (to or from barge, lighter, or water), when berthed at wharf or when moored in slip adjacent to wharf. Wharfage is solely the charge for use of wharf and does not include charges for any other service.
(3) Free time means the specified period during which cargo may occupy space assigned to it on terminal property free of wharf demurrage or terminal storage charges immediately prior to the unloading or subsequent to the discharge of such cargo on or off the vessel.
(4) Wharf demurrage means a charge assessed against cargo remaining in or on terminal facilities after the expiration of free time unless arrangements have been made for storage.
(5) Terminal storage means the service of providing warehouse or other terminal facilities for the storage of inbound or outbound cargo after the expiration of free time, including wharf storage, shipside storage, closed or covered storage, open or ground storage, bonded storage and refrigerated storage, after storage arrangements have been made.
(6) Handling means the service of physically moving cargo between point of rest and any place on the terminal facility, other than the end of ship’s tackle.
(7) Loading and unloading means the service of loading or unloading cargo between any place on the terminal and railroad cars, trucks, lighters or barges or any other means of conveyance to or from the terminal facility.
(8) Usage means the use of terminal facility by any rail carrier, lighter operator, trucker, shipper or consignee, its agents, servants, and/or employees, whether it performs line haul service, lighter service, or truck loading or unloading, or the use of said facilities for any other gainful purpose for which a charge is not otherwise specified.
(9) Checking means the service of counting and checking cargo against appropriate documents for the account of the cargo or the vessel, or other person requesting same.
(10) Heavy lift means the service of providing heavy lift cranes and equipment for lifting cargo.

§ 515.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.
This section displays the control numbers assigned to information collection requirements of the Commission in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96-511. The Commission intends that this section comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which
PART 520—FILING OF TARIFFS BY TERMINAL BARGE OPERATORS IN PACIFIC SLOPE STATES

§ 520.1 Scope.

(a) The rules and regulations set forth in this part cover the filing of tariffs by terminal barge operators in Pacific Slope States in the foreign and domestic commerce of the United States.

(b) Terminal barge operators moving containers or containerized cargo by barge between points in the Continental United States shall file a schedule of their rates, charges and services solely with the Federal Maritime Commission where:

(1) The cargo is moving between a point in a foreign country or a noncontiguous State, territory, or possession and a point in the United States.

(2) The transportation by barge between points in the United States is furnished by a terminal operator as a substitute in lieu of a direct vessel call by the common carrier by water transporting the containers or containerized cargo under a through bill of lading.

(3) Such terminal operator is a Pacific Slope State municipality, or other public body or agency subject to the jurisdiction of the Federal Maritime Commission, and the only one furnishing the particular circumscribed barge service on January 2, 1975.

(c) Such terminal operator is in compliance with the rules and regulations of the Federal Maritime Commission for the operation of such barge service.

(d) The terminal operator providing such service shall be subject to the provisions of the Shipping Act, 1916 and/or the Shipping Act of 1984.

§ 520.2 Tariff filing requirements.

(a) Terminal barge operators subject to this part shall comply with the tariff filing requirements of Part 550 of this Chapter with respect to the publication of rates, charges, and services for cargo moving in the foreign and/or domestic offshore commerce of the United States.

(b) Terminal barge operators, while exempt from the tariff filing form requirements of Part 550 of this Chapter with respect to their operations as water carriers carrying cargo in the domestic offshore trades, shall comply with all other required regulations, where applicable.

(c) Tariff(s) filed pursuant to § 520.2(a) shall specifically provide that the rates charged are based upon factors normally considered by a regular commercial operator in the same service.

Note.—In accordance with 44 U.S.C. 3500(c)(5), any information request or requirement in this part is not subject to the requirements of section 3507(f) of the Paperwork Reduction Act, because there are nine or fewer respondents.

(d) Where a consignee is prevented from removing its cargo by factors beyond its control (such as, but not limited to, longshoremen's strikes, trucking strikes or weather conditions) which affect an entire port area or a substantial portion thereof, and when a consignee is prevented from removing its cargo by a longshoremen's strike which affects only one pier or less than a substantial portion of the port area, carriers shall (after expiration of free time) assess demurrage against imports at the rate applicable to the first demurrage period, for such time as the inability to remove the cargo may continue. Every departure from the regular demurrage charges shall be reported to the Commission.

(e) The Commission makes no finding approving or disapproving demurrage rates presently effective as to import property at the port of New York.

(f) Following a longshoremen's strike of five (5) days or more:

(1) Free time shall be extended for a period not less than five (5) days (exclusive of Saturdays, Sundays, and legal holidays) beyond the time at which it would normally terminate, for cargo which was in a free time period at the commencement of the longshoremen's strike.

(2) First period demurrage shall be extended for a period not less than five (5) calendar days beyond the time at which it would normally terminate, for cargo which was subject to first period demurrage at the commencement of the longshoremen's strike.

(g) The extensions set forth in paragraphs (f)(1) and (f)(2) of this section, shall apply only: (1) If the cargo is actually picked up within such extended time or (2) If, pursuant to an appointment system adopted by both carriers and consignees, cargo is picked up within twenty-four (24) hours of advance notification that cargo is available for pickup and readily accessible, in which latter event, time shall not be extended more than twenty-four (24) hours beyond the additional free time or demurrage period.

Note.—In accordance with 44 U.S.C. 3500(c)(5), any information request or requirement in this part is not subject to the requirements of section 3507(f) of the Paperwork Reduction Act, because there are nine or fewer respondents.

§ 525.1 Free time and demurrage charges at the Port of New York.

(a) Free time of five days (exclusive of Saturdays, Sundays, and legal holidays), computed from the start of business on the first day after complete discharge of the vessel, is adequate free time on import property at New York under present conditions.

(b) Free time on import property at New York shall not be less than five days, except on property of such a special nature as to require earlier removal because of local ordinances or other governmental regulations, or because piers are not equipped to care for such property for such period, or except as the Commission may hereafter direct.

(c) Except as provided in §§ 530.3(e)(2), 530.4(e) and 530.4(g) of this Chapter, where a carrier is for any reason, unable, or refuses, to tender cargo for delivery during free time, free time must be extended for a period equal to the duration of the carrier's disability or refusal. If such condition arises after the expiration of free time, either no demurrage or first period demurrage, whichever is specified in the appropriate tariff, will be charged for a period equal to the duration of the carrier's inability or refusal.
PART 530—TRUCK DETENTION AT THE PORT OF NEW YORK

Sec.
530.1 General provisions.
530.2 Documentation.
530.3 Terminals operating on appointment system.
530.4 Terminals operating a non-appointment system.
530.5 Combination non-appointment/appointment system.
530.6 Computation of time.
530.7 Penalties.
530.8 Submission of claims for penalties.
530.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

Appendix A—New York/New Jersey Port District

§ 530.1 General provisions.
(a) The Port of New York is that area designated as "The Port District" on the map [Appendix A].
(b) For purposes of this part, a terminal operator is any person who receives cargo from motor carriers and/or delivers cargo to motor carriers in connection with transportation by common carrier by water, excluding persons who operate marine terminal facilities controlled by the Department of Defense including the military department and all agencies of the Department of Defense.
(c) Motor carriers (common, contract, or private), terminal operators, including steamship companies acting as terminal operators, and steamship companies whose action or inaction otherwise impedes expedient pickup and delivery of cargo by motor carriers at marine terminal facilities within the Port of New York, shall be subject to the provisions established by terminal operators in accordance with this part, which provisions shall be reflected in the tariff of each such terminal operator.
(d) Importers and exporters, or motor carriers or other agents of importers or exporters, and terminal operators at marine terminal facilities in the Port of New York shall identify itself to the Federal Maritime Commission not more than 10 days after the effective date of this part and shall thereafter promptly notify the Commission of any change in responsibility. Based thereon, the Federal Maritime Commission (Commission) will publish and maintain a current list identifying, as to each such marine terminal facility, the party responsible for receipt and settlement of claims arising under this part.
(f) All communications to the Federal Maritime Commission required by this part shall be directed to the Federal Maritime Commission, Office of the Secretary, 1100 L Street NW., Washington, D.C. 20573.
(g)(1) Except as provided in paragraph (g)(2) of this section, no penalty shall be imposed upon a terminal operator under this part if receipt or delivery of cargo at a marine terminal facility is prevented or delayed by strike or work stoppage, act of God, fire, serious accident, or severe or unusual weather condition. The Commission shall be notified in writing by the party claiming the existence of the condition who shall specify the date and time of commencement and termination of any such strike, work stoppage, or severe or unusual weather or other condition.
(2) No terminal operator shall be absolved from liability under this part for delays resulting from inadequate or insufficient labor, and/or equipment, other than reasonable delays necessary to obtain special equipment required for handling unusual cargo on a non-appointment basis.
(h) Terminal operators shall not be liable for delays due to United States Government regulations; nor shall terminal operators be liable for time consumed by receipt or delivery of cargo by marks other than by bill of lading, provided at the request of the shipper, consignee or motor carrier.
(i) Steamship companies responsible for house-to-house movement of containers, i.e., containers moving as a unit from origin to destination, are responsible under this part for delay occasioned by lack of sufficient chassis, or unavailability, action or inaction of their container inspection personnel. For purposes of this part, "containers" shall include empty as well as stuffed containers.
(j) Disputes concerning liability under any provisions of this part shall be settled by an impartial Adjudicator selected by the Commission.
(k) Terminal operators are not required to deliver cargo to motor carriers prior to the time that the ocean vessel which transported said cargo is fully discharged. If a terminal operator exercises the option of delivering cargo to motor carriers prior to the time that the ocean carrier which transported said cargo is fully discharged, the terminal operator shall notify the consignee or its designated agent that the cargo is on the pier, at its place of rest, and segregated by bill of lading, and shall identify the terminal operator employee giving such notification.
(l) Marine terminal facilities in the Port of New York shall be operated in accordance with the appointment, non-appointment, or combination appointment/non-appointment procedures established by the terminal operator in accordance with this part. Each terminal operator shall identify in its respective tariff whether its marine terminal facility will be operated on an appointment, non-appointment, or combination appointment basis. Said tariff shall incorporate the specific procedures applicable at each such marine terminal facility, which procedures shall comply with the provisions of this part, be prominently displayed at the marine facility, and shall be modified on not less than 30 days' notice.

§ 530.2 Documentation.
(a)(1) Delivery orders shall not be mailed or delivered to terminal operators, nor mailed or delivered to steamship companies for receipt on behalf of terminal operators, prior to arrival of motor carrier vehicles at marine terminal facilities. Dock receipts may be lodged with terminal operators or steamship companies for receipt on behalf of terminal operators prior to arrival of motor carrier vehicles at marine terminal facilities. Upon arrival at marine terminal facilities, motor carrier vehicle operators shall have physical possession of delivery orders required by this part, and shall either have physical possession of dock receipts required by this part or shall have had said dock receipts lodged with the terminal operator or steamship company in accordance with the above-described procedure. Motor carrier vehicles having physical possession of delivery orders or dock receipts immediately shall be issued a sequentially numbered and time-stamped gate pass by order of arrival. When dock receipts are lodged with the terminal operator or steamship company, the sequentially numbered and time-stamped gate pass immediately shall be issued upon tender of the dock receipt to the gate man by the motor carrier vehicle driver. The sequential number and all time stamps and notations recorded on the gate pass and any other arrival document shall be recorded on the copy of the delivery
order or dock receipt retained by the motor carrier. Motor carrier vehicles not complying with the requirements of this paragraph shall be denied entry to the marine terminal facility.

(2) Motor carriers shall be permitted to receive cargo on Open Delivery Orders, i.e., single delivery orders covering multiple truckloads or shipments, and deliver cargo on Open Dock Receipts, i.e., single dock receipts covering multiple truckloads or shipments, upon presenting to the terminal operator, subsequent to receipt or delivery of the initial load, satisfactory evidence of authorization to effect receipt or delivery of the remaining truckloads or shipments, as established by the terminal operator and published in its tariff.

(b) Dock receipts required as full and complete documentation for receipt of export cargo shall include the following information:

(1) Name of the motor carrier.
(2) Name of forwarding agent. (If none, insert “none”.)
(3) Shipper.
(4) Name of vessel.
(5) Pier, berth, or area designated for receipt of cargo.
(6) Date of discharge.
(7) Container identification and seal number. (On full container loads.)
(8) Booking number.
(9) Cargo to be held on dock should be so indicated in space provided for vessel name.
(10) Marks, number of packages, commodity, cube and weight.
(11) An original and three copies of the dock receipt authorized by the terminal operator, or service is refused; or, at the request of said motor carrier, the terminal operator may correct or reject the deficient document, if any.

(c) Delivery order required as full and complete documentation for the delivery of import cargo shall provide the following information:

(1) Name and address of party issuing delivery order.
(2) Address of terminal.
(3) Name and address of motor carrier making pickup.
(4) Vessel name.
(5) Voyage number or estimated date of arrival.
(6) Number Lading number.
(7) Port of Lading.
(8) City of destination. (On full container loads.)
(9) Container identification number. (On full container loads.)
(10) Booking number. (On receipt of empty containers.)
(11) Marks, number of packages, commodity, cube and weight. When partial lots are to be delivered, they should be identified by marks.
(12) Date free time expires.
(13) Date through which demurrage is paid/guaranteed after free time has expired.
(14) An original and two copies of the delivery order, the original legibly signed in ink, with the name of the signer typed below the signature, shall be tendered to the terminal operator, one copy of which shall be returned to and retained by the motor carrier in accordance with § 530.2(a)(1).

(d) (1) Terminal operators shall not honor delivery orders with strikeouts or other changes to the original.
(2) If a motor carrier named in an original delivery order substitutes another motor carrier in its place, the motor carrier named in the original delivery order shall provide a turnover order to the second carrier containing all information required by the original delivery order. Both the original delivery order and the turnover order must be presented to the terminal operator by the motor carrier requesting delivery of cargo. Upon written request, in accordance with procedures established by the terminal operator and published in its tariff, special arrangements may be made to accommodate general agency situations.

(e) If a motor carrier presents documents to the terminal operator which do not contain all information required by this part, or which are complete but contain inaccurate information, said motor carrier shall be required to surrender its gate pass and shall be denied service; or, at the request of said motor carrier, the terminal operator may correct or complete the deficient document and service said motor carrier in accordance with this part.

(f) If documents are rejected by the terminal operator, or service is refused for any other reason, the terminal operator shall provide the motor carrier written explanation, time-stamped, of the deficiencies in documentation or other reason(s) for refusal of service, and shall attach thereto a copy of the deficient document, if any.

(g) Section 530.2(e) shall not be applicable if documents are incorrect because of substitution of one vessel for another, redocking of a vessel from a scheduled pier to another, or change in consignment of an export shipment from a scheduled vessel to another due to an early closeout of the scheduled vessel or other such rescheduling for the convenience of the steamship company or terminal operator. Delay occasioned in such circumstances shall be included in the computation of time for purposes of this rule and chargeable to the party responsible for such change.

§ 530.3 Terminals operating on appointment system.

Subject to the following provisions of this section, terminal operators shall establish the basis upon which appointments will be available and shall publish in their tariffs reasonable methods and procedures for booking appointments.

(a) (1) Except for good cause, all requests for appointments shall be granted. If a request for an appointment is not granted, the terminal operator shall record the request and reason for refusal.
(2) Appointments, when granted, shall be identified by sequentially assigned numbers. The terminal operator shall record the date and time of requests for appointments, the name of the person making the request, the number and identification number of scheduled appointments; and shall identify the terminal operator employee granting the appointment.

(b) Appointments to receive delivery of cargo shall not be granted by terminal operators unless and until a freight release covering subject cargo has been provided by the steamship company. Appointments shall be granted only if the terminal operator is advised of the nature, type and quantity of cargo to be delivered or received. If, because of the size, weight or shape of the cargo, special equipment is required, the terminal operator shall so advise the motor carrier at the time the appointment is granted, and the motor carrier shall advise the terminal operator of the type of “rolling stock” which it will employ to effectuate the interchange of cargo.

(c) (1) Gate passes shall be issued to motor carriers by order of arrival at the marine terminal facility. Motor carriers arriving after the time of a scheduled appointment shall be deemed to have missed the appointment and may be denied service.
(2) Except where a terminal operator has arranged for delivery of cargo on the last day of free time, or on the first or second day of demurrage, in accordance with paragraph (c)(2) of this section, motor carriers may cancel appointments (without penalty), provided the terminal operator is given three (3) working hours' notice of said cancellation.

(d) (1) Upon receipt of a gate pass issued pursuant to paragraph (c)(1) of this section, motor carrier personnel holding dock receipts or other satisfactory evidence of authorization to effect delivery or cargo shall proceed...
immediately to the receiving clerk of the terminal operator who shall immediately time-stamp the gate pass upon presentation of documents. After said documents are determined to be in proper order, the motor carrier shall be routed for unloading.

(2) Upon receipt of a gate pass issued pursuant to paragraph (c)(1) of this section, motor carrier personnel holding delivery orders or other satisfactory evidence of authorization to receive delivery of cargo shall proceed to the Bureau of Customs for completion of required procedures, and thereafter, shall immediately proceed to the delivery clerk of the terminal operator who shall immediately time-stamp the gate pass upon presentation of documents. After said documents are determined to be in proper order, the motor carrier shall be routed for loading.

(e)(1) See §525.1(c) of this chapter for provisions regarding extension of free time.

(2) At full-appointed terminals, if an appointment is not available as requested, an appointment shall be granted within 72 hours (three business days) of said request, except as provided by paragraphs (e)(2)(i) and (e)(2)(ii) of this section.

(i) Cargo permitted 5 days free time—Extension of free time. (A) If an appointment is requested at least 48 hours prior to the expiration of free time, the terminal operator shall arrange to deliver cargo prior to expiration of free time, or extend free time until an appointment is granted.

(B) If an appointment is requested less than 48 hours prior to expiration of free time, the motor carrier shall arrange for delivery of cargo prior to expiration of time, or suspend collection of demurrage charges for one day as to cargo already on demurrage, or extend free time until an appointment is granted.

(c) If a motor carrier attempts to make an appointment at a facility operating a combination system, and no appointment is available, and then said motor carrier seeks service as a non-appointment vehicle, said motor carrier shall be treated as a non-appointment vehicle for purposes of extension of free time.

§530.5 Combination non-appointment/appointment system.

(a) An express line or non-appointment line may be established in conjunction with an appointment system in such a manner as the terminal operator determines best suits the needs of the particular facility.

(b) All rules applicable to non-appointment facilities (§530.4) shall be applicable to the non-appointment portion of a combination non-appointment/appointment terminal operation.

(c) If a motor carrier attempts to make an appointment at a facility operating a combination system, and no appointment is available, and then said motor carrier seeks service as a non-appointment vehicle, said motor carrier shall be treated as a non-appointment vehicle for purposes of extension of free time.

§530.6 Computation of time.

(a) Validation time is: (1) Time of issuance of a gate pass upon a motor
carrier's arrival at a marine terminal facility or (2) if, upon arrival, a motor carrier is scheduled for a later service period, the time of commencement of that scheduled service period, or (3) if a motor carrier is issued a preference slip pursuant to §530.4(e) or §530.4(f), the time scheduled thereon.

(b) Time for purposes of this part shall accrue from validation or appointment time. Delay demonstrated by the terminal operator to be due to United States Government regulations, action or inaction of motor carrier personnel, or other such cause, shall be excluded from computation of time. Time elapsed, if any, between appointment or validation time and presentation of documents to the delivery or receiving clerk shall be presumed to be due to such cause.

§ 530.7 Penalties.

(a) A terminal operator who refuses to serve a motor carrier after rejecting, for lack of full and complete documentation, a delivery order or dock receipt which does contain the information required by this part, shall be subject to a penalty of $30.

(b) If a motor carrier fails to meet a scheduled appointment at a marine terminal facility, said motor carrier shall be subject to a charge of $15. If, pursuant to §530.3(b) a motor carrier is advised that special equipment will be required and the motor carrier fails to meet said appointment, the motor carrier shall be subject to a charge of $30.

(c) If, pursuant to §530.2(e), a terminal operator completes or corrects deficient documents presented by a motor carrier, a charge of $15 shall be assessed against said motor carrier.

(d) If, contrary to §530.3(b) a freight release covering subject cargo has not been authorized prior to a scheduled appointment, the terminal operator that granted said appointment shall be assessed a penalty of $30.

(e) If, pursuant to §530.1(k) or a request under §530.4(f) a terminal operator notifies a motor carrier that cargo is not on the pier, at its place of rest, and segregated by bill of lading, and cargo is not on the pier, at its place of rest, and segregated by bill of lading, when the motor carrier attempts to obtain said cargo, the terminal operator shall be subject to a penalty of $30.

(f) Time allowances—(1) Containers handled as a single unit. If service is not completed within the following times, penalty charges will accrue against the terminal operator at a rate or $4 per 15 minutes, or any fraction thereof, in excess of these times.

Appointment .................................. 75 minutes.
Non-appointment .............................. 120 minutes.

(2) Non-containerized cargo. When vehicles are loaded by the terminal operator, or unloaded by the terminal operator at the request of the motor carrier, within the time periods set forth below, there will be no penalty. If a vehicle is not loaded or unloaded within the following time periods, penalty charges will accrue against the terminal operator at a rate of $4.00 per 15 minutes, or any fraction thereof, in excess of these times.

(i) Non-Appointment Vehicles:
0 to 5,000 pounds .................................. 210 minutes.
5,001 to 10,000 pounds .......................... 240 minutes.
10,001 to 15,000 pounds ....................... 270 minutes.
15,001 to 20,000 pounds ...................... 210 minutes.
20,001 to 25,000 pounds ...................... 240 minutes.
Over 25,000 pounds ................................ 270 minutes.

(ii) Appointment Vehicles:
2,000 pounds or less .................................. 90 minutes.
2,001 to 5,000 pounds ............................ 120 minutes.
5,001 to 10,000 pounds .......................... 150 minutes.
10,001 to 15,000 pounds ....................... 180 minutes.
15,001 to 20,000 pounds ...................... 210 minutes.
20,001 to 25,000 pounds ...................... 240 minutes.
Over 25,000 pounds .................................. 270 minutes.

(g) When freight is unloaded by the driver or other personnel of the motor carrier and unloading is not completed within the times prescribed by paragraph (f) of this section, as computed from the time that the vehicle is spotted at a place convenient for unloading, the terminal operator shall be entitled to a penalty payment of $4 for each 15 minute period or any fraction thereof in excess of the specified time, unless the delay is demonstrated by the motor carrier to have been occasioned by the action or inaction of the terminal operator.

(h) A motor carrier admitted to a marine terminal facility for loading or unloading—or holding an appointment for loading or unloading—shall be completely loaded or unloaded prior to the close of that business day. If the motor carrier is not completely loaded or unloaded when the terminal closes on that business day, time for purposes of this part shall accrue only while the terminal is conducting operations. In addition:

(1) Motor carriers holding appointments shall be entitled to a penalty payment of $30 from the terminal operator whether the shutout of the vehicle was due to refusal of management to authorize overtime, or labor’s refusal to work overtime.

(2) Non-appointment vehicles shall be entitled to a penalty payment of $30 from the terminal operator if the shutout of the vehicle was due to refusal of management to authorize overtime. If the shutout results from labor’s refusal to work overtime, the terminal operator shall not be subject to a penalty.

(3) Management shall be presumed to have refused to authorize overtime, unless the terminal operator establishes otherwise.

§ 530.8 Submission of claims for penalties.

(a) All communication required by this section shall be via certified mail; return receipt requested.

(b) Any person claiming payments under this section shall file a written claim with the terminal operator or motor carrier against whom said claim is made.

(c)(1) Claims shall be filed within forty-five (45) calendar days from the date on which the claim arose or said claim shall be barred. The party against whom claim is made shall submit within (20) calendar days from receipt of said claim payment thereon or reject. In rejecting a claim, the terminal operator or motor carrier shall set forth the reason or reasons for said rejection and shall provide available documentation substantiating said rejection. Claims rejected because they do not contain sufficient information may be resubmitted no later than twenty (20) days from receipt of rejection.

(2) Rejected claims may be submitted for review within twenty (20) days of receipt of rejection to the Adjudicator who will affirm or reverse the rejection of claims within 30 days of receipt of the request for review. All decisions of the Adjudicator shall be final and binding.

(d)(1) Claims submitted by motor carriers, or importers or exporters on whose behalf motor carriers act, shall include the motor carrier’s copy of the applicable delivery order or dock receipt, any other relevant document, a brief, but complete description of the facts giving rise to the claim, and a statement of the amount claimed.

(2) Claims filed by terminal operators shall include the terminal operator’s copy of the applicable delivery order or dock receipt, a copy of the gate pass and any other arrival documents issued, copies of all other relevant documents, a brief explanation of the facts giving rise to the claim, and a statement of the amount claimed.

(e)(1) If the party identified as the terminal operator at a marine terminal facility under §530.1(e) rejects a claim pursuant to §530.1(1) or §530.2(g), or otherwise denies a claim on the ground that the delay was caused by the steamship company, the original claim and a statement of the reasons for rejection shall be forwarded within seven days to the steamship company alleged by the terminal operator to be liable for the claim, copy to the claimant.
[2] The steamship company shall pay or reject the claim within twenty (20) calendar days from receipt thereof.

(3) If the claim is rejected by the steamship company, the claimant may submit both rejections to the Adjudicator who shall review the rejection of the claim by both parties and determine liability as between the two.

§ 530.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

This section displays the control numbers assigned to information collection requirements of the Commission in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96-511. The Commission intends that this section comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which requires that agencies display a current control number assigned by the Director of the Office of Management and Budget (OMB) for each agency information collection requirement:

<table>
<thead>
<tr>
<th>Section</th>
<th>OMB control No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>530.1 through 530.3</td>
<td>3072-0010</td>
</tr>
<tr>
<td>530.8</td>
<td>3072-0010</td>
</tr>
</tbody>
</table>

BILLING CODE 470-01-M
Appendix A to 46 CFR
Part 530

(From 1981 "New York Port Handbook")

New York/New Jersey Port District

PORT DISTRICT BOUNDARY LINE

BILLING CODE 6730-01-C
PART 540—SECURITY FOR THE PROTECTION OF THE PUBLIC


Sec. 540.1 Scope.

(a) The regulations contained in this subpart set forth the procedures whereby persons in the United States who arrange, offer, advertise or provide passage on a vessel having berth or stateroom accommodations for 50 or more passengers and embarking passengers at U.S. ports shall establish their financial responsibility or, in lieu thereof, file a bond or other security for obligations under the terms of ticket contracts to indemnify passengers for nonperformance of transportation to which they would be entitled. Included also are the qualifications required by the Commission for issuance of a Certificate (Performance) and the basis for the denial, revocation, modification, or suspension of such Certificates.

(b) Failure to comply with this part may result in denial of an application for a certificate. Vessels operating without the proper certificate may be denied clearance and their owners may also be subject to a civil penalty of not more than $5,000 in addition to a civil penalty of $200 for each passage sold, such penalties to be assessed by the Federal Maritime Commission (46 U.S.C. app. 91, 817d and 817e).

§ 540.2 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) Person includes individuals, corporations, partnerships, associations, and other legal entities existing under or pursuant to the Paperwork Reduction Act.

(b) Vessel means any commercial vessel having berth or stateroom accommodations for 50 or more passengers and embarking passengers at U.S. ports.

(c) Commission means the Federal Maritime Commission.

(d) United States includes the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States, or the laws of any foreign country.

Subpart B—Proof of Financial Responsibility, Bonding and Certification of Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages

Sec. 540.23 Procedure for establishing financial responsibility.

540.24 Insurance, surety bonds, self-insurance, guarantees, and escrow accounts.

540.25 Evidence of financial responsibility.

540.26 Denial, revocation, suspension, or modification.

540.27 Miscellaneous.

Form FMC-132B
Form FMC-133B

Subpart C—Assessment, Remission, and Mitigation of Civil Penalties

540.30 Scope.

540.31 Definitions.

540.32 Procedure.

540.33 Petition for remission or mitigation of penalty.

540.34 Settlement; execution of agreement form.

540.35 Referral to Department of Justice.

540.36 Payment of penalties.

590.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

Appendix A—Example of Settlement Agreement to be used under 46 CFR 540.36

Appendix B—Example of promissory not to be used under 46 CFR 540.36

(f) Certificate (Performance) means a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation issued pursuant to this subpart.

(g) Passenger means any person who is to embark on a vessel at any U.S. port and who has paid any amount for a ticket contract entitling him to water transportation.

(h) Passenger revenue means those monies wherever paid by passengers who are to embark at any U.S. port for water transportation and all other accommodations, services and facilities relating thereto.

(i) Unearned passenger revenue means that passenger revenue received for water transportation and all other accommodations, services, and facilities relating thereto not yet performed.

(j) Insurer means any insurance company, underwriter, corporation, or association or underwriters, ship owners' protection and indemnity association, or other insurer acceptable to the Commission.

(k) Evidence of insurance means a policy, certificate of insurance, cover note, or other evidence of coverage acceptable to the Commission.

§ 540.3 Proof of financial responsibility, when required.

No person in the United States may arrange, offer, advertise or provide passage on a vessel unless a Certificate (Performance) has been issued to or covers such person.

§ 540.4 Procedure for establishing financial responsibility.

(a) In order to comply with section 3 of Pub. L. 89-777 (80 Stat. 1357, 1358) enacted November 6, 1966, there must be filed an application on Form FMC-131 for a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation. Copies of Form FMC-131 may be obtained from the Secretary, Federal Maritime Commission, Washington, D.C. 20573, or at the Commission's offices at New York, NY; New Orleans, LA; San Francisco, CA; Miami, FL; Los Angeles, CA; Hato Rey, PR; and Chicago, IL.

(b) An application for a Certificate (Performance) shall be filed in duplicate with the Secretary, Federal Maritime Commission, by the vessel owner or charterer at least 60 days in advance of the arranging, offering, advertising, or providing of any water transportation or tickets in connection therewith except that any person other than the owner or charterer who arranges, offers, advertises, or provides passage on a vessel may apply for a Certificate (Performance). Late filing of the application will be permitted only for good cause shown. All applications and evidence required to be filed with the Commission shall be in English, and any monetary terms shall be expressed in terms of U.S. currency. The Commission shall have the privilege of verifying any statements made or any evidence submitted under the rules of this subpart. An application for a Certificate (Performance) shall be accompanied by a filing fee remittance of $1,600.

(c) The application shall be signed by a duly authorized officer or representative of the applicant with a copy of evidence of his or her authority. In the event of any material change in the facts as reflected in the application, an amendment to the application shall be filed no later than five (5) days following such change. For the purpose of this subpart, a material change shall be one which: (1) Results in a decrease in the amount submitted to establish financial responsibility to a level below that required to be maintained under the rules of this subpart, or (2) requires that the amount to be maintained be increased above the amount submitted to establish financial responsibility.

(d) Filing with the Commission for nonpayment of premiums, calls or assessments or for other cause, shall not be effected: (i) Until notice in writing has been given to the assured or to the insurer and to the Secretary of the Commission at its office, in Washington, D.C. 20573, by certified mail, and (ii) after 30 days expire from the date notice is actually received by the Commission, or until after the Commission revokes the Certificate (Performance), whichever occurs first. Notice of termination or cancellation to the assured or insurer shall be simultaneous to such notice given to the Commission. The insurer shall remain liable for claims covered by said evidence of insurance arising by virtue of an event which had occurred prior to the effective date of said termination or cancellation. No such termination or cancellation shall become effective while a voyage is in progress.

(2) The insolvency or bankruptcy of the assured shall not constitute a default to the insurer as to claims included in said evidence of insurance and in the event of said insolvency or bankruptcy, the insurer agrees to pay any unsatisfied final judgments obtained on such claims.

(3) No insurance shall be acceptable under these rules which restricts the liability of the insurer where privity of the owner or charterer has been shown to exist.

(4) Paragraphs (a)(1) through (a)(3) of this section shall apply to the guaranty as specified in paragraph (c) of this section.

(b) Filing with the Commission evidence of an escrow account, acceptable to the Commission, for indemnification of passengers in the event of nonperformance of water transportation.

(c) Filing with the Commission a guaranty on Form FMC-133A, by a guarantor acceptable to the Commission, for indemnification of passengers in the event of nonperformance of water transportation.

(d) Filing with the Commission for qualification as a self-insurer such evidence acceptable to the Commission as will demonstrate continued and stable passenger operations over an extended period of time in the foreign or domestic trade of the United States. In addition, applicant must demonstrate financial responsibility by maintenance of working capital and net worth, each in an amount calculated as in the introductory text of this section, except that the Commission, for good cause shown, may waive the requirement as to the amount of working capital. The Commission will take into consideration...
all current contractual requirements with respect to the maintenance of such working capital and net worth to which the applicant is bound. Evidence must be submitted that the working capital and net worth required above are physically located in the United States. This evidence of financial responsibility shall be supported by and subject to the following which are to be submitted on a continuing basis for each year or portion thereof while the Certificate (Performance) is in effect:

(1) A current quarterly balance sheet, except that the Commission, for good cause shown, may require only an annual balance sheet;
(2) A current quarterly statement of income and surplus, except that the Commission, for good cause shown, may require only an annual statement of income and surplus;
(3) An annual current balance sheet and an annual current statement of income and surplus to be certified by appropriate certified public accountants;
(4) An annual current statement of the book value or current market value of any assets physically located within the United States together with a certification as to the existence and amount of any encumbrances thereon;
(5) An annual current credit rating report by Dun and Bradstreet or any similar concern found acceptable to the Commission;
(6) A list of all contractual requirements or other encumbrances (and to whom the applicant is bound in this regard) relating to the maintenance of working capital and net worth;
(7) All financial statements required to be submitted under this section shall be due within a reasonable time after the close of each pertinent accounting period;
(8) Such additional evidence of financial responsibility as the Commission may deem necessary in appropriate cases.

§ 540.8 Surety bonds.
(a) Where financial responsibility is not established under § 540.5, a surety bond shall be filed on Form FMC-132A. Such surety bond shall be issued by a bonding company authorized to do business in the United States and acceptable to the Commission for indemnification of passengers in the event of nonperformance of water transportation.
(b) In the case of a surety bond which is to cover all passenger operations of the applicant subject to these rules, such bond shall be in an amount calculated as in the introductory text of § 540.5.
(c) In the case of a surety bond which is to cover an individual voyage, such bond shall be in an amount determined by the Commission to equal the gross passenger revenue for that voyage.
(d) The liability of the surety under the rules of this subpart to any passenger shall not exceed the amount paid by any such passenger, except that, no such bond shall be terminated while a voyage is in progress.

§ 540.7 Evidence of financial responsibility.
Where satisfactory proof of financial responsibility has been given or a satisfactory bond has been provided, a Certificate (Performance) covering specified vessels shall be issued evidencing the Commission's finding of adequate financial responsibility to indemnify passengers for nonperformance of water transportation. The period covered by the Certificate (Performance) shall be indeterminate, unless a termination date has been specified thereon.

§ 540.8 Denial, revocation, suspension, or modification.
(a) Prior to the denial, revocation, suspension, or modification of a Certificate (Performance), the Commission shall advise the applicant of its intention to deny, revoke, suspend, or modify and shall state the reasons therefor. If the applicant, within 20 days after the receipt of such advice, requests a hearing to show that such evidence of financial responsibility filed with the Commission does meet the rules of this subpart, such hearing shall be granted by the Commission, except that a Certificate (Performance) shall become null and void upon cancellation or termination of the surety bond, evidence of insurance, guaranty, or escrow account.
(b) A Certificate (Performance) may be denied, revoked, suspended, or modified for any of the following reasons:
(1) Making any willfully false statement to the Commission in connection with an application for a Certificate (Performance);
(2) Circumstances whereby the party does not qualify as financially responsible in accordance with the requirements of the Commission;
(3) Failure to comply with or respond to lawful inquiries, rules, regulations or orders of the Commission pursuant to the rules of this subpart.
(c) If the applicant, within 20 days after notice of the proposed denial, revocation, suspension, or modification under paragraph (b) of this section, requests a hearing to show that such denial, revocation, suspension, or modification should not take place, such hearing shall be granted by the Commission.
§ 540.9 Miscellaneous.
(a) If any evidence filed with the application does not comply with the requirements of this subpart, or for any reason fails to provide adequate or satisfactory protection to the public, the Commission will notify the applicant stating the deficiencies thereof.
(b) Any financial evidence submitted to the Commission under the rules of this subpart shall be written in the full and correct name of the person to whom the Certificate (Performance) is to be issued, and in case of a partnership, all partners shall be named.
(c) The Commission's bond (Form FMC-132A), guaranty (Form FMC-133A), and application (Form FMC-131) forms are hereby incorporated as a part of the rules of this subpart. Any such forms filed with the Commission under this subpart must be in duplicate.
(d) Any securities or assets accepted by the Commission (from applicants, insurers, guarantors, escrow agents, or others) under the rules of this subpart must be physically located in the United States.
(e) Each applicant, insurer, escrow agent and guarantor shall furnish a written designation of a person in the United States as legal agent for service of process for the purposes of the rules of this Subpart. Such designation must be acknowledged, in writing, by the designee. In any instance in which the designated agent cannot be served because of its death, disability, or unavailability, the Secretary, Federal Maritime Commission, will be deemed to be the agent for service of process. A party serving the Secretary in accordance with the above provision must also serve the Certificate, insurer, escrow agent, or guarantor, as the case may be, by registered mail at its last known address on file with the Commission.
(f) [Reserved]
(g) Financial data filed in connection with the rules of this subpart shall be confidential except in instances where information becomes relevant in connection with hearings which may be requested by applicant pursuant to § 540.8 (a) or (b).
(h) Every person who has been issued a Certificate (Performance) must submit to the Commission a semiannual statement of any changes that have taken place with respect to the information contained in the application or documents submitted in support thereof. Negative statements are required to indicate no change. Such
statements must cover every 6-month period of the fiscal year immediately subsequent to the date of the issuance of the Certificate (Performance). In addition, the statements will be due within 30 days after the close of every such 6-month period.

(i) [Reserved]

(j) The amount of: (1) Insurance as specified in § 540.5(a), (2) the escrow account as specified in § 540.5(b), (3) the guaranty as specified in § 540.5(c), or (4) the surety bond as specified in § 540.6, shall not be required to exceed 10 million dollars (U.S.).

(k) Every person in whose name a Certificate (Performance) has been issued shall be deemed to be responsible for any unearned passage money or deposits in the hands of its agents or of any other person or organization authorized by the certificant to sell the certificant’s tickets. Certificants shall promptly notify the Commission of any arrangements, including charters and subcharters, made by it or its agent with any person pursuant to which the certificant does not assume responsibility for all passenger fares and deposits collected by such person or organization and held by such person or organization as deposits or payment for services to be performed by the certificant. If responsibility is not assumed by the certificant, the certificant also must inform such person or organization of the certification requirements of Pub. L. 89-777 and not permit use of its name or tickets in any manner unless and until such person or organization has obtained the requisite Certificate (Performance) from the Commission.

Form FMC-131

FEDERAL MARITIME COMMISSION
Washington, D.C. 20573

Application for Certificate of Financial Responsibility

In compliance with the provisions of Pub. L. 89-777 and 46 CFR Part 540, application is hereby made for a Certificate of Financial Responsibility (check one or both as applicable):

1. (a) [Reserved]

2. (b) Total escrow deposit which is to be paid by the certificant before a Certificate (Performance) will be issued.

3. (c) [Reserved]

4. Name of State or country in which incorporated or organized.

5. Date of the incorporation or organization.

6. (a) [Reserved]

7. (b) Name and address of each partner.

8. Submit a copy of passenger ticket or other contract evidencing the sale of passenger transportation.

9. Name and address of applicant’s U.S. agent or other person authorized to accept legal service in the United States.

10. Items 11-15 are optional methods; answer only the one item which is applicable to this application. Check the appropriate box below:

   (a) Insurance (item 11).

   (b) Escrow (item 12).

   (c) Guaranty (item 14).

   (d) Self-insured (item 15).

11. (a) Total amount of performance insurance which is to be computed in accordance with § 540.5 of 46 CFR Part 540. (Evidence of insurance must be filed with the Federal Maritime Commission before a Certificate (Performance) may be issued.)

12. (a) Name and address of applicant’s escrow agent. (Applicant may pledge cash or U.S. Government securities, in lieu of a surety bond, to fulfill the indemnification provisions of Pub. L. 89-777.)

13. (b) Total escrow deposit which is to be computed in accordance with § 540.5 of 46 CFR Part 540. (Escrow agreement must be filed with the Federal Maritime Commission before a Certificate (Performance) will be issued.)

14. Name and address of applicant’s insurer for performance policy.

15. (a) Name and address of applicant’s surety agent (as appropriate).

16. (b) Method by which insurance amount is determined (attach data substantiating that amount is not less than that prescribed in § 540.5 of 46 CFR Part 540).

17. (c) Name and address of applicant’s surety for surety policy.

18. (d) Method by which escrow amount is determined (attach data substantiating that amount is not less than that prescribed by § 540.5 of 46 CFR Part 540).

The filing of sailing schedules will be acceptable in answers to this question.
13(a) Total amount of surety bond in accordance with § 540.6 of 46 CFR Part 540. (The bond must be filed with the Federal Maritime Commission before a Certificate (Performance) may be issued.)

(b) Method by which bond amount is determined. (Attach data substantiating that amount is not less than that prescribed in § 540.6 of 46 CFR Part 540.)

(c) Name and address of applicant’s surety on performance bond.

14(a) Total amount of guaranty which is to be computed in accordance with § 540.5 of 46 CFR Part 540. (Guaranty must be filed with the Federal Maritime Commission before a Certificate (Performance) may be issued.)

(b) Method by which guaranty amount is determined. (Attach data substantiating that amount is not less than that prescribed in § 540.5 of 46 CFR Part 540.)

(c) Name and address of applicant’s guarantor.

15. If applicant intends to qualify as a self-insurer for a Certificate (Performance) under § 540.6 of 46 CFR Part 540, attach all data, statements, and documentation required therein.

Part III—Casualty

Answer Items 16–22 if Applying for Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons

16. Name of passenger vessel subject to section 2 of Pub. L. 89–777 operated by you to or from U.S. ports which has largest number of berth or stateroom accommodations. State the maximum number of berth or stateroom accommodations.

17. Amount of death or injury liability coverage based on number of accommodations aboard vessel named in Item 16 above, calculated in accordance with § 540.24 of 46 CFR Part 540.

Items 18–22 Are Optional Methods: Answer Only the One Item Which Is Applicable to This Application

18(a) Total amount of applicant’s insurance. (Evidence of the insurance must be filed with the Federal Maritime Commission before a Certificate (Casualty) will be issued.)

(b) Name and address of applicant’s insurer.

19(a) Total amount of surety bond. (Bond must be filed with the Federal Maritime Commission before a Certificate (Casualty) will be issued.)

(b) Name and address of applicant’s surety for death or injury bond.

20(a) Total amount of escrow deposit. (Escrow agreement must be filed with the Federal Maritime Commission before a Certificate (Casualty) will be issued.)

(b) Name and address of applicant’s escrow agent.

21(a) Total amount of guaranty. (Guaranty must be filed with the Federal Maritime Commission before a Certificate (Casualty) will be issued.)

(b) Name and address of applicant’s guarantor.

22. If applicant intends to qualify as a self-insurer for a Certificate (Casualty) under § 540.24(c) of 46 CFR Part 540, attach all data, statements and documentation required therein.

Part IV—Declaration

This application is submitted by or on behalf of

(a) Name,
(b) Name and title of official,
(c) Home office— Street and number,
(d) City,
(e) State or country,
(f) ZIP Code,
(g) Principal office in the United States— Street and number,
(h) City,
(i) State.

I declare that I have examined this application, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct and complete.

By (Signature of official)
Schedule ("the Vessels"), which are or may become engaged in voyages to or from United States ports, and the Applicant desires to establish its financial responsibility in accordance with Section 3 of Pub. L. 89-777, 80th Congress, approved November 8, 1966 ("the Act") then, provided that the Federal Maritime Commission ("FMC") shall have accepted, as sufficient for that purpose, the Applicant's application, supported by this Guaranty, and provided that FMC shall issue to the Applicant a Certificate ("Certificate"), the undersigned Guarantor hereby guarantees to discharge the Applicant's legal liability to indemnify the passengers of the Vessels for nonperformance of transportation within the meaning of Section 3 of the Act, in the event that such legal liability has not been discharged by the Applicant within 21 days after any such passenger has obtained a final judgment (after appeal, if any) against the Applicant from a United States Federal or State Court of competent jurisdiction, or has become entitled to payment of a specified sum by virtue of a compromise settlement agreement made with the Applicant, with the approval of the Guarantor, whereby, upon payment of the agreed sum, the Applicant is to be fully, irrevocably and unconditionally discharged from all further liability to such passenger for such nonperformance.

2. The Guarantor's liability under this Guaranty in respect to any passenger shall not exceed the amount paid by such passenger; and the aggregate amount of the Guarantor's liability under this Guaranty shall not exceed $50,000.

3. The Guarantor's liability under this Guaranty shall attach only in respect of events giving rise to a cause of action against the Applicant, in respect of any of the Vessels, for nonperformance of transportation within the meaning of Section 3 of the Act, occurring after the Certificate has been granted to the Applicant, and before the expiration date of this Guaranty, which shall be the earlier of the following dates:

(a) The date on which the Certificate is withdrawn, or for any reason becomes invalid or ineffective; or
(b) The date 30 days after the date of receipt by FMC of notice in writing (including telex or cable) that the Guarantor has elected to terminate this Guaranty except that:

(i) If, on the date which would otherwise have been the expiration date under the foregoing provisions (a) or (b) of this Clause 3, any of the Vessels is on a voyage wherein passengers have been embarked at a United States port, then the expiration date of this Guaranty shall, in respect of such Vessel, be postponed to the date on which the last passenger on such voyage shall have finally disembarked; and

(ii) Such termination shall not affect the liability of the Guarantor for refunds arising from ticket contracts made by the Applicant for the supplying of transportation and other services prior to the date such termination becomes effective.

4. If, during the currency of this Guaranty, the Applicant requests that a vessel owned or operated by the Applicant, and not specified in the annexed Schedule, should become subject to this Guaranty, and if the Guarantor accedes to such request and so notifies FMC in writing (including telex or cable), then, provided that within 30 days of receipt of such notice, FMC shall have granted a Certificate, such Vessel shall thereupon be deemed to be one of the Vessels included in the said Schedule and subject to this Guaranty.

5. The Guarantor hereby designates, with offices at

[Address of Guarantor]


(Date and Place of Execution)

[Signature and Title]

Guarantor

Schedule of Vessels Referred to in Clause 1

Vessels Added to This Schedule in Accordance With Clause 4

Subpart B—Proof of Financial Responsibility, Bonding and Certification of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages

§ 540.20 Scope.

The regulations contained in this subpart set forth the procedures whereby owners or charterers of vessels having berth or stateroom accommodations for 50 or more passengers and embarking passengers at U.S. ports shall establish their financial responsibility to meet any liability which may accrue for death or injury to passengers or other persons on voyages to or from U.S. ports. Included also are the qualifications required by the Commission for issuance of a Certificate (Casualty) and the basis for the denial, revocation, suspension, or modification of such Certificates.

§ 540.21 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) Person includes individuals, corporations, partnerships, associations, and other legal entities existing under or authorized by the laws of the United States or any state thereof or the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States, or the laws of any foreign country.

(b) Vessel means any commercial vessel having berth or stateroom accommodations for 50 or more passengers and embarking passengers at U.S. ports.

(c) Commission means the Federal Maritime Commission.

(d) United States includes the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States.

(e) Berth or stateroom accommodations or passenger accommodations includes all temporary and all permanent passenger sleeping facilities.

(f) Certificate (Casualty) means a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages issued pursuant to this subpart.

(g) Voyage means voyage of a vessel to or from U.S. ports.

(h) Insurer means any insurance company, underwriter, corporation or association of underwriters, ship owners' protection and indemnity association, or other insurer acceptable to the Commission.

(i) Evidence of insurance means a policy, certificate of insurance, cover note, or other evidence of coverage acceptable to the Commission.

(j) For the purpose of determining compliance with § 540.22, "passengers embarking at United States ports" means any persons, not necessary to the business, operation, or navigation of a vessel, whether holding a ticket or not, who board a vessel at a port or place in the United States and are carried by the vessel on a voyage from that port or place.

§ 540.22 Proof of financial responsibility, when required.

No vessel shall embark passengers at U.S. ports unless a Certificate (Casualty) has been issued to or covers the owner or charterer of such vessel.

§ 540.23 Procedure for establishing financial responsibility.

(a) In order to comply with section 2 of Pub. L. 89-777 (80 Stat. 1357, 1358) enacted November 8, 1966, there must be filed an Application on Form FMC-131 with the Secretary, Federal Maritime Commission, Washington, DC 20573, or at the Commission's offices at New York, NY; New Orleans, LA; San Francisco, CA; Miami, FL; Los Angeles, CA; Hato Rey, PR; and Chicago, IL.

(b) An application for a Certificate (Casualty) shall be filed in duplicate.
with the Secretary, Federal Maritime Commission, by the vessel owner or charterer at least 60 days in advance of the sailing. Late filing of the application will be permitted only for good cause shown. All applications and evidence required to be filed with the Commission shall be in English, and any monetary terms shall be expressed in terms of U.S. currency. The Commission shall have the privilege of verifying any statements made or any evidence submitted under the rules of this subpart. An application for a Certificate (Casualty) shall be accompanied by a filing fee remittance of $500.

(c) The application shall be signed by a duly authorized officer or representative of the applicant with a copy of evidence of his authority. In the event of any material change in the facts as reflected in the application, an amendment to the application shall be filed no later than five (5) days following such change. For the purpose of this subpart, a material change shall be one which: (1) Results in a decrease in the amount submitted to establish financial responsibility to a level below that required to be maintained under the rules of this subpart, or (2) requires that the amount to be maintained be increased above the amount submitted to establish financial responsibility. Notice of the application for, issuance, denial, revocation, suspension, or cancellation to the guarantor acceptable to the Commission. Any such guaranty shall be in an amount calculated as in paragraph (a) of this section.

(3) No insurance shall be acceptable to the Commission except that the Commission, for good cause shown, may require only an annual statement of income and surplus.

(4) Paragraphs (a)(1) through (a)(3) of this section shall apply to the guaranty as specified in paragraph (d) of this section.

(b) Filing with the Commission a surety bond on Form FMC-132B issued by a bonding company authorized to do business in the United States and acceptable to the Commission. Such surety bond shall evidence coverage for liability which may be incurred for death or injury to passengers or other persons on voyages in an amount based upon the number of passenger accommodations aboard the vessel, calculated as follows:

Twenty thousand dollars for each passenger accommodation up to and including 500; plus

Fifteen thousand dollars for each additional passenger accommodation between 501 and 1,000; plus

Ten thousand dollars for each additional passenger accommodation between 1,001 and 1,200; plus

Five thousand dollars for each passenger accommodation in excess of 1,200; plus

except that, if the applicant is operating more than one vessel subject to this subpart, the amount prescribed by this paragraph shall be based upon the number of passenger accommodations on the vessel being so operated which has the largest number of passenger accommodations.

(1) Termination or cancellation of the evidence of insurance, whether by the assured or by the insurer, and whether for nonpayment of premiums, calls or assessments, or for other cause, shall not be effected; (i) Until notice in writing has been given to the assured or to the insurer and to the Secretary of the Commission at its office in Washington, D.C. 20573, by certified mail, and (ii) until after 30 days expire from the date notice is actually received by the Commissioner, or until after the Commission revokes the Certificate (Casualty), whichever occurs first. Notice of termination or cancellation to the assured or insurer shall be simultaneous to such notice given to the Commission. The insurer shall remain liable for claims covered by said evidence of insurance arising by virtue of an event which had occurred prior to the effective date of said termination or cancellation. Notice of such termination or cancellation shall become effective while a voyage is in progress.

(2) The insolvency or bankruptcy of the assured shall not constitute a defense to the insurer as to claims included in said evidence of insurance and in the event of said insolvency or bankruptcy, the insurer agrees to pay any unsatisfied final judgments obtained on such claims.

(3) No insurance shall be acceptable under these rules which restricts the liability of the insurer where privity of the owner or charterer has been shown to exist.

(4) Paragraphs (a)(1) through (a)(3) of this section shall apply to the guaranty as specified in paragraph (d) of this section.

(c) Filing with the Commission a guaranty on Form FMC-133B by a guarantor acceptable to the Commission. Any such guaranty shall be in an amount calculated as in paragraph (a) of this section. The Commission will take into consideration all current contractual requirements with respect to the maintenance of working capital and/or net worth to which the applicant is bound. Evidence must be submitted that the working capital and net worth required above are physically located in the United States. This evidence of financial responsibility shall be supported by and subject to the following which are to be submitted on a continuing basis for each year or portion thereof while the Certificate (Casualty) is in effect:

(1) A current quarterly balance sheet, except that the Commission, for good cause shown, may require only an annual balance sheet;

(2) A current quarterly statement of income and surplus except that the Commission, for good cause shown, may require only an annual statement of income and surplus;

(3) An annual current balance sheet and an annual current statement of income and surplus to be certified by appropriate certified public accountants;

(4) An annual current statement of the book value or current market value of any assets physically located within the United States together with a certificate as to the existence and amount of any encumbrances thereon;

(5) An annual current credit rating report by Dun and Bradstreet or any similar concern found acceptable to the Commission;

(6) A list of all contractual requirements or other encumbrances (and to whom the applicant is bound in this regard) relating to the maintenance of working capital and net worth;

(7) All financial statements required to be submitted under this section shall be due within a reasonable time after the close of each pertinent accounting period;

(8) Such additional evidence of financial responsibility as the Commission may deem necessary in appropriate cases.

(d) Filing with the Commission a guaranty on Form FMC-133B by a guarantor acceptable to the Commission. Any such guaranty shall be in an amount calculated as in paragraph (a) of this section.

(e) Filing with the Commission evidence of an escrow account, acceptable to the Commission, the amount of such account to be calculated as in paragraph (a) of this section.

(f) The Commission will, for good cause shown, consider any combination of the alternatives described in

§ 402.42 Insurance, surety bonds, self-insurance, guaranties, and escrow accounts.

Evidence of adequate financial responsibility for the purposes of this subpart may be established by one of the following methods:

(a) Filing with the Commission evidence of insurance issued by an insurer providing coverage for liability which may be incurred for death or injury to passengers or other persons on voyages in an amount based upon the number of passenger accommodations aboard the vessel, calculated as follows:

Twenty thousand dollars for each passenger accommodation up to and including 500; plus

Fifteen thousand dollars for each additional passenger accommodation between 501 and 1,000; plus

Ten thousand dollars for each additional passenger accommodation between 1,001 and 1,200; plus

Five thousand dollars for each passenger accommodation in excess of 1,200; plus

except that, if the applicant is operating more than one vessel subject to this subpart, the amount prescribed by this paragraph shall be based upon the number of passenger accommodations on the vessel being so operated which has the largest number of passenger accommodations.

(1) Termination or cancellation of the evidence of insurance, whether by the assured or by the insurer, and whether for nonpayment of premiums, calls or assessments, or for other cause, shall not be effected; (i) Until notice in writing has been given to the assured or to the insurer and to the Secretary of the Commission at its office in Washington, D.C. 20573, by certified mail, and (ii) until after 30 days expire from the date notice is actually received by the Commissioner, or until after the Commission revokes the Certificate (Casualty), whichever occurs first. Notice of termination or cancellation to the assured or insurer shall be simultaneous to such notice given to the Commission. The insurer shall remain liable for claims covered by said evidence of insurance arising by virtue of an event which had occurred prior to the effective date of said termination or cancellation. Notice of such termination or cancellation shall become effective while a voyage is in progress.

(2) The insolvency or bankruptcy of the assured shall not constitute a defense to the insurer as to claims included in said evidence of insurance and in the event of said insolvency or bankruptcy, the insurer agrees to pay any unsatisfied final judgments obtained on such claims.

(3) No insurance shall be acceptable under these rules which restricts the liability of the insurer where privity of the owner or charterer has been shown to exist.

(4) Paragraphs (a)(1) through (a)(3) of this section shall apply to the guaranty as specified in paragraph (d) of this section.

(b) Filing with the Commission a surety bond on Form FMC-132B issued by a bonding company authorized to do business in the United States and acceptable to the Commission. Such surety bond shall evidence coverage for liability which may be incurred for death or injury to passengers or other persons on voyages in an amount calculated as in paragraph (a) of this section, and shall not be terminated while a voyage is in progress.

(c) Filing with the Commission for qualification as a self-insurer such evidence acceptable to the Commission as will demonstrate continued and stable passenger operations over an extended period of time in the foreign or domestic trade of the United States. In addition, applicant must demonstrate financial responsibility by maintenance

of working capital and net worth, each in an amount calculated as in paragraph (a) of this section. The Commission will take into consideration all current contractual requirements with respect to the maintenance of working capital and/or net worth to which the applicant is bound. Evidence must be submitted that the working capital and net worth required above are physically located in the United States. This evidence of financial responsibility shall be supported by and subject to the following which are to be submitted on a continuing basis for each year or portion thereof while the Certificate (Casualty) is in effect:

(1) A current quarterly balance sheet, except that the Commission, for good cause shown, may require only an annual balance sheet;

(2) A current quarterly statement of income and surplus except that the Commission, for good cause shown, may require only an annual statement of income and surplus;

(3) An annual current balance sheet and an annual current statement of income and surplus to be certified by appropriate certified public accountants;

(4) An annual current statement of the book value or current market value of any assets physically located within the United States together with a certification as to the existence and amount of any encumbrances thereon;

(5) An annual current credit rating report by Dun and Bradstreet or any similar concern found acceptable to the Commission;

(6) A list of all contractual requirements or other encumbrances (and to whom the applicant is bound in this regard) relating to the maintenance of working capital and net worth;

(7) All financial statements required to be submitted under this section shall be due within a reasonable time after the close of each pertinent accounting period;

(8) Such additional evidence of financial responsibility as the Commission may deem necessary in appropriate cases.

(d) Filing with the Commission a guaranty on Form FMC-133B by a guarantor acceptable to the Commission. Any such guaranty shall be in an amount calculated as in paragraph (a) of this section.

(e) Filing with the Commission evidence of an escrow account, acceptable to the Commission, the amount of such account to be calculated as in paragraph (a) of this section.

(f) The Commission will, for good cause shown, consider any combination of the alternatives described in
§ 540.25 Evidence of financial responsibility.

Where satisfactory proof of financial responsibility has been established, a Certificate (Casualty) covering specified vessels shall be issued evidencing the Commission's finding of adequate financial responsibility to meet any liability which may be incurred for death or injury to passengers or other persons on voyages. The period covered by the certificate shall be indeterminate unless a termination date has been specified therein.

§ 540.26 Denial, revocation, suspension, or modification.

(a) Prior to the denial, revocation, suspension, or modification of a Certificate (Casualty), the Commission shall advise the applicant of its intention to deny, revoke, suspend, or modify, and shall state the reasons therefor. If the applicant, within 20 days after the receipt of such advice, requests a hearing to show that the evidence of financial responsibility filed with the Commission does meet the rules of this subpart, such hearing shall be granted by the Commission, except that a Certificate (Casualty) shall become null and void upon cancellation or termination of evidence of insurance, surety bond, guaranty, or escrow account.

(b) A Certificate (Casualty) may be denied, revoked, suspended, or modified for any of the following reasons:

(1) Making any willfully false statement to the Commission in connection with an application for a Certificate (Casualty);

(2) Circumstances whereby the party does not qualify as financially responsible in accordance with the requirements of the Commission;

(3) Failure to comply with or respond to lawful inquiries, rules, regulations, or orders of the Commission pursuant to the rules of this subpart.

(c) If the applicant, within 20 days after notice of the proposed denial, revocation, suspension, or modification under paragraph (b) of this section, requests a hearing to show that such denial, revocation, suspension, or modification should not take place, such hearing shall be granted by the Commission.

§ 540.27 Miscellaneous.

(a) If any evidence filed with the application does not comply with the requirements of this subpart, or for any reason, fails to provide adequate or satisfactory protection to the public, the Commission will notify the applicant stating the deficiencies thereof.

(b) Any financial evidence submitted to the Commission under the rules of this subpart shall be written in the full and correct name of the person to whom the Certificate (Casualty) is to be issued, and in case of a partnership, all partners shall be named.

(c) The Commission's bond (Form FMC-132B), guaranty (Form FMC-133B), and application (Form FMC-131 as set forth in Subpart A of this part) forms are hereby incorporated as a part of the rules of this subpart. Any such forms filed with the Commission under this subpart must be in duplicate.

(d) Any securities or assets accepted by the Commission (from applicants, insurers, guarantors, escrow agents, or others) under the rules of this subpart must be physically located in the United States.

(e) Each applicant, insurer, escrow agent, and guarantor shall furnish a written designation of a person in the United States as legal agent for service of process for the purposes of the rules of this subpart. Such designation must be acknowledged, in writing, by the designee. In any instance in which the designated agent cannot be served because of death, disability, or unavailability, the Secretary, Federal Maritime Commission, will be deemed to be the agent for service of process. A party serving the Secretary in accordance with the above provision must also serve the certificant, insurer, escrow agent, or guarantor, as the case may be, by registered mail, at its last known address on file with the Commission.

(f) In the case of any charter arrangement involving a vessel subject to the regulations of this subpart, the vessel owner (in the event of a subcharter, the charterer shall file) must within 10 days file with the Secretary of the Commission evidence of any such arrangement.

(g) Financial data filed in connection with the rules of this subpart shall be confidential except in instances where information becomes relevant in connection with hearings which may be requested by applicant pursuant to § 540.26(a) or § 540.26(b).

(h) Every person who has been issued a Certificate (Casualty) must submit to the Commission a semiannual statement of any changes that have taken place with respect to the information contained in the application or documents submitted in support thereof. Negative statements are required to indicate no change. Such statements must cover every such 6-month period commencing with the first 6-month period of the fiscal year immediately subsequent to the date of the issuance of the Certificate (Casualty). In addition, the statements will be due within 30 days after the close of every 6-month period.

Form FMC-132B

FEDERAL MARITIME COMMISSION

Surety Co. Bond No. —

FMC Certificate No. —

Passenger Vessel Surety Bond (46 CFR Part 540)

Know all men by these presents, that We

_________________________ (Name of applicant),

of _____________________ (City), _____________________ (State and country), as Principal (hereinafter called Principal), and — (Name of surety), a company created and existing under the laws of _____________________ (State and country) and authorized to do business in the United States, as Surety (hereinafter called Surety) are held and firmly bound unto the United States of America in the penal sum of —, for which payment, well and truly to be made, we bind ourselves and our heirs, executors, administrators, successors, and assigns, jointly and severally, firmly by these presents.

Whereas, the Principal intends to become a holder of a Certificate (Casualty) pursuant to the provisions of Subpart B of Part 540 of Title 46, Code of Federal Regulations, and has elected to file with the Federal Maritime Commission such a bond to insure financial responsibility to meet any liability it may incur for death or injury to passengers or other persons on voyages to or from U.S. ports, and

Whereas, this bond is written to assure compliance by the Principal as an authorized holder of a Certificate (Casualty) pursuant to Subpart B of Part 540 of Title 46, Code of Federal Regulations, and shall inure to the benefit of any and all passengers or other persons to whom the Principal may be held legally liable for any of the damages herein described.

Now, therefore, the condition of this obligation is such that if the Principal shall pay or cause to be paid to passengers or other persons any sum or sums for which the Principal may be held legally liable by reason of the Principal's failure faithfully to meet any liability the Principal may incur for death or injury to passengers or other persons on voyages to or from U.S. ports, while this bond is in effect pursuant to and in accordance with the provisions of Subpart B of Part 540 of Title 46, Code of Federal Regulations, then this obligation shall be void, otherwise, to remain in full force and effect.

The liability of the Surety with respect to any passenger or other persons shall in no event exceed the amount of the Principal's legal liability under any final judgment or settlement agreement, except that, if the aggregate amount of such judgments and settlements exceeds an amount computed in accordance with the formula contained in section 2(a) of Pub. L. 89-777, then the
Suresy's total liability under this surety bond shall be limited to an amount computed in accordance with such formula.

The Surety agrees to furnish written notice to the Federal Maritime Commission forthwith of all suits filed, judgments rendered, and payments made by said Surety under this bond. This bond is effective the day of , 19-- 12:01 a.m., standard time, at the address of the Principal as stated herein and shall continue in force until terminated as hereinbefore provided. The Principal or the Surety may at any time terminate this bond by written notice sent by certified mail to the other and to the Federal Maritime Commission at its Office in Washington, D.C., such termination to become effective thirty (30) days after actual receipt of said notice by the Commission, except that no such termination shall become effective while a voyage is in progress. The Surety shall not be liable hereunder for any liability incurred for death or injury to passengers or other persons on voyages to or from U.S. ports after the termination of this bond as herein provided, but such termination shall not affect the liability of the Surety hereunder for such liability incurred for death or injury to passengers or other persons on voyages to or from U.S. ports prior to the date such termination becomes effective.

In witness whereof, the said Principal and Surety have executed this instrument on the day of , 19--

PRINCIPAL

Name ____________________________

[Signature and title]

Witness ____________________________

SURETY

Name ____________________________

[SEAL] ____________________________

[Signature and title]

Witness ____________________________

Only corporations or associations of individual insurers may qualify to act as Surety; and they must establish to the satisfaction of the Federal Maritime Commission legal authority to assume the obligations of surety and financial ability to discharge them.

Form FMC-133B

FEDERAL MARITIME COMMISSION

Guaranty No. ____________________________

FMC Certificate No. ____________________________

Guaranty in Respect of Liability for Death or Injury, Section 2 of the Act

1. Whereas — — — — (Name of Applicant) (Hereinafter referred to as the "Applicant") is the Owner or Charterer of the passenger vessel(s) specified in the annexed Schedule ("the Vessels"), which are or may become engaged in voyages to or from U.S. ports, and the Applicant desires to establish its financial responsibility in accordance with section 2 of Pub. L. 89-777, as Congress, approved November 6, 1966 ("the Act") then, provided that the Federal Maritime Commission ("FMC") shall have accepted, as sufficient for that purpose, the Applicant's application, supported by this Guaranty, and provided that FMC shall issue to the Applicant a Certificate (Casualty) ("Certificate"), the undersigned Guarantor hereby guarantees to discharge the applicant's legal liability in respect of claims for damages for death or injury to passengers or other persons on voyages of the Vessels to or from U.S. ports, in the event that such legal liability has not been discharged by the Applicant within 21 days after any such passenger or other person, in the event of death, his or her personal representative, has obtained a final judgment (after appeal, if any) against the Applicant from a U.S. Federal or State Court of competent jurisdiction, or has become entitled to payment of a specified sum by virtue of a compromise settlement agreement made with the Applicant, with the approval of the Guarantor, whereby, upon payment of the agreed sum, the Applicant is to be fully, irrevocably and unconditionally discharged from all further liability to such passenger or other person, or to such personal representative, with respect to such claim.

2. The Guarantor's liability under this Guaranty shall be limited to the amount of the Applicant's legal liability under any such judgment or settlement agreement, except that, if the aggregate amount of such judgments and settlements exceeds an amount computed in accordance with the formula contained in section 2(a) of the Act, then the Guarantor's total liability under this Guaranty shall be limited to an amount computed in accordance with such formula.

3. The Guarantor's liability under this Guaranty shall attach only in respect of events giving rise to causes of action against the Applicant in respect of any of the Vessels for damages for death or injury within the meaning of section 2 of the Act, occurring after the Certificate has been granted to the Applicant and before the expiration date of this Guaranty, which shall be the earlier of the following dates:

(a) The date whereon the Certificate is withdrawn, if the surety shall have become invalid or ineffective; or
(b) The date 30 days after the date of receipt by FMC of notice in writing (including telex or cable) that the Guarantor has elected to terminate this Guaranty, except that if, on the date which would otherwise have been the expiration date of this Guaranty under the foregoing provisions of this Clause 3, any of the Vessels is on a voyage in respect of which such Vessel would not have received clearance in accordance with section 2 of the Act without the Certificate, then the expiration date of this Guaranty shall, in respect of such Vessel, be postponed to the date on which the last passenger on such voyage shall have fully disembarked.

4. If, during the currency of this Guaranty, the Applicant requests that a vessel owned or operated by the Applicant, and not specified in the annexed Schedule, should become subject to this Guaranty, and if the Guarantor accedes to such request and notifies FMC in writing (including telex or cable), then provided that, within 30 days of receipt of such notice FMC shall have granted a Certificate, such vessel shall thereupon be deemed to be one of the Vessels included in the said Schedule and subject to this Guaranty.


By ____________________________

(Address and Guarantor)

[Name and Title]

Schedule of Vessels Referred to in Clause 1

Vessels Added to This Schedule in Accordance With Clause 4

Subpart C—Assessment, Remission, and Mitigation of Civil Penalties

§ 540.30 Scope.

Sections 2 and 3 of Pub. L. 89-777 subject any person who violates the provisions of those sections to a civil penalty of not more than $5,000, in addition to a civil penalty of $200 for each passage sold, such penalties to be assessed by the Federal Maritime Commission. These sections further provide that such penalties may be "remitted or mitigated" by the Commission "upon such terms as they in their discretion shall deem proper." This subpart sets forth regulations prescribing standards and procedures for the collection, mitigation, and remission of civil penalties incurred under sections 2 and 3 of Pub. L. 89-777, and the rules and regulations promulgated pursuant thereto.1

§ 540.31 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) Person includes individuals, corporations, partnerships, associations, and other legal entities existing under or authorized by the laws of the United States or any State thereof or the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, or any territory or possession of the United States, or the laws of any foreign country.

(b) Commission means the Federal Maritime Commission.

1Sections 2(d) and 3(d) of Pub. L. 89-777 authorize the Federal Maritime Commission to prescribe such regulations as may be necessary to carry out the provisions of secs. 2 and 3.
§ 540.32 Procedure.

(a) If it is adjudged or otherwise determined that a violation has occurred and it is decided to invoke a statutory penalty, a registered letter will be sent to the offender informing him of the nature of the violation, the statutory and factual basis of the penalty, and the amount of the penalty. This notice shall further advise the offender that, within 20 days, or such longer period as the Commission in its discretion may allow, he or she may either pay the penalty demanded or petition for the remission or mitigation of such penalty.

(b) All correspondence, petitions, forms, or other instruments regarding the collection, remission or mitigation of any penalty under this subpart should be addressed to the Bureau of Hearing Counsel, Federal Maritime Commission, Washington, D.C. 20573.

§ 540.33 Petition for remission of mitigation of penalty.

(a) An offender may submit any oral or written material or information in answer to the notification letter explaining, mitigating, showing extenuating circumstances, or, where there has been no formal proceeding on the merits, denying the violation. Material or information so presented will be considered in making the final determination as to whether to mitigate the penalty and the amount for which it will be mitigated, or whether to remit it in full.

(b) When no penalty is invoked or the penalty is remitted, no further action by the offender will be necessary. When the penalty is mitigated, such mitigation will be made conditional upon the full payment within 15 days or such longer period as the Commission in its discretion may allow unless the offender within that time executes a promissory note as provided by § 540.36.

§ 540.34 Settlement; execution of agreement form.

When a statutory penalty is mitigated and the offender agrees to settle for that amount, he or she shall be provided with a Settlement Agreement Form (Appendix A), to be signed, in duplicate, and returned. This form, after reciting the nature of the violation, will contain a statement evidencing the offender’s agreement to settlement of the Commission’s penalty claim for the amount set forth in the agreement and shall also embody an “approval and acceptance” provision. Upon settlement of the penalty in the agreed amount, one copy of the Settlement Agreement shall be returned to the debtor with the “Approval and Acceptance” thereon signed by the Director, Bureau of Hearing Counsel.

§ 540.35 Referral to Department of Justice.

(a) The Commission will refer violations to the Department of Justice with the recommendation that action be taken to collect the full statutory penalty when:

(1) The offender, within the prescribed time, does not explain the violation, petition for mitigation or remission, or otherwise respond to letters or inquiries;

(2) The offender, having responded to such letters or inquiries, fails or refuses to pay the statutory or mitigated penalty, as determined by the Commission, within the prescribed time.

(b) No action looking to the remission or mitigation of a penalty shall be taken on any petition, irrespective of the amount involved, if the case has been referred to the Department of Justice for collection.

§ 540.36 Payment of penalties.

Payment of penalties by the offender shall be made by:

(a) A bank cashier’s check or other instrument acceptable to the Commission.

(b) Regular installments by check after the execution of a promissory note containing a confess-judgment agreement (Appendix B).

(c) A combination of the alternatives described in paragraphs (a) and (b) of this section. All checks or other instruments submitted in payment of claims shall be made payable to “Federal Maritime Commission.”

§ 540.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

This section displays the control numbers assigned to information collection requirements of the Commission in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96-511. The Commission intends that this section comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which requires that agencies display a current control number assigned by the Director of the Office of Management and Budget (OMB) for each agency information collection requirement:

Appendix A—Example of Settlement Agreement To Be Used Under 46 CFR 540.30–540.36

Settlement Agreement FMC File No. —

This Agreement is entered into between:

(1) the Federal Maritime Commission and,

(2) hereinafter referred to as Respondent.

WHEREAS, the Commission is considering the institution of an assessment proceeding against Respondent for the recovery of civil penalties provided under the Act ——, for —— alleged violation(s) of Section(s) ——.

WHEREAS, this course of action is the result of practices believed by the Commission to have been engaged in by Respondent to wit:

WHEREAS, the parties are desirous of expeditiously settling the matter according to the conditions and terms of this Agreement and wish to avoid the delays and expense which would accompany agency litigation concerning these penalty claims; and,

WHEREAS, Section —— of the Act —— authorizes the Commission to collect and compromise civil penalties arising from the alleged violation(s) set forth and described above; and,

WHEREAS, the Respondent has terminated the practices which are the basis of the alleged violation(s) set forth herein, and has instituted and indicated its willingness to maintain measures designed to eliminate, discourage and prevent these practices by Respondent or its officers, employees and agents.

NOW THEREFORE, in consideration of the premises herein, and in compromise of all civil penalties arising from the violation(s) set forth and described herein that may have occurred between —— and ——, the undersigned Respondent herewith tenders to the Federal Maritime Commission a bank cashier’s check in the sum of $ ——, upon the following terms of settlement:

1. Upon acceptance of this agreement of settlement in writing by the Director of the Bureau of Hearing Counsel of the Federal Maritime Commission, this instrument shall forever bar the commencement or institution of any assessment proceeding or other claims for recovery of civil penalties from Respondent arising from the alleged violations set forth and described herein, that have been disclosed by Respondent to the
Commission and that occurred between
---------- (date) and ---------- (date).

2. The undersigned voluntarily signs this instrument and states that no promises or representations have been made to the Respondent other than the agreements and consideration herein expressed.

3. It is expressly understood and agreed that this Agreement is not to be construed as an admission of guilt by undersigned Respondent to the alleged violations set forth above.

4. Insofar as this agreement may be inconsistent with Commission procedures for compromise and settlement of violations as set out at 46 CFR Part 505, the parties hereby waive application of such procedures.

By
Title
Date

Approval and Acceptance

The above Terms and Conditions and Amount of Consideration are hereby Approved and Accepted:

By the Federal Maritime Commission.

(Hearing Counsel)

Director, Bureau of Hearing Counsel.

Date

Appendix B—Example of Promissory Note To Be Used Under 46 CFR 540.36

Promissory Note Containing Agreement for Judgment

FMC File No.----------

For value received, ---------- promises to pay to the Federal Maritime Commission (the Commission) the principal sum of $---------- to be paid at the offices of the Commission in Washington, D.C. by bank cashier's or certified check in the following installments:

$---------- within --- months of execution of the settlement agreement by the Director of the Bureau of Hearing Counsel;

$---------- within --- months of execution of the agreement;

$---------- within --- months of execution of the agreement;

[Further payments if necessary]

In addition to the principal amount payable hereunder, interest on the unpaid balance thereof shall be paid with each installment. Such interest shall accrue from the date of the execution of this Promissory Note by the Director of the Bureau of Hearing Counsel, and be computed at the rate of [---------- percent (-----%) per annum.]

If any payment of principal or interest shall remain unpaid for a period of ten (10) days after becoming due and payable, the entire unpaid principal amount of this Promissory Note, together with interest thereon, shall become immediately due and payable at the option of the Commission without demand or notice, said demand and notice being hereby expressly waived.

If a default shall occur in the payment of principal or interest under this Promissory Note, ---------- (Respondent) does hereby authorize and empower any U.S. attorney, any of its assistants or any attorney of any court of record, Federal or State, to appear for him or her, and to enter and confess judgment against ---------- (Respondent) for the entire unpaid principal amount of this Promissory Note, together with interest, in any court of record, Federal or State; to waive the issuance and service of process upon ---------- (Respondent) in any suit on this Promissory Note; to waive any venue requirement in such suit; to release all errors which may intervene in entering up such judgment or in issuing any execution thereon; and to consent to immediate execution on said judgment.

---------- (Respondent) hereby ratifies and confirms all that said attorney may do by virtue thereof.

This Promissory Note may be prepaid in whole or in part by Respondent by bank cashier's or certified check at any time, provided that accrued interest on the principal amount prepaid shall be paid at the time of the prepayment.

By
Title
Date

By the Commission.

Francis C. Humey,
Secretary.

[FR Doc. 84-24313 Filed 9-13-84; 8:45 am]

BILLING CODE 6720-01-M
Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 600, 803, 1002, and 1003

Medical Device Reporting; Final Rule
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 600, 803, 1002, and 1003
[Docket No. 79N-0182]

Medical Device Reporting

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that requires manufacturers and importers of medical devices, including diagnostic devices, to report to FDA whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. FDA is taking this action under the Medical Device Amendments of 1976.

The final rule is intended to assure that FDA is informed promptly of all serious problems or potentially serious problems associated with marketed devices. FDA is the principal public health agency responsible for ensuring that devices are safe and effective. To carry out its responsibilities, the agency needs to be informed whenever a manufacturer or importer receives or otherwise becomes aware of information about device problems. Only if FDA is provided with such information will it be able to evaluate the risk, if any, associated with a device and take whatever action is necessary to reduce or eliminate the public's exposure to this risk. Depending on the facts and circumstances, these steps could include contacting the manufacturer or importer of the device and monitoring its voluntary actions to respond to the problem, initiating a consumer or user education program, or initiating regulatory action, such as injunction, seizure, or other enforcement action.

DATES: Comments on the conforming amendments by October 15, 1984. Effective November 13, 1984. For additional information concerning this effective date, see "Paperwork Reduction Act of 1980" appearing in the preamble of this document.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm.

4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert A. Forst, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

Background

In the Federal Register of November 16, 1980 (45 FR 76183), under the authority of sections 502(t), 519, 701(a), and 704(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(t), 360i, 371(a), and 374(e)), FDA issued a proposed rule that would have required device manufacturers, importers, and distributors to submit to FDA reports concerning devices that (1) may have caused a death or injury; (2) may have had a deficiency that could result in a death or injury or that could give inaccurate diagnostic information and, thereby, result in improper treatment; or (3) were the subject of a remedial action. Interested persons were given until February 17, 1981, to submit written comments on the proposal. FDA received more than 200 written comments. In addition, on February 2, 1981, FDA held a public hearing on the proposal at which 30 persons presented information and views. (The public hearing, announced in the proposal and originally scheduled for January 22, 1981, was rescheduled by notice published in the Federal Register of January 9, 1981 (46 FR 23641)).

Most of the comments on the 1980 proposal criticized its reporting requirements as being too broad in scope and claimed that the burden on manufacturers, importers, and distributors of complying with the requirements would outweigh any resulting benefits to the public health. Other comments, however, stated that to assure that devices are not adulterated or misbranded and are otherwise safe and effective, FDA needs to receive reports of death and serious injury, or at least death.

Subsequently, by a notice published in the Federal Register of November 24, 1981 (46 FR 57568), FDA placed the 1980 proposed rule in abeyance. FDA took this action to permit further review and evaluation of the comments received on the proposal, to permit a review of the proposal in light of Executive Order 12291, which was issued on February 17, 1981, and to permit the initiation, completion, and analysis of an inspection program of complaint files maintained by manufacturers under the current good manufacturing practice (CGMP) regulations for medical devices (21 CFR Part 820). The inspection program was designed to provide FDA with data to determine, among other things, whether FDA inspection of manufacturers' complaint files could substitute for some or all of the proposed reporting requirements.

After publication of the notice of abeyance, FDA continued to review and evaluate the comments on the 1980 proposal. The agency concluded that the broad reporting requirements of the proposed rule were not appropriate. FDA tentatively concluded, however, that information regarding device-related deaths and serious injuries should be reported even if records of these events are maintained in the manufacturers' complaint files because the resources available to the agency for inspectional programs permit FDA to review most such files only once every 2 years. FDA also tentatively concluded that the need for information concerning serious problems or potentially serious problems relating to device-related deaths, serious injuries, and malfunctions that could cause deaths or serious injuries, remains.

For these reasons, in the Federal Register of May 27, 1983 (48 FR 24014), under the authority of sections 510 and 704(a) of the act (21 U.S.C. 360 and 374(a)), as well as the sections of the act cited in the November 1980 proposal, FDA issued a reproposed rule under which manufacturers and importers of medical devices would have been required to report to FDA whenever the manufacturer or importer had information that reasonably suggested, or a person made in allegation of which the manufacturer or importer was aware, that one of its marketed medical devices (1) caused or contributed to a death or serious injury or (2) malfunctioned, if a recurrence of the malfunction was likely to cause or contribute to a death or serious injury.

FDA acknowledged that the reporting requirements in the 1983 reproposal were narrower than those in the 1980 proposal, which would have required device manufacturers and distributors (including importers) to submit reports to FDA about devices that may have caused a death or injury or that may have a deficiency that could result in a death or injury. (For a complete discussion of the differences between the proposal and the reproposal, see 48 FR 24014.)

Since publication of the reproposal, FDA has completed its "Survey of Device Manufacturer Complaint Files" (Ref. 1) (the Survey) announced in the November 24, 1981, notice of abeyance, and has analyzed the data collected. The results of this analysis compel three conclusions. First, the results show that...
FDA review of manufacturers' complaint files cannot substitute for a reporting requirement: review of such files is not a timely or efficient way for the agency to learn of device problems and could not enable FDA to protect the public health adequately. Second, the results show that the reporting requirements of the final rule do not duplicate existing reporting systems and are not unduly burdensome. Third, the results show that under the 1980 proposal, FDA would have received more than 225,000 reports each year from manufacturers alone, and that less than 12 percent of these reports would have been related to incidents involving death, serious injury, or malfunctions that could have led to death or serious injury. Given the resources available to FDA to administer a device reporting program, the agency could not review more than 225,000 reports each year, determine which ones required further investigation and action by the agency, and proceed in a timely manner to protect the public from hazardous or potentially hazardous devices. A copy of the Survey is on file in the Dockets Management Branch (FDA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville MD 20857, under Docket No. 79N-0182 and is available for review by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

Statutory Authority and Legislative History

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to maintain such records, make such reports, and provide such information to FDA as may reasonably be necessary to assure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. The legislative history of the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) reflects clear congressional intent to permit FDA to require under the authority of section 519 of the act that device manufacturers, importers, and distributors report to FDA device defects and adverse reactions to the firms' devices. H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 23 (1976). In discussing the notification provisions of section 518 of the act (21 U.S.C. 360h), the House Report, the principal legislative document on the amendments, states:

The notification provision is similar to, and to some extent patterned after, comparable authority contained in the National Traffic and Motor Vehicle Safety Act of 1968, the Radiation Control for Health and Safety Act of 1968, and the Consumer Product Safety Act of 1972. These statutes also include requirements that manufacturers provide notification of defects in their products to appropriate Federal agencies. The Committee determined that a comparable provision in new section 518(a) with respect to devices would be unnecessary since the Secretary could require the reporting of such information under the recordkeeping and reporting authority provided in new section 519 of the Act.

Statutory Authority and Legislative History

Section 519 of the act requires the Secretary to promulgate substantive binding regulations for the efficient enforcement of the act. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973); see also Weinberger v. Benton Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973); National Ass’n of Pharmaceutical Manufacturers v. FDA, 637 F.2d 877 (2d Cir. 1981); National Confectioners Ass’n v. Califano, 569 F.2d 690 (D.C. Cir. 1978); National Nutritional Foods Ass’n v. Weinberger, 512 F.2d 688 (2d Cir.), cert. denied, 423 U.S. 827 (1975). Section 502(d)(2) of the act deems a device to be adulterated, and thus prohibited from commerce under sections 301 and 304 of the act (21 U.S.C. 321 and 334), if it fails to furnish any material information required under section 519 of the act respecting the device. Section 704(e) of the act provides that every person required under section 519 of the act to maintain records and every person who is in charge or custody of such records shall, upon request of any authorized FDA employee, permit such employee at all reasonable times to have access to, and to copy and verify, such records. Section 704(a) of the act provides that for purposes of enforcement of the act, any duly authorized FDA employee is authorized, among other things, (1) to enter, at reasonable times, any factory, warehouse, or establishment in which devices are manufactured, processed, packed, or held, or to enter any vehicle being used to transport or hold devices and (2) to inspect, at reasonable times and within reasonable limits in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. Section 510 of the act requires every person who owns or operates any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device to register with FDA the person or firm that owns, and all such establishments and to list with FDA each device introduced by the person for commercial distribution. FDA's need for information about the safety and effectiveness of devices is implicit in other sections of the act, e.g., section 513 (21 U.S.C. 360c) on device classification, section 514 (21 U.S.C. 360d) on performance standards, and section 515 (21 U.S.C. 360e) on premarket approval. Thus, for example, reporting requirements may be a condition of approval under section 515.

Comments on the Reproposed Rule

In response to the 1983 reproposal, FDA received 84 written comments from interested persons. Comments were received from device manufacturers, industry trade associations, the Office of Management and Budget (OMB), and members of the public. The following is a summary of the significant comments received on the reproposal, including comments received from OMB [see paragraphs 39, 50, and 62 of this preamble], and the agency's response to them. The summary takes into account the significant comments on the proposed rule which are relevant to the reproposal and the final rule but which were not addressed in the preamble to the reproposal.
General Comments

1. Many comments assert that the proposed and reproposed rule would violate section 519 of the act, which prohibits the promulgation of reporting and recordkeeping requirements that are unduly burdensome. FDA also received comments that claim that the proposed and reproposed rule would not impose any undue burden on device manufacturers, importers, or distributors. The reporting requirements included in the reproposed rule were considerably narrower than those included in the November 1980 proposal, which FDA concluded were unnecessarily broad (see 48 FR 24014). Whether or not the provisions of the proposed rule would have been unduly burdensome, FDA could not have processed in an effective manner all the information they would have captured (see the “Background” section of this proposal). FDA does not believe that the provisions of the reproposed rule would have been unduly burdensome (see 48 FR 24015). In any event, as explained throughout this preamble, in the final rule, FDA has made certain that manufacturers and importers are required to report to the agency only such information as may be reasonably necessary to assure the protection of the public health. Based on the Survey, FDA estimates that it will receive, 25,100 reports annually. FDA expects that most manufacturers and importers will not need to submit any reports under the final rule. FDA recognizes, however, that some manufacturers and importers will need to submit several reports to the agency. In short, the number of reports required will vary considerably from manufacturer to manufacturer and importer to importer. Given the nature of the events that are required to be reported—device-related deaths and serious injuries, and device malfunctions that are likely to lead to deaths or serious injuries—FDA has concluded that the final rule strikes the proper balance and protects the public health while avoiding undue burdens on industry. FDA notes that the submission of 25,100 reports to FDA each year under the final rule will represent less than 4 reports for every registered device establishment.

The purpose of the final rule is to assure that FDA is informed whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. From the sake of convenience, information that is required to be reported under the final rule is referred to throughout this preamble as information about a reportable event. Only if FDA is provided with information about reportable events will it be able to evaluate the risk, if any, associated with a device and take whatever steps are necessary to reduce or eliminate the public’s exposure to this risk. Depending on the facts and circumstances, these steps could include contacting the manufacturer or importer of the device and monitoring its voluntary actions to respond to the problem, initiating a consumer or user education program, or initiating regulatory action, such as injunction, seizure, or other enforcement action. Moreover, the agency needs to receive information about reportable events promptly so that it can react rapidly to the problem and thereby prevent, to the extent possible, recurrence of any death or serious injury.

2. One comment states that FDA has not identified the occurrence of any death or serious injury of which the agency did not have timely notice. The comment also states that FDA has not identified any death or serious injury which would be prevented by the reproposed rule. The results of the Survey show that reportable deaths and serious injuries do occur for which FDA does not receive timely notice. For example, following FDA’s receipt of a complaint about an inter-aortic pump, an FDA inspection uncovered an additional 50 complaints. The firm subsequently recalled the pump. In another instance, following FDA’s receipt of a complaint about an intravenous pump, an FDA inspection uncovered more than 94 additional complaints and resulted in major changes in the device’s labeling. FDA’s experience in administering the amendments demonstrates that in these and similar instances, the agency could eliminate or reduce device-related deaths and serious injuries if FDA had timely notice of reportable events. In and of itself, therefore, reporting under the final rule will not eliminate device-related deaths or serious injuries; however, such reporting will enable FDA to take action to reduce or prevent deaths and serious injuries associated with devices.

3. Many comments contend that FDA’s existing voluntary reporting system provides adequate collection of and access to information concerning reportable events. The comments state that the purpose of the voluntary system is to encourage reports from users to manufacturers to enable manufacturers to correct any device problems; reporting to FDA will not improve this procedure. FDA also received comments stating that the existing voluntary system is not adequate to keep FDA informed of medical device problems. FDA does not believe that reporting under the current voluntary system is an adequate substitute for this final rule. At present, FDA receives reports of device problems through its voluntary Device Experience Network (DEN) system. DEN consists of reports made to the Problem Reporting Program, which is coordinated by the United States Pharmacopeial Convention, Inc., and reports made to the Government Wide Quality Assurance Program (GWQAP) and the National Electronic Injury Surveillance System (NEISS).

Based on its experience, FDA does not believe that information about all reportable events is provided to FDA under DEN. As part of the Problem Reporting Program, from time to time FDA has actively encouraged the reporting of adverse device experiences to DEN through such organizations as the American Association of Critical Care Nurses, the American College of Pathologists, and the American College of Physicians. During these periods, the number of device experience reports has significantly increased. When there is no such encouragement, FDA believes that many incidents go unreported. Through the GWQAP program, FDA receives complaints only about those products purchased under contract by the Veterans Administration and the Department of Defense. Likewise, NEISS is limited in scope; the only device-related problems that are reported to NEISS, and subsequently, to FDA, are those medical problems that are treated in the emergency rooms of participating hospitals.

FDA acknowledges that the final rule does not require users to report to manufacturers, importers, or FDA. Voluntary reporting under DEN is not an adequate substitute for the requirements of the rule because DEN is not comprehensive and because, as the results of the Survey show, information that is provided by users to
manufacturers is not always provided by manufacturers to FDA.

4. One comment argues that any final rule should require device users to report directly to FDA.

Section 519 of the act authorizes FDA to issue regulations to require manufacturers, importers, and distributors to report to FDA product defects and adverse reactions to the firms' devices (see the "Statutory Authority and Legislative History" section and paragraph 51 of this preamble). For the reasons discussed in paragraphs 26a and 26b of this preamble, the final rule does not apply to a distributor other than a wholly owned distributor, which is considered to be an affiliate company under the control of the manufacturer.

Accordingly, the final rule applies to a device user only if the user also is a manufacturer or importer.

FDA encourages device users to submit reports of device problems through the agency's voluntary DEN system (see paragraph 3 of this preamble). FDA plans to continue this voluntary system to complement the reporting requirements of the final rule.

5. One comment argues that the reproposed rule is unnecessary because it duplicates requirements under §§ 820.162 and 820.198 of the CGMP regulations to investigate device-related incidents of death and serious injury.

The comment also argues that under § 7.46 (21 CFR 7.46) of FDA's guideline on policy, procedures, and industry responsibilities concerning recalls, a manufacturer is required to notify the appropriate FDA district office immediately if the manufacturer believes that one of its marketed devices is in violation of the act.

Under § 820.162, after a device has been released for distribution, a manufacturer is required to investigate any failure of a device or any of its components to meet its performance specifications and to establish and maintain a written record of the investigation, including the manufacturer's conclusions and followup. Under § 820.198, a manufacturer is required to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications and any complaint pertaining to injury, death, or any hazard to safety and to maintain a written record of the investigation.

Under § 820.180, a manufacturer is required to retain records of such investigations. However, §§ 820.162, 820.198, and 820.180 do not require any report or other information about a failure or complaint to be transmitted to FDA. In many instances, FDA becomes aware of these failures and complaints only when the agency reviews a manufacturer's complaint files. Generally, FDA conducts a CGMP inspection, including a records review, at a firm only every other year. The agency does not expect that such inspections will be conducted any more frequently in the future. If the agency were to rely on its inspection of manufacturer records for notification of reportable events, there could be as much as a 2-year period intervening between such an event and the time the agency became aware of it. During that intervening period, the agency would be able to do little to reduce or eliminate the risk presented by the device, simply because it would be unaware of the risk.

The results of the Survey show that reliance on §§ 820.162 and 820.198, as suggested by the comments, would require FDA to examine more than 225,000 complaints to identify those that are reportable events under the final rule. As explained in the "Background" section and paragraph 17 of this preamble, FDA could not review 225,000 reports submitted to the agency to determine which ones required further investigation by FDA, and proceed in a timely manner to protect the public from hazardous or potentially hazardous devices. It follows that the agency could not effectively review and process, on site, more than 225,000 complaints annually.

In short, investigation of device failures and complaints of failures and maintenance of records of such investigations, required by the CGMP regulations, help achieve the public health objectives of those regulations but are not a substitute for the reporting requirements of this final rule. Also, the CGMP regulations do not apply to importers.

Likewise, FDA's recall guidelines do not require a device manufacturer or importer to submit any information to the agency. Under § 7.46, a firm is requested to notify FDA voluntarily whenever the firm removes or corrects a distributed product that the firm believes to be in violation of the act; any submission under § 7.46.is wholly voluntary and the failure to submit information under that section is not a violation of law. The final rule makes mandatory the submission of a report whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

8. One comment argues that FDA should complete its investigation of manufacturers' complaint files before establishing reporting requirements to ensure that only necessary requirements are imposed.

FDA does not believe that completion of the Survey was a prerequisite to the promulgation of this or any other medical device reporting rule. As stated in the "Background" section of this preamble, however, FDA has completed the Survey. The agency has concluded that this final rule imposes only those requirements necessary to enable FDA to carry out its responsibilities to protect the public health and that the data from the Survey support this conclusion.

7. One comment recommends that any final rule not require submission of a report of a device incident which could be construed as an admission that the death or serious injury was caused by the device.

The information required in the report is set forth in § 803.24(c) of this final rule. FDA does not believe that the submission of information that reasonably suggests that a device may have caused or contributed to a death or serious injury will be treated by the courts as an admission that the device actually caused or contributed to a death or serious injury. FDA advises, however, that whether the courts will treat the submission of this information as an admission is strictly within the authority of the courts to decide, on a case-by-case basis.

8. Two comments argue that the reproposed rule violates the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), because the requirement to report a malfunction, if, as a result of a recurrence of the malfunction, the device or any other device marketed by the manufacturer or importer is likely to cause or contribute to a death or serious injury, calls for speculation and will result in reports of minor device problems. A third comment argues that the reproposed rule violates section 3506(a) of the Paperwork Reduction Act of 1980, which provides that "[e]ach agency shall be responsible for carrying out its information management activities in an efficient, effective, and economical manner" because requiring reports based on mere allegation is speculative, inefficient, ineffective, and uneconomical.

FDA disagrees with the comments. The requirement to which the first two comments refer calls for the exercise of professional judgment rather than
speculation (see paragraphs 58 and 60 of this preamble). Further, if information reasonably suggests that a device has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, the device problem is not "minor." FDA has demonstrated the practical utility of and the need for the information required to be submitted under the final rule. The rule accordingly complies with the Paperwork Reduction Act of 1980.

The final rule does not require reports based on "mere allegation." For this reason, the third comment is not directly relevant. The final rule requires reporting whenever information reasonably suggests that a reportable event has occurred. As discussed in paragraph 38 of this preamble, if a health care professional informs a manufacturer or importer that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, such information reasonably suggests that a reportable event has occurred.

FDA believes that it is not speculative, inefficient, ineffective, or uneconomical for the agency to require the submission of information about reportable events before such events have been confirmed by the manufacturer or importer. Reasonable persons may differ as to whether a death or serious injury is device-related. Reasonable persons also may differ as to whether, as a result of recurrence of a malfunction, a device is likely to cause or contribute to a death or serious injury. FDA, as the public health agency responsible for protecting the public from unsafe devices, should make an independent evaluation of the device's role, if any, in a reportable event. It would be irresponsible for FDA to wait for confirmation of a reportable event by a manufacturer or importer before requiring reporting of any information about such event.

9. Two comments recommend that the final rule not become effective for 180 days after publication in the Federal Register to enable manufacturers and importers to establish internal procedures to administer the new reporting requirements.

FDA disagrees with the comments. FDA believes that 90 days is a reasonable period for manufacturers and importers to establish a procedure for complying with the provisions of the final rule. Manufacturers should already have in place procedures for investigating device failures under § 820.162, for reviewing, investigating, and evaluating device complaints under § 820.198, and for maintaining records under § 820.180 (see paragraph 5 of this preamble). (Those provisions of the CGMP regulations became effective on Dec. 18, 1978.) Thus, the only additional requirements that the final rule imposes on manufacturers are those of establishing procedures for preparing and submitting a report or additional information to the agency, and for retaining records under final § 803.31(d) (see paragraph 90 of this preamble).

FDA recognizes that importers are not subject to the requirements of §§ 820.162 and 820.198. FDA believes, however, that 90 days is a sufficient period for importers to establish a complaint file and procedures for maintaining such a file; to establish procedures for preparing and submitting a report or additional information to the agency, and to establish procedures for retaining records under final § 803.31(a) and (b) (see paragraphs 89, 90, and 61 of this preamble).

To assure that device manufacturers and importers are aware of their responsibilities under this final rule, FDA will mail to every manufacturer and importer registered with FDA a copy of the rule as published in the Federal Register.

Economic Impact

10. Many comments claim that the reproposed rule would be too costly in comparison with any benefit to be derived from it.

FDA disagrees with the comments. As explained throughout this preamble, FDA has concluded that receipt of information about reportable events is necessary to enable the agency to carry out its responsibilities to protect the public health. The threshold assessment of the cost impact of the final rule shows that the cost of the rule will be no more than $4 million based on the submission of 25,100 reports. The benefits from the final rule—the prevention or reduction of device-related deaths and serious injuries—justify the anticipated cost of the final rule to device manufacturers and importers.

11. Several comments state that, due to the definition of serious injury in the reproposed rule, FDA would require reporting of minor device problems and anticipated adverse experiences. These comments argue that FDA based its threshold assessment of the reproposed rule on an estimate of the number of reports of serious device problems which would be submitted, thereby underestimating the number of reports that would be submitted to the agency. The comments argue further that reporting of minor device problems and anticipated adverse reactions would not provide any benefit to the public health.

Under § 803.3(e) of the reproposed rule, a serious injury was defined as an injury that (1) is life threatening, (2) necessitates immediate medical or surgical intervention by a health care professional to (i) preclude permanent impairment of a body function or permanent damage to body structure, or (ii) relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure. FDA agrees that some device problems that led to such an injury could fairly be characterized as "minor" device problems. FDA believes that it is not underestimating the number of reports which would be submitted to the agency. The comments argue that FDA based its rule, if any, in a reportable event. It thus, the only additional requirements that the final rule imposes on manufacturers are those of establishing procedures for preparing and submitting a report or additional information to the agency, and for retaining records under final § 803.31(d) (see paragraph 90 of this preamble).

FDA agrees with the comments. FDA believes that the threshold assessment for the final rule does not include the cost of submitting reports of minor device problems because such reports are not required by the rule.

12. Several comments state that FDA has neglected to include in the threshold assessment for the reproposed rule any estimate of the cost of submitting additional information when required by FDA and of complying with FDA inspections initiated in response to the receipt of a report.

The cost of submitting additional information to FDA if required under § 803.24(e) is not significant. Under § 820.162 of the CGMP regulations, if a device has been released for distribution, a manufacturer already is required to investigate any failure of a device or any of its components to meet its performance specifications and to establish and maintain a written record of the investigation, including the manufacturer's conclusions and followup. Under § 820.198, a manufacturer already is required to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications and any complaint pertaining to injury, death, or any hazard to safety and to maintain a written record of the investigation.
Accordingly, any additional information required under § 803.24(a) should already have been gathered, reviewed, and evaluated under §§ 820.182 and 820.195. The agency has found that an FDA inspection initiated in response to the receipt of a report cannot be estimated because any such cost would depend critically on the results of the inspection. For manufacturers, virtually the only costs imposed by the final rule are those of establishing procedures for, and preparing and submitting, a report or additional information to the agency and for retaining records under final § 803.31(d) (see paragraphs 90 and 91 of this preamble).

Under the final rule, importers are not required to review, evaluate, or investigate a reportable event. For importers, therefore, the only costs imposed by the final rule are those of establishing procedures for, and maintaining, complaint files; establishing procedures for, and preparing and submitting, a report or additional information to the agency; and establishing procedures for, and retaining, records under final § 803.31(a) and (b) (see paragraphs 89, 90, and 91 of this preamble).

13. One comment states that FDA did not include in its threshold assessment the cost of legal review of a report before initial submission. The per report cost used by FDA to determine the total cost of the final rule took into account 13 independent estimates submitted to FDA in comments on the November 1980 proposal. Although the estimates did not include data or information concerning the cost of legal review, they apparently include all costs that those preparing the estimates thought necessary in submitting a report to FDA, including legal review. FDA notes that the rule does not require those submitting reports to FDA to subject the reports first to legal review.

14. Several comments state that FDA failed to include in its threshold assessment for the reproposed rule the costs of more expensive product liability insurance and increased product liability litigation that would be caused by the reproposed rule. FDA has no reason or evidence to believe that the final rule will result in increased product liability litigation and, therefore, did not include in its threshold assessment costs associated with such litigation (see paragraph 43 of this preamble). The cost of product liability insurance is determined primarily, though not exclusively, by the product liability experience of the insurance carrier. If an increase in product liability litigation does not occur as a result of the final rule, then an increase in product liability insurance will not occur as a result of the final rule.

FDA notes that none of the comments contain any data to substantiate the claim that product liability insurance premiums and litigation would increase as a result of the promulgation of any medical device reporting rule, nor do the comments include any basis for the statement that insurance carriers will raise the cost of product liability insurance in anticipation of increased product liability litigation.

15. Four comments contend that FDA has underestimated the number of reports that would be received under the reproposal.

FDA agrees with the comments. In the threshold assessment for the reproposed rule, FDA estimated that 7,050 reports would be submitted annually. This estimate was based on data from DEN, which as discussed in paragraph 3 of this preamble, is not comprehensive. Based on data from the Survey, FDA estimates that under the final rule no more than 25,100 reports will be submitted annually (see paragraph 1 of this preamble). FDA believes that the data collected under the Survey are valid and has used the 25,100 estimate in its threshold assessment for the final rule.

16. One comment claims that under the reproposed rule, the diagnostic device industry would be required to submit 2,000,000 reports each year.

FDA disagrees with the comment. Based on the Survey, FDA projected that 18,000 reports of failure to diagnose are received each year by manufacturers of diagnostic devices. FDA estimates that under the final rule, only a fraction of these failures to diagnose will be required to be reported.

Scope

17a. Several comments suggest that to protect the public health adequately, FDA return to the reporting requirements in the November 1980 proposal.

Under the 1980 proposal, manufacturers, distributors, and importers would have been required to submit to the agency reports concerning devices that (1) may have caused a death or injury; (2) may have had a deficiency that could result in a death or injury or that could give inaccurate diagnostic information and, thereby, result in improper treatment; or (3) were the subject of a remedial action by the manufacturer. FDA received more than 200 written comments on the proposed rule, and 30 persons presented information and views at a public hearing on the proposal. After reviewing these comments, FDA tentatively concluded that the requirements proposed in 1980 would have been unnecessarily broad, and might have resulted in reports not useful to the agency (49 FR 24014). The data from the final rule support this conclusion. Under the proposal, FDA would have received more than 225,000 reports annually from device manufacturers. Most of these reports would have been for minor device problems that now are adequately corrected without FDA involvement. This figure, moreover, does not include reports that would have been received from device distributors and importers. Given the resources available to FDA to administer a device reporting program, the agency could not review more than 225,000 reports each year, determine which ones required further investigation and action by the agency, and take whatever steps were necessary to reduce or eliminate the public's exposure to devices that proved hazardous or potentially hazardous (see the "Background" section and paragraphs 1 and 5 of this preamble). FDA believes that the reporting requirements of the final rule will ensure that the agency is informed of the more serious device problems that may require FDA involvement to protect the public health.

FDA advises that on its own initiative, it has revised final §§ 803.1(a) and 803.24 to require reporting whenever information reasonably suggests that a device "may have" caused or contributed to a death or serious injury, instead of whenever information reasonably suggests that a device "has" caused or contributed to a death or serious injury, as was reproposed in §§ 803.1(a) and 803.24. FDA revised the final rule in this manner because the agency needs to learn of instances in which there may be an association, as well as a causal connection, between the use of a device and a death or serious injury. If data or other information establish the existence of such an associated, relabeling of the device to disclose the association may be required under sections 502(a) and 201(n) of the act (21 U.S.C. 352(a) and 321[n]), as was the case when the occurrence of toxic shock syndrome was found to be associated with the use of menstrual tampons (see 47 FR 26982; June 22, 1982) (21 CFR 801.430). Data or other information establishing the existence of an association between the use of a device and a death or serious injury also could provide the basis for action by FDA under section 518 of the act to require notification and other remedies. In addition, regulatory action...
under other provisions of the act, publicity, FDA-requested recalls under Part 7, or educational programs could be based on a finding that a death or serious injury is associated with a device. 36332 Federal Register / Vol. 49, No. 180 / Friday, September 14, 1984 / Rules and Regulations, however, that imposition of an unqualified obligation to cease distribution upon receipt of information that reasonably suggests that a death or serious injury related to the device has occurred. The requirement recommended by the comment is beyond the scope of this rulemaking proceeding. FDA believes, however, that imposition of an obligation to cease distribution upon receipt of information about a reportable death or serious injury, before the manufacturer, importer, or FDA had conducted any investigation of the event, would be unwise. The decision to cease distribution should be made on a case-by-case basis, taking into account such factors as the risks inherent in, and the benefits presented by, the use of the device, and the nature of the information that reasonably suggests that the device "may have caused or contributed to" the death or serious injury. FDA believes that where the facts and circumstances warrant, a responsible manufacturer or importer will voluntarily cease distribution of a marketed device. FDA notes that where the facts and circumstances are such that the device is in violation of the law, e.g., misbranded or adulterated within the meaning of section 501 or 502 of the act (21 U.S.C. 351 or 352), the agency will take whatever action is necessary to protect the public health. 18. One comment suggests that for class I (general controls), class II (performance standards), and class III (premarket approval) devices FDA adopt the reporting requirements currently imposed by FDA as a condition to premarket approval for class III devices that now require such approval.

FDA disagrees that the reporting requirements referred to in the comments should apply to all marketed devices. These requirements are specially designed to enable the agency to monitor the performance in the population-at-large of devices which, unlike class I and class II devices, and class III devices that do not now require premarket approval, do not have a history of marketing. For the reasons discussed in paragraph 96 of this preamble, however, manufacturers and importers of class III devices that now require premarket approval are subject to the provisions of the final rule, along with any specific requirements imposed on the approval orders for such devices.

19. One comment suggests that reports be required if a device does not meet its labeling specifications or a performance standard and, thereby, is ineffective. According to the comment, under the reproposed rule, a report would not be required unless such ineffectiveness falls under the definition of serious injury.

For the reasons discussed throughout this preamble, FDA has limited the reporting requirements under the final rule to instances in which information reasonably suggests that a device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Although the need for reports is not as great if the ineffectiveness of the device does not directly or indirectly pose a risk of death or serious injury, FDA strongly encourages voluntary reporting about ineffective devices.

20. One comment suggests that FDA exclude from the final rule any requirement to report adverse experiences disclosed in a device's labeling. The comment claims that this exclusion would be consistent with FDA's position stated in the preamble to the reproposed rule (48 FR 24019) "that FDA may notify a manufacturer or importer that a report of a particular type of event is no longer required (e.g., the injury reported becomes recognized by FDA as an inherent risk of using the device in which event it would become part of the product labeling)."

FDA recognizes that there are inherent risks associated with the use of certain devices and that the labeling for some of these devices properly informs the user of these risks. However, the comment misconstrued the statement cited by the comment. Even if the occurrence of a reportable event is disclosed in the device's labeling, a manufacturer or importer is subject to the obligation to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

In general, the agency reviews labeling for medical devices before marketing as part of its review of three types of documents, premarket approval applications, reclassification petitions, and premarket notification submissions. The largest category of documents is premarket notification submissions under section 510(k) of the act and Subpart E of Part 807 of FDA's regulations (21 CFR Part 807). FDA's review of these submissions is intended to permit the agency to determine the status of a postamendments device under section 513(f) of the act, which requires premarket approval or reclassification of any postamendments device that is not "substantially equivalent" to a preamendments or reclassified device. In determining whether a postamendments device is substantially equivalent to a preamendments or reclassified device, FDA considers whether the device presents risks and benefits not materially different from those of the preamendments or reclassified device. For a postamendments device to be "substantially equivalent," its intended use must be the same as, and its materials, design, and energy source, among other things, must not differ materially from, those of a preamendments or reclassified device. In addition, any variation between the postamendments device and the already marketed device must not materially affect safety or effectiveness. See H.R. Rep. No. 94-853, supra, at 36. Congress did not intend or authorize FDA to review a premarket notification submission for the purpose of determining whether the postamendments device that is the subject of the submission is safe or effective, except on a comparison basis. A determination by FDA that a postamendments device is "substantially equivalent" is thus not a determination that the device is not adulterated or misbranded and is otherwise safe and effective.

FDA's review of premarket notification submissions is not sufficiently comprehensive for the agency to state precisely how many reviewed devices have labeling that discloses, or adequately discloses, whatever risks are inherent in the use of the device. Furthermore, some devices have labeling that lists certain adverse experiences in the precautions or contraindications section of the labeling but that does not describe the frequency or expected severity of the adverse experiences. For these reasons, final § 803.24(a) requires that a manufacturer or importer report to FDA whenever information reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, regardless of the device's labeling, unless, under final § 803.24(d)(4), FDA notifies the manufacturer or importer, in writing, that a report of a particular type of event is no longer required (see paragraph 97 of this preamble).
FDA has included a narrow exception from reporting certain device malfunctions if, within 15 days of initial receipt of the information, certain conditions are met. When information reasonably suggests that a reportable malfunction has occurred, a manufacturer or importer is nevertheless not required to report if (i) the manufacturer or importer determines that a death or serious injury has not occurred; (ii) the device's labeling sets forth information concerning the potential for death or the type of serious injury that the malfunction may cause or contribute to; (iii) the device's labeling describes the malfunction, and the routine service, repair, or maintenance instructions to correct the malfunction; (iv) the malfunction has occurred or is occurring at or below the frequency and severity stated in the labeling or, if there is not any pertinent statement in the labeling, at or below the frequency and severity that are usual for the device; and (v) the malfunction does not lead the manufacturer or importer to undertake a remedial action involving any device other than the device product in which the malfunction occurred (see the discussion beginning at paragraph 51 of this preamble and new § 803.24(d)(2)(ii) of the final rule).

21. One comment suggests that only reports of life-threatening occurrences be submitted. The comment explains that when first fitted, many orthotic and prosthetic devices may cause discomfort to the patient. This discomfort may require medical intervention or some adjustment that may result in temporary impairment of body function or structure, according to the comment.

The agency believes that it needs to be informed of events other than life-threatening events. For those that cause permanent impairment of a body function or damage to body structure. Under the revised definition of serious injury in final § 803.3(h), however, an injury that is not life threatening or that does not result in permanent impairment is not "serious" unless the injury necessitates medical or surgical intervention by a health care professional to preclude permanent impairment of a body function or damage to body structure or to relieve unanticipated temporary impairment of a body function or damage to body structure (see paragraph 39 of this preamble). If the event described in the comment is not a "serious injury" as defined in § 803.3(h), then a report is not required.

22. One comment states that U.S. manufacturers should not be required to report incidents that occur in foreign countries. The comment states that foreign manufacturers are not required to submit reports to FDA concerning incidents that occur in foreign countries. The comment then argues that not requiring U.S. manufacturers to submit reports of incidents that occur in foreign countries would place U.S. manufacturers in the same competitive position as foreign manufacturers.

FDA disagrees with the comment. The agency is interested in information about any reportable event without regard to the location of the event because such information may enable FDA to assist in the protection of the public health. The rule applies equally to manufacturers and importers because both are required to register with FDA. If an importer receives information about a reportable event, a report is required regardless of the location of the event. FDA decided to exclude foreign manufacturers from the rule because, under section 519 of the act, FDA does not have authority to require a foreign manufacturer that does not offer a device for import into the United States to submit to FDA reports about the device. FDA does not believe that this lack of authority provides a competitive disadvantage to a foreign manufacturer whose device is not in commercial distribution in the United States.

23. Several comments argue that any final rule should not apply to class I devices. These comments argue that class I devices are not critical devices within the meaning of Part 820 or significant risk devices within the meaning of Part 812 of FDA's regulations governing investigational device exemptions (21 CFR Part 812), and that Part 820 and Part 812, respectively, contain different safeguards for these types of devices.

As noted in the preamble to the reproposal (48 FR 24017), FDA agrees that, in general, the lower the level of classification, the lower the risk posed by a device and the less likelihood that death or serious injury would be associated with such device.

Consequently, even without an exemption, manufacturers or importers would receive, and subsequently report to FDA, fewer reports about deaths or serious injuries associated with class I devices than they would for class II or class III devices. Yet, if information reasonably suggests that a marketed device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, its level of classification is irrelevant. Regardless of the nature of a marketed device or its classification, FDA needs to be notified of all reportable events so that the agency can respond to them.

24. One comment argues that FDA should not impose any reporting requirements until the agency has promulgated final rules classifying all devices into class I, class II, or class III. Another comment argues that any final rule should not apply to hearing aids, which FDA has proposed to classify into class II (47 FR 32860, January 22, 1982), because there allegedly have not been any injuries associated with these devices.

FDA disagrees with these comments. As discussed in paragraph 23 of this preamble, if information reasonably suggests that one of a manufacturer's or importer's marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, FDA needs to be notified. Whether the device that is the subject of the reportable event has previously been associated with injuries or is the subject of a final classification rule is irrelevant, as is the classification of the device.

25. One comment suggests that the phrase "has information" in reproposed § 803.1(a) be changed to "has received or becomes aware of information." This comment claimed that, as reproposed, a report would be required if an employee of a firm read a journal article describing a device-related incident. FDA advises that it intended the reproposed rule to apply in the circumstance described by the comment. FDA has revised § 803.24 in the final rule by substituting the phrase "receives or otherwise becomes aware of information" for the phrase "has information" to make clear this intent. FDA also has revised § 803.24 in the final rule to specify that a manufacturer or importer is required to report when the manufacturer or importer receives or otherwise becomes aware of information in a journal which reasonably suggests that a reportable event involving one of the manufacturer's or importer's marketed devices has occurred (see paragraph 53 of this preamble).

26a. Several comments suggest that independent distributors be required to report to manufacturers. The comments argue that, in many instances, the independent distributor rather than the
manufacturer of the device receives information about device problems. According to the comments, if the independent distributor does not provide this information to the manufacturer, FDA will remain uninformed and the manufacturer will be insulated from the reporting requirements, which will place in an unfair competitive position a manufacturer who sells directly to device users.

As noted in the preamble to the reproposed rule (48 FR 24016), FDA believes that manufacturers and importers generally are the most knowledgeable about their devices and are best able to evaluate any hazards or problems associated with their devices. In all likelihood, a manufacturer or importer whose identity is known will be informed by device users and independent distributors of reportable events due to the nature of these events. Therefore, under the final rule, only device manufacturers and importers are required to report. If, after implementing the final rule, FDA determines that requiring reports from independent distributors is necessary to be promptly informed of reportable events, the agency will propose such reporting requirements.

FDA does not believe that the final rule places at an unfair competitive advantage a manufacturer that has elected to sell directly to device users. FDA believes that the independent distributor has ample incentive to inform, and will inform, the manufacturer of reportable events and, accordingly, that such events will be reported to FDA.

26b. One comment asks whether a manufacturer is required to submit a report if information of a death or serious injury associated with the use of one of its devices is given to a distributor that is wholly owned by the manufacturer.

FDA advises that for the purpose of the final rule, a wholly owned distributor is considered to be an “affiliate company” under the control of the manufacturer. Accordingly, information received by a wholly owned distributor is deemed to be information received by a manufacturer. Thus, a manufacturer is required to report if information about a reportable event associated with one of the manufacturer’s marketed devices is provided to a distributor that is wholly owned by the manufacturer.

27. One comment suggests that a distributor be permitted to submit reports on behalf of a manufacturer with the manufacturer’s consent. The comment states that some distributors are much larger than some small manufacturers and better equipped to comply with the reporting requirements of any final rule.

FDA disagrees with the comment. A manufacturer is ultimately responsible for its devices and can easily furnish the information required in the report under final § 803.24(c). Under § 820.162 of the CGMP regulations, after a device has been released for distribution, a manufacturer is required to investigate any failure of a device or any of its components to meet its performance specifications and to establish and maintain a record of the investigation, including the manufacturer’s conclusions and followup. Under § 820.198, a manufacturer is required to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications and any complaint pertaining to death, injury, or any hazard to safety and to maintain a written record of the investigation. Submission of this information to FDA pursuant to a request for additional information under final § 803.24(e) should be easily within the means and expertise of the manufacturer.

28. One comment requests that FDA clarify whether the reproposed rule applies to diagnostic devices. The comment notes that diagnostic devices were specifically identified as subject to the provisions of the November 1980 proposal and that the reproposal was unclear. Another comment states that reports of death or serious injury due to misdiagnosis should not be submitted because whether a diagnostic device has caused or contributed to a death or serious injury is speculative, at best.

FDA advises that, except for in vitro diagnostic products, manufacturers of which are required to be registered under Part 607 (21 CFR Part 607) of FDA’s regulations governing establishment registration and product listing for manufacturers of human blood and blood products (see paragraph 94 of this preamble) and for general purpose articles (see paragraph 29 of this preamble), the final rule applies to all marketed devices, including diagnostic devices. FDA agrees that it may be difficult to determine whether a death or serious injury is a result of the failure of a diagnostic device to perform properly. However, if the information about the event reasonably suggests (see paragraph 38 of this preamble) that the event may have resulted from the failure of a diagnostic device to perform properly, a reportable event has occurred, and a report is required.

29. One comment requests clarification of the application of the reproposed rule to general purpose articles. The comment argues that general purpose articles should not be subject to the final rule even if a person manufactures other medical devices that are subject to the rule.

FDA agrees with the comment. General purpose articles are articles such as chemical reagents or laboratory equipment whose uses are generally known by a person trained in their use and which are not labeled or promoted for medical uses (see 21 CFR 807.65(c)). A manufacturer of general purpose articles is not required to submit reports concerning those products even if the manufacturer also markets other medical devices.

Definitions

30. Many comments request that FDA include a definition of “Malfunction” in the final rule. According to the comments, the statement in the preamble that “a device malfunction occurs whenever [the device] fails to perform its intended function” is inadequate and may result in numerous unnecessary reports (48 FR 24018).

FDA notes that a report about a malfunction is required only when information reasonably suggests that a device has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

FDA agrees that a definition of malfunction should be added to the final rule. FDA has defined “malfunction” in final § 803.3(c) and has redesignated reproposed § 803.3(c) as § 803.3(d). A “malfunction” is the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the objective intent of the person legally responsible for labeling the device. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised. This definition was chosen to make the final rule consistent with §§ 820.162 and 820.198 and with the
requirements to those firms listing manufacturer. The comment concludes manufacturer and the "distributing" reports from both the contract manufacturer, another firm's specifications, as well as manufacture a device according to § 807.65 from the requirement to register, is not subject to the requirements of this final rule. A private label distributor, i.e., a distributor that obtains a device from a manufacturer with the label already applied and that does not repackage or otherwise alter the device's package or label, is not required to register under Part 807 and, therefore, is not subject to the final rule. The agency advises that it intends to monitor closely the effect of this exclusion on the public health. If FDA determines that to protect the public health adequately it needs to make private label distributors or any other persons subject to the rule, FDA will propose appropriate amendments to the rule.

32. A comment argues that mail order firms and retailers should be excluded from the definition of manufacturer in any final rule. FDA advises that only mail order firms or retailers that are required to register under § 807.20 and that are not exempted under § 807.65 from the requirement to register are subject to the final rule.

33. One comment suggests that a manufacturer be defined as any person who is required to list a medical device under Part 807, other than a person who initially distributes a device imported into the United States. The comment asserts that the definition of "manufacturer" in § 803.3(c) of the reproposed § 803.3(c) (final § 803.3(d)) to exclude private label distributors other than those that set specifications for a device or are importers. A person who does not perform any of the activities listed in § 807.20(a) (1) through (5), which specifies who is required to register, or who is exempted under § 807.66(e) from the requirement to register, is not subject to the requirements of this final rule. A private label distributor, i.e., a distributor that obtains a device from a manufacturer with the label already applied and that does not repackage or otherwise alter the device's package or label, is not required to register under Part 807 and, therefore, is not subject to the final rule. The agency advises that it intends to monitor closely the effect of this exclusion on the public health. If FDA determines that to protect the public health adequately it needs to make private label distributors or any other persons subject to the rule, FDA will propose appropriate amendments to the rule.

34. One comment asks whether "person" includes a corporate entity. It does. In response to this inquiry, FDA has added to the final rule new § 803.6(e), which defines the term "person" as any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity.

35. Several comments object to the definition of "remedial action" in reproposed § 803.3(d) (final § 803.3(g)). The comments claim that, as defined, remedial action could include "communications" to insurance carriers, product liability attorneys, or employees who are subject to disciplinary actions. The comments argue that the definition should be limited to manufacturer actions concerning the labeling, manufacture, or distribution of a device. FDA did not intend nor does the agency believe that the definition of "remedial action" includes the "communications" referred to in the comments. Generally, remedial actions include notification or other activities that are directed to devices, health institutions, health professionals, device users, manufacturers, importers, distributors, or retailers and that are intended to correct a reportable event. FDA believes that such activities may not be limited to actions concerning the labeling, manufacture, or distribution of a device, e.g., the repair of a device in the field.

36. One comment suggests that the definition of "remedial action" in reproposed § 803.3(d) (final § 803.3(g)) be made consistent with that of "recall" in § 7.3(g), which does not include withdrawals or stock recoveries. Another comment suggests that the term "remedial action" be changed to "corrective action" and defined as any action taken by a manufacturer or importer as a result of its investigation in response to information received concerning a potential or actual device-related death or serious injury.

FDA disagrees that the definition of "remedial action" should be made consistent with that of "recall" in § 7.3(g). Although not all market withdrawals or stock recoveries constitute "remedial actions," information about those initiated in response to reportable events is necessary to enable FDA to take action to protect the public health. FDA does not believe that the suggested definition of "corrective action" differs significantly from that of "remedial action" or that changing the term "remedial action" to "corrective action" would serve any useful purpose.

37. One comment suggests that FDA define "person alleges." FDA has deleted this phrase from the final rule. Therefore, a definition is not necessary (see paragraphs 8 and 38 of this preamble concerning reporting of "allegations").

38. Several comments argue that the phrase "information that reasonably suggests" suggests a conclusion may be provided in response to information received concerning a potential or actual device-related death or serious injury, than this information "reasonably suggests" that a reportable event has occurred.

FDA agrees that the phrase "information that reasonably suggests" should be defined. FDA has added to the final rule new § 803.3(f), which provides that "information that reasonably suggests" a conclusion means (1) information (such as professional, scientific, or medical facts or opinions) from which a reasonable person would reach the conclusion, and (2) a statement to a manufacturer or importer by a health care professional [e.g., a doctor of medicine, osteopathy, dental surgery, podiatry, or chiropractic, or an optometrist, pharmacist, registered nurse, or a hospital administrator], reaching the conclusion.

Under final §§ 803.3(f)(1) and 803.24(a), information that reasonably suggests a conclusion may be provided by any user of a device, e.g., a consumer, or any other person as defined in final § 803.3(e). Under final §§ 803.3(f)(2) and 803.24(a), if a physician, for example, informs a manufacturer or importer that he or she had to replace one of the firm's implanted devices because the device
malfunctioned and a serious injury occurred, the information provided by the physician reasonably suggests that a reportable event has occurred. The manufacturer or importer may not wait until it receives the device from the physician or until it has conducted its own analysis of the device before it reports under final § 803.24(b)(1). Similarly, if a serious injury did not occur, but the physician informs the manufacturer or importer that the device has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a serious injury (or death), if the malfunction were to recur, the information provided by the physician reasonably suggests that a reportable event has occurred. The manufacturer or importer may not wait until it receives the device from the physician or until it has conducted its own analysis of the device before it reports under final § 803.24(b)(2).

FDA recognizes that new § 803.3(f)(2) provides that information furnished by a health care professional is information that per se reasonably suggests that a reportable event has occurred. FDA has concluded that this per se provision is warranted because of such persons’ special education, training, experience, expertise, and knowledge with respect to medical devices.

FDA notes that even if information received from a health care professional or any other source initially appears to require a report, a report nevertheless is not required if, within the time period for reporting, the manufacturer or importer determines that certain conditions are met (see final § 803.24(d)(3) and paragraph 51 of this preamble).

39. Many comments, including comments from OMB, object to the definition of serious injury in reproposed § 803.3(e)(1) (final § 803.3(h)(1)) on the ground that it would result in the submission of reports of minor injuries. Some of these comments argue that only permanent impairment or damage should be reported; others argue that only unanticipated events should be reported. According to the comments, users accept the fact that some unavoidable risk may be associated with a device given the condition of the patient and the inherent nature or function of the device. OMB recommends that the phrase “necessitates immediate medical or surgical intervention” in reproposed § 803.3(e)(2) (final § 803.3(h)(2)) be qualified by the phrase “by a health professional.” OMB also recommends that FDA not include in the definition of serious injury unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure.

FDA advises that it intended the definition of serious injury in the reproposed rule to include those serious health problems that require prompt action to protect the public health (48 FR 24018). In the reproposal, FDA used the word “immediate” to modify “medical or surgical intervention” and the word “unanticipated” to modify “temporary impairment of a body function or damage to body structure” to eliminate reports of minor injury. The comments have persuaded FDA that the reproposed definition could be interpreted such that manufacturers and importers would be required to submit reports of minor injuries.

FDA has revised the definition of serious injury in reproposed § 803.3(e)(2) (final § 803.3(h)(2)) by providing that the medical or surgical intervention must be undertaken “by a health care professional” to preclude permanent impairment of a body function or permanent damage to body structure or to relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure. FDA made the revision because any medical or surgical intervention that is undertaken by other than a health care professional is likely to be undertaken in response to minor injuries, e.g., cuts or bruises caused by needle pricks or a defective syringe. FDA also has revised the definition by deleting the word “immediate” before the phrase “medical or surgical intervention” because FDA does not believe that an injury is “serious” only if it necessitates immediate, e.g., emergency or same day, medical or surgical intervention. For serious pacemaker malfunctions, explanation may be indicated, but not always immediately. Thus, FDA has combined § 803.3(e)(2), (3), and (4) of the reproposal as § 803.3(h)(3) and has revised final § 803.3(h)(3) to read “necessitates medical or surgical intervention by a health care professional to (1) preclude permanent impairment of a body function or permanent damage to body structure or (2) relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure.”

FDA disagrees with the comments that argue that only permanent impairment or damage need be reported. Unanticipated temporary impairment or damage whose relief necessitates medical or surgical intervention by a health care professional is a significant event. Such impairment or damage cannot be successfully treated by a layperson. Further, if left untreated by a health care professional, unanticipated temporary impairment or damage could well result in permanent impairment or damage.

FDA disagrees with the comments that argue that only unanticipated injuries need be reported. FDA believes that a device-related incident that is life threatening, results in permanent health impairment, or requires medical or surgical intervention by a health care professional to preclude permanent health impairment should be reported to FDA whether or not anticipated. Such an incident is serious and FDA needs to know about it to determine, for example, whether the probable benefits to health from the use of the device outweigh the probable risks of injury from such use, and whether the agency needs to take any action to eliminate or reduce the public’s exposure to these risks. The final rule requires a report of an incident involving temporary health impairment only if such impairment is unanticipated. The determination whether a temporary health impairment is unanticipated will be made by the manufacturer or importer. To make clear its intent, FDA has added to final § 803.3(h)(3), the following sentence: “Temporary impairment to a body function or temporary damage to body structure is unanticipated if reference is made in the labeling for such impedance or damage is not made in the labeling for the device or, if such reference is made in the labeling for the device, the manufacturer or importer of the device determines that such impairment or damage has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device.”

40. Several comments argue that “unanticipated temporary impairment” is too vague to provide useful guidance. One of these comments suggests adding to the final rule language from the preamble to the reproposal (48 FR 24018) which stated that electrical shocks, severe lacerations, or broken bones are unanticipated events. Another comment asserts that the discussion in the preamble is inadequate because electrical shocks are not defined as to severity or duration, severe laceration is undefined, and all broken bones are considered of equal seriousness.

FDA believes that the changes to the definition of “serious injury” (final § 803.3(h)(3), discussed in paragraph 38 of this preamble, make clear the meaning
of “unanticipated temporary impairment.” FDA does not believe that specifying in the final rule electrical shocks, severe lacerations, or broken bones will further define “unanticipated temporary impairment,” or that these specific conditions are necessary as a definition.

41. One comment suggests that FDA delete reproposed § 803.3(e) (2) and (4) or add to the definition of serious injury the concept of significant medical intervention or significant temporary impairment. According to the comment, many minor injuries are corrected by medical intervention and, although unanticipated, are temporary and insignificant.

FDA disagrees with the suggestion. Under § 803.3(h) of the final rule, a serious injury is one that necessitates medical or surgical intervention by a health care professional to preclude permanent health impairment or to relieve unanticipated temporary health impairment. FDA believes that this and other changes in final § 803.3(h), as discussed in paragraph 39 of this preamble, will eliminate reports of minor injuries. Thus, there is no need to establish whether medical or surgical intervention is “significant” or whether an unanticipated temporary health impairment that requires such intervention is “significant.”

42. One comment questions whether FDA intended that all four conditions under reproposed § 803.3(e) (final § 803.3(h)) be satisfied before a report is required or whether it is necessary that only one condition be met. Another comment suggests that FDA make each condition under reproposed § 803.3(e) (final § 803.3(h)) conjunctive rather than disjunctive. Other comments, however, argue that FDA needs to receive reports of an event that meets only one of the conditions.

Under final § 803.3(h), there are only three types of serious injury. If any one of these types occurs, then an injury is “serious” and a report is required. Making all provisions of § 803.3(h) conjunctive would mean that an event would have to be life threatening before a report could be required under the final rule, which would be inconsistent with the intent of Congress in enacting section 519 of the act (see “Statutory Authority and Legislative History” of this preamble) and would prevent FDA from adequately protecting the public from serious health risks that are less than life threatening.

Confidentiality

43. Many comments express concern that the public availability of unverified reports will lead to spurious product liability claims or unjustly damage a manufacturer’s reputation and request that FDA add to the final rule a section on the confidentiality of reports. The comments suggest that the reports be considered trade secret or confidential commercial information and, as such, not available for public disclosure under § 20.61 of FDA’s regulations governing public information (21 CFR 20.61). The comments also suggest that the name of the manufacturer or importer of the device, any patient or other device user, any health care professional, or any health care institution be deleted from a report before its public disclosure.

FDA has added to the final rule new § 803.3(h) Public availability of reports. FDA is generally required under the Freedom of Information Act (the FOIA) (5 U.S.C. 552) to make publicly available reports received under this final rule. The public availability of such reports is governed by the FOIA and Part 20. As specified in new § 803.3(h), in accordance with the FOIA and FDA’s regulations, before a report is made publicly available, FDA will delete from the report information whose disclosure would constitute a clearly unwarranted invasion of personal privacy (see 5 U.S.C. 552(b)(6); § 20.63) or which constitutes trade secret or confidential commercial or financial information (see 5 U.S.C. 552(b)(4); § 20.61). However, FDA will make available to a patient who requests a report all the information in the report concerning that patient, except for trade secret or confidential commercial or financial information.

FDA notes that a good deal of information in reports of adverse reactions to approved new drugs (see 21 CFR 314.14) and in reports of device problems received under DEN is publicly available (see §§ 20.111 and 20.113). None of the comments demonstrates that a spurious product liability claim or unjust damage to any manufacturer’s reputation has resulted from the public availability of such reports.

44. One comment suggests that reports received under any final rule be kept confidential until after FDA’s investigation of the incident has been completed. Another comment suggests that a report be released only if FDA determines that the incident is device related.

Under § 20.64, information submitted to FDA under the final rule may be considered an investigatory record compiled for law enforcement purposes and, therefore, not available for public disclosure until FDA’s investigation is complete. FDA will determine on a case-by-case basis whether § 20.64 applies. FDA does not have the authority under the FOIA or Part 20 to withhold a report submitted under the final rule if the agency determines that the event that is the subject of the report is not device related.

45. One comment suggests that to ensure the confidentiality of reports FDA destroy them 1 year after the date of their receipt.

FDA disagrees with the comment. The agency believes that retention of the reports for an indeterminate period will enable the agency to undertake trend analyses and to determine the need for regulations, administrative or judicial enforcement actions, standards, guidelines, or educational programs.

46. One comment suggests that reports be kept confidential if there is ongoing litigation concerning the involvement of the device with a death or serious injury.

Under the FOIA and Part 20, FDA is without authority to withhold publicly available information because of ongoing litigation to which the government is a party. If the government is a party to the litigation, the information would be withheld from public disclosure under § 20.64 as an investigatory record compiled for law enforcement purposes.

47. One comment suggests that reports submitted in response to a request for additional information under reproposed § 803.24(e) be kept confidential.

FDA lacks authority to categorize all such reports as confidential (see paragraphs 43 and 48 of this preamble). All reports and additional information, whether submitted under § 803.24 (b) or (e) of the final rule, are subject to the same statutes and regulations regarding public disclosure.

48. One comment suggests that before disclosing a report, FDA should provide the manufacturer or importer an opportunity to explain why public disclosure of information submitted in a report is not required for protection of the public health.

The comment’s suggestion is inappropriate. Whether information is or is not required for protection of the public health is not relevant to whether the information is exempt from public disclosure under the FOIA and Part 20 (see paragraph 43 of this preamble). Under § 20.45, in situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, FDA will consult with the person who has submitted or divulged the data or information or who would be affected by disclosure before determining whether or not such data or information is available for public disclosure.
49a. Many comments request that FDA add an express disclaimer to each report released, such as “Neither the submission of information by a manufacturer or importer pursuant to this rule, nor public release of such information, constitutes an admission that a device has malfunctioned or establishes the existence of any causal connections between a product and a death or serious injury.”

FDA cannot accede to the request. Whether information submitted in a report or subsequently released by FDA constitutes an admission or establishes causation is for litigants to dispute, and the courts to decide, on a case-by-case basis. As explained in paragraph 7 of this preamble, however, FDA does not believe that the submission of the information required by the final rule will be treated by the courts as an admission.

49b. One comment suggests that the final rule recognize that a court order may prohibit release of information to FDA.

If a court order prohibits a manufacturer or importer from submitting certain information to FDA, the agency will respect the order. FDA accordingly does not believe that any provision concerning court orders needs to be included in the final rule.

When a Report Is Required

50. Several comments argue that the reproposal would require the submission of a report upon receipt by the manufacturer of a mere allegation that a death or serious injury had been caused by one of its devices. These comments claim that the legislative history of section 519 of the act does not authorize FDA to require reports of allegations that are unsubstantiated or known to be false. OMB states that requiring reporting of unsubstantiated allegations that a reportable event has occurred would be unreasonable. OMB recommends that manufacturers and importers be required to review all such “allegations” within 15 working days of initial receipt, but should not be required to report to FDA unless the manufacturer or importer determines that evidence suggests or could reasonably suggest that a device “caused or contributed to a death or serious injury.”

FDA agrees that the reproposal would have required the submission of a report upon the receipt by a manufacturer or importer of an allegation that a death or serious injury had been caused by one of its devices. As noted in paragraph 8 of this preamble, however, the requirement to report allegations has been deleted from the final rule. For the reasons discussed in paragraph 38 of this preamble, FDA has provided in new § 803.3(f), which defines the phrase “information that reasonably suggests,” that information furnished by a health care professional is information that reasonably suggests that a reportable event has occurred.

For the reasons discussed in paragraph 39 of this preamble, FDA does not agree that information about device-related deaths or serious injuries be confirmed before FDA may require that such information be reported to the agency. To carry out its responsibilities under the act, the agency needs to be informed whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury. If the final rule applied only when information reasonably suggested that a device “had” caused or contributed to a death or serious injury, FDA would not learn of instances in which there could have been an association, as well as a causal connection, between the use of a device and a death or serious injury (see paragraph 17 of this preamble). FDA notes that under final § 803.24(d)(3), even if information initially appears to require a report, a report nevertheless is not required if, within the time period for reporting, the manufacturer or importer determines that certain conditions are met (see paragraph 51 of this preamble).

51. Many comments argue that a manufacturer or importer should be required to submit a report only if the manufacturer or importer confirms that a reportable incident is device related. These comments state that manufacturers and importers receive many complaints that upon investigation are determined not to involve the manufacturer's or importer's device. One comment suggests that manufacturers or importers be required to submit unconfirmed reports only if FDA can assist in the acquisition of information to determine whether the incident was device related. Other comments argue that manufacturers or importers should submit such reports regardless of whether the manufacturer or importer believes the incident to be device related.

The legislative history provides that reasonable reporting requirements include reports of defects, adverse reactions, and patient injuries (see the “Statutory Authority and Legislative History” section of this preamble). Nowhere in section 519 of the act or its legislative history is FDA's authority limited to requiring only information about reportable events that have been confirmed by the manufacturer or importer of the device. The legislative history clearly states that the limitations under section 519 of the act should not be construed as restricting FDA's authority to obtain information needed to ensure that the public is protected from potentially hazardous devices.

Where a device may have caused or contributed to a death or serious injury, FDA, as the public health agency responsible for protecting the public from unsafe devices, should make an independent evaluation of the device's role, if any, in the death or serious injury. So long as a reasonable person would conclude that a device may have caused or contributed to a death or serious injury, where there is such a difference of opinion, FDA should review and evaluate the role of the device. Requiring reports of death or serious injury, whether or not confirmed to be device related, is consistent with both the existing requirements (21 CFR 310.301) and recently proposed revisions for reporting adverse reactions associated with new human drugs (47 FR 40622; October 19, 1982).

FDA notes that there are cases in which a device malfunctions and the nature or severity of the malfunction is such that, although the device did not actually cause or contribute to a death or serious injury, the device or another device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. For example, an incubator thermostat may malfunction in such a way that the incubator could cause or contribute to a death or serious injury of a premature baby; however, at the time of the malfunction, the incubator is not in use and, thus, the device does not cause or contribute to a death or serious injury. Under a system of reporting only confirmed device-related deaths and serious injuries, this type of incident would not be reported simply because there would not have been a death or serious injury determined to have been device-related.

When a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its devices has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, the manufacturer or importer may not wait until the malfunction recurred before notifying the agency of the
malfuction. If FDA is to be able to prevent or reduce deaths or serious injuries from devices that malfunction, or is to be able otherwise to minimize the risk to the public health from such devices, the agency needs to receive this information in a timely manner from all manufacturers and importers.

FDA recognizes that a manufacturer or importer may receive information that erroneously attributes a reportable event to one of its devices. For this reason, FDA has revised §803.24(d) in the final rule to enumerate the circumstances in which a report is not required even though the manufacturer or importer has received or otherwise become aware of information that initially appears to require a report under §803.24(a). A report respecting a death or serious injury is not required if, within 5 calendar days of initial receipt of the information, the manufacturer or importer determines that a death or serious injury has not occurred (§803.24(d)(3)(i)). A report respecting a death, serious injury, or malfunction is not required if, within 5 calendar days of receipt of the information about the malfunction, the manufacturer or importer determines that the information is erroneous in that the device that is the subject of the information was manufactured or imported by another manufacturer or importer (§803.24(d)(3)(ii)). In such circumstances, however, FDA strongly encourages the manufacturer or importer to report the event to FDA and, if known, to the manufacturer or importer that actually marketed the device.

A report respecting a malfunction is not required if, within 15 working days of receipt of information about the malfunction, (i) the manufacturer or importer determines that a death or serious injury has not occurred; (ii) the device's labeling sets forth information concerning the potential for death or the type of serious injury that the malfunction may cause or contribute to; (iii) the device's labeling describes the malfunction, and the routine service, repair, or maintenance instructions to correct the malfunction; (iv) the malfunction has occurred or is occurring at or below the frequency and severity stated in the labeling for the device or, if there is not any pertinent statement in the labeling, at or below the frequency and severity that are usual for the device; and (v) the malfunction does not lead the manufacturer or importer to undertake a remedial action involving any device other than the device for which the malfunction occurred (§803.24(d)(3)(iii)).

50. One comment states that isolated reports of adverse occurrences from use of a device may be received by many manufacturers or importers and discarded in good faith as not device related; however, the reports aggregated by FDA may reveal a previously unsuspected device problem. Many comments state that manufacturers or importers receive a lot of complaints that, upon verification, are determined to be the result of user error, a failure to service or maintain the device properly, or use of the device beyond its labeled useful life. According to the comments, the submission of reports in these circumstances will not lead to any public benefit and, therefore, is an unnecessary cost to the manufacturer or importer.

One comment states that user error may indicate improper instructions, inadequate labeling, or the need for an educational program.

FDA agrees that analysis by the agency of information from isolated reports submitted by many manufacturers and importers may result in the discovery of unsuspected device problems. FDA does not agree that reportable events attributable to user error, failure to service or maintain a device, or use of a device beyond its labeled useful life should not be reported. Reportable events determined by the manufacturer or importer to be the result of user error, improper service or maintenance, or improper use may indicate, for example, that the device is misbranded within the meaning of section 502(f) of the act (21 U.S.C. 352(f)) in that its labeling fails to bear adequate directions for use or to comply with §801.100 of FDA's regulations governing labeling for devices. FDA agrees with the comment that states that reports of events attributable to user error also may indicate the need for an educational program for consumers and professional users.

53. One comment requests clarification as to when a manufacturer or importer has accumulated sufficient information to determine that the information "reasonably suggests" or "alleges" a death or serious injury. Another comment asks how allegations would arise, how a manufacturer or importer would be made aware of them, and how a mere allegation would be reported to FDA.

As noted in paragraph 8 of this preamble, the requirement to submit a report based on an "allegation" has been deleted from the final rule. The phrase "information that reasonably suggests" is defined in new §803.3(f) of the final rule and discussed in paragraph 38 of this preamble. A manufacturer or importer is required to report whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Revisions in final §803.24(a) describe more specifically the circumstances in which a report is required: the manufacturer or importer receives or otherwise becomes aware of information in the medical or scientific literature which reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§803.24(a)(2)(i)); or the manufacturer or importer, through its own research, testing, evaluation, servicing, or maintenance of one of its devices, receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§803.24(a)(2)(ii)).

54. Many comments suggest that the phrase "or a person alleges and the manufacturer or importer is aware of the allegation" be deleted from any final rule. The comments are based on the reasonable allegation would be included in the phrase "reasonably suggests," and that reporting unreasonable, irresponsible, or unlikely allegations would be an unnecessary expenditure of industry and FDA resources. The comments further argue that reports of allegations will be misleading to the public and unjustly damage a manufacturer's reputation, that disgruntled employees, competitors, or other persons with interests adverse to the manufacturer could trigger the submission of frivolous reports, and that the reproposal would require the submission of information that may be erroneous, vague, based upon idle rumor, or clearly absurd.

FDA has deleted from the final rule the phrase "or a person alleges and the manufacturer or importer is aware of the
allegation” (see paragraph 8 of this preamble), has added new § 803.3(f) (see paragraph 38 of this preamble), and has revised § 803.24(a) (see paragraphs 17, 25, and 53 of this preamble) to define more clearly when a report is required. FDA believes that these revisions, together with the revisions in final § 803.24(d) (see paragraphs 20 and 51 of this preamble), address each of the concerns raised by the comments without compromising FDA’s ability to protect the public health.

Whether an allegation made in the course of litigation is required to be reported depends on whether the allegation reasonably suggests that one of the manufacturer’s or importer’s marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

56. Several comments argue that a report should be required only if a death or serious injury has occurred and that device malfunctions should not be reported. According to the comments, the reproposal would require that the manufacturer or importer determine whether the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

55. One comment suggests that FDA not require the submission of allegations during litigation where the manufacturer or importer has a reasonable basis to believe that the allegation is not well founded.

As explained in paragraph 57 of this preamble, FDA believes that the allegation reasonably suggests that one of the manufacturer’s or importer’s marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

56. Several comments argue that a report should be required only if a death or serious injury has occurred and that device malfunctions should not be reported. According to the comments, the reproposal would require that the manufacturer or importer determine whether the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

57. Several comments suggest that to eliminate reports of routine service and maintenance, a device malfunction should not be required to be reported if such malfunction (i) has not recurred and is not likely to recur; (ii) did not occur during the performance of an intended therapeutic or diagnostic use of the device; or (iii) was corrected or is correctable by routine service or maintenance.

FDA agrees in part with the comments. FDA believes that agency resources allocated to the implementation of this final rule should not be spent monitoring device problems that can be corrected by routine service or maintenance. As discussed in paragraph 20 of this preamble, new § 803.24(d)(3)(iii) has been added to provide that a report is not required under certain specified circumstances. FDA believes that these changes in the final rule will eliminate reports of routine device service, repair, and maintenance.

FDA disagrees with the comment suggesting that the malfunction must recur or be likely to recur before the manufacturer or importer is required to report. FDA believes that if a device malfunctioned, another device marketed by the manufacturer or importer also could malfunction because, generally, all devices of the same type are produced under the same manufacturing practices. FDA also disagrees with the comment that the malfunction must occur during the performance of an intended therapeutic or diagnostic use of the device. A reportable malfunction under § 803.24(a) (1) or (2) of the final rule could occur when a device is not in use. FDA needs to know about such malfunctions so that it can take action to reduce or eliminate the risk of death or serious injury should the malfunction recur when the device is in use (see paragraphs 51 and 56 of this preamble).

58. One comment argues that a malfunction should not be required to be reported if it results from improper or inadequate maintenance by the user, unauthorized modification, or misuse or negligent handling.

FDA disagrees with the comment. For the reasons explained in paragraph 52 of this preamble, FDA does not believe the requirement to submit a report under final § 803.24(a) (1)(ii) or (2) be determined by the manufacturer’s or importer’s assessment whether the malfunction is due to user error or misuse.

59. One comment asserts that a death or serious injury should not be required to be reported unless it is associated with or related to a device malfunction.

FDA disagrees with the comment. A device that performs to its specifications or otherwise performs as intended does not “malfunction” as defined in the final rule. However, because of flaws in its labeling or because of user error (see paragraph 52 of this preamble), such a device could cause or contribute to a death or serious injury. Therefore, FDA concludes that reporting should not be limited in the manner suggested by the comment.

60. One comment requests guidance about who determines the severity of a malfunction and whether it would generate a serious injury. Under final § 803.24(a), the manufacturer or importer determines whether information “reasonably suggests” (see § 803.3(f) of the final rule and paragraph 38 of this preamble) that a malfunction has occurred and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If a health care professional informs a manufacturer or importer that one of its marketed devices has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be
likely to cause or contribute to a death or serious injury if the malfunction were to recur, a reportable malfunction has occurred. In such circumstance, the manufacturer or importer does not determine the severity of the malfunction or whether the malfunction would generate a serious injury. In all other circumstances, the manufacturer or importer is required to make a determination with respect to the likelihood (see paragraph 56 of this preamble) that, as a result of a recurrence of the malfunction, the device or any other device marketed by the manufacturer or importer will cause or contribute to a death a serious injury. To the extent that this determination requires an assessment of the severity of the malfunction, the manufacturer or importer necessarily would have to make such assessment.

61. Three comments suggest that the phrase "or contributed to" in reproposed § 803.24(a) be eliminated because it is vague. The comments claim that the phrase will cause manufacturers or importers to submit a report for every service call or even when the device played only a minor role in the reportable event. One comment suggests the phrase "likely to cause or contribute to" be replaced by "likely to be a determinant" in the case of a malfunction.

FDA disagrees in part with the comments. If a manufacturer or importer receives information that reasonably suggests that one of its devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, a report is required. In this context, the phrase "contribute to" means to play a part in the death or serious injury. As defined, FDA believes that the phrase "contribute to" is not vague, provides adequate guidance to manufacturers and importers concerning a reportable event, and will not result in the submissions of reports of every service call. Deaths or serious injuries in which a device played a part, however, are reportable events under the final rule.

FDA disagrees that the phrase "likely to cause or contribute to" should be replaced by the phrase "likely to be a determinant" in the case of a malfunction. The latter phrase would limit reportable events to those in which a malfunction likely was a cofactor, would be inconsistent with the legislative history of the amendments in general and section 519 in particular, and would preclude FDA from carrying out its statutory mandate to evaluate the risk, if any, associated with potentially hazardous devices.

Time Requirements

62. Several comments argue that the 15-working-day time period is too long. The comments recommend shortening the time period for reporting a death or serious injury. OMB notes that 15 working days is 3 weeks and suggests that FDA reassess whether device-related deaths should be reported earlier than 3 weeks after they occur. Several comments state that the time periods used in the November 1980 proposal (45 FR 76183), 72 hours for reports by telephone of death and 7 working days for written reports of injury, would be reasonable because under the reproposed FDA would not require much information in the telephone or written report.

FDA agrees that to enable timely involvement by the agency, FDA needs to receive reports of death and serious injury sooner than 15 working days after the manufacturer or importer receives or otherwise becomes aware of the information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury. As discussed in paragraph 39 of this preamble, FDA has revised the definition of "serious injury" in final § 803.3(b) to exclude minor injuries. For this reason, FDA believes that serious injuries and deaths should be subject to the same reporting requirements. Accordingly, FDA has revised final § 803.24(b) to require a telephone report as soon as possible but no later than within 5 calendar days of initial receipt, by the manufacturer or importer, of information that reasonably suggests that a device-related death or serious injury has occurred.

FDA recognizes that the 5-calendar-day time period for telephone reports of device-related deaths and serious injuries is shorter than the 15-working-day time period proposed for reports of any fatal or life-threatening adverse drug experience not mentioned in the product labeling (46 FR 46622; October 19, 1981). The shorter time period is warranted because the relationship between a device and a death or serious injury generally is easier to discern than is the relationship between a death or serious injury and a drug product; in the latter circumstance, but not the former, factors such as a clinically significant drug/drug interactions or sensitivity reactions may make it difficult to determine whether there is any link between the product and the death or serious injury. For these reasons, FDA believes that the 5-calendar-day time period for providing FDA, by telephone, information about device-related deaths and serious injuries is reasonable.

Under final § 803.24(b)(1), the manufacturer or importer is also required to submit a followup written report within 15 working days of initial receipt of the information by the manufacturer or importer requiring a telephone report.

FDA recognizes that the 5-day time period for telephone reports of deaths and the 15-day time period for written reports of serious injuries are longer than those specified in the November 1980 proposal. FDA emphasizes, however, that under final § 803.24(b) telephone reports of device-related serious injuries are required to be submitted as soon as possible, but no later than within 5 calendar days of initial receipt of the information; under the proposal, information about such injuries would not have been required until 7 working days after receipt of the information. The change from 3 to 5 calendar days for reporting device-related deaths gives manufacturers or importers a reasonable time to gather the information specified in final § 803.24(c) and to determine under final § 803.24(d)(3) (i) or (ii) that a report is not required.

63. Many comments state that a manufacturer or importer should be deemed to be in compliance with any final rule based upon reproposed § 803.24(b) if the manufacturer or importer transmits the written report within the specified 15-day time period. Requiring receipt by FDA within the 15-day time period would discriminate against manufacturers and importers located on, for instance, the west coast, because transmittal time is longer for them than for manufacturers and importers located close to FDA in Maryland, where reproposed § 803.33 would require reports to be submitted.

FDA agrees with the comments and has revised final § 803.24(b) to require that the written report be submitted to FDA, i.e., postmarked or otherwise dated upon dispatch, to FDA within 15 working days of initial receipt of the information by the manufacturer or importer.

64. Several comments request clarification of whether the 15-working-day time period applies to the written report required under reproposed § 803.24(a) and to any additional information required by FDA under § 803.24(e).

The 15-working-day time period in final § 803.24(b) applies only to the written report. As FDA stated in the
preamble to the reproposal (48 FR 24020), if FDA requires a manufacturer or importer to submit additional information, FDA will state in the request the date by which the manufacturer or importer is required to submit the information. Final § 803.24(e) has been revised accordingly.

65. One comment requests clarification as to whether the 15-working-day time period applies if a telephone report is made. The telephone report to which the comment refers was an option under reproposed § 803.24(b). If such a report was made, a confirming written report would have been required to be received by FDA within 15 working days of initial receipt of the information. As explained in paragraph 62 of this preamble, under final § 803.24(b)(1), a telephone report within 5 calendar days is required in certain circumstances. Within 15 working days of initial receipt of the information, a written report is required to be submitted to FDA. Thus, the 15-working-day time period still applies when a telephone report is made.

66. Several comments suggest that the 15-working-day time period in reproposed § 803.24(b) was extended to at least 30 days. The comments argue that such a time period would allow importers time to consult with the foreign manufacturers before submitting reports and would allow all manufacturers time to obtain the information required in the report by reproposed § 803.24(c). Other comments suggest that FDA permit manufacturers or importers to request extensions of time, if necessary, to obtain the required information.

FDA disagrees with the comments. FDA believes that it would be inconsistent with section 519 of the act and its legislative history and with FDA's responsibility to protect the public health for the agency to permit manufacturers or importers to wait 30 working days—a month and a half—before reporting to FDA that one of its marketed devices may have caused or contributed to a death or serious injury. In response to comments arguing that the 15-working-day time period in the reproposal would be too long, after reconsidering the appropriateness of that time period, especially in light of the minimal amount of information that is required to be included in the report, and as discussed in paragraph 62 of this preamble, FDA has concluded that it is reasonable to require the prompt submission of information that reasonably suggests that a device may have caused or contributed to a death or serious injury. Therefore, the final rule requires a manufacturer or importer to provide such information to the agency as soon as possible, but no later than within 5 calendar days of its initial receipt (see paragraph 62 of this preamble). FDA believes that manufacturers and importers should be able to assemble, process, and submit the information required in the report within the allotted time period. The final rule does not require that the manufacturer or importer provide in the report under final § 803.24(c) any information not in its possession (see paragraphs 12, 69, and 81 of this preamble). Therefore, an extension of time should not be necessary.

67. Several comments suggest that the phrase “essential information” in reproposed § 803.24(b) be eliminated because it is vague and that the phrase “the information in § 803.24(c)” be used. FDA agrees with the comment and has revised final § 803.24(b)(1) and (2) accordingly.

68. Several comments argue that FDA should require only one submission concerning a reportable event, and that this information should be required to be submitted only after the manufacturer or importer has completed its investigation of the event. FDA disagrees with the comment. Only a minimal amount of information about a reportable event is required in the report under final § 803.24(c). If information reasonably suggests that a marketed device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, FDA needs to be promptly advised to evaluate the possible risk to health posed by the device and to take whatever steps are necessary to reduce or eliminate the public's exposure to this risk. In some cases, FDA may conclude that the information provided in the report is adequate for FDA to take whatever additional action is necessary to protect the public health. In other cases, FDA may conclude that further action by FDA or the manufacturer or importer is not necessary. In still other cases, FDA may determine that it needs information in addition to that provided in the report. The submission of a report to FDA soon after the reportable event has occurred will enable the agency to initiate its own investigation, if deemed necessary, or to assist the manufacturer or importer in obtaining information from third parties. Thus, whether FDA will need information about a reportable event in addition to that provided under final § 803.24(c) will depend on the facts and circumstances of each matter. In any case, for the reasons discussed in paragraphs 50, 51, 53, and 57 of this preamble, FDA has concluded that it should not delay its review or any investigation of a reportable event until after a manufacturer or importer has completed its investigation of the same event.

69. One comment argues that FDA may require only the submission of information in the possession of the manufacturer or importer and that FDA does not have authority to require that a manufacturer or importer collect the additional information.

FDA disagrees with the comment. Section 519(a) of the act authorizes FDA to require manufacturers and importers to maintain such records, make such reports, and provide such information to FDA as may reasonably be necessary to assure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. Nowhere in section 519 of the act or its legislative history is there any indication that Congress intended to limit FDA's authority in the manner claimed by the comment. Moreover, section 519(a)(5) of the act provides that the agency may not require the manufacturer or importer of a class I device to maintain for such a device records respecting information not in its possession or to submit with respect to such device information not in its possession, unless such report or information is necessary to determine if the device should be reclassified or is adulterated or misbranded. Thus, by negative implication, as well as its explicit language, section 519(a) of the act authorizes FDA to require the collection and submission of information not in the possession of manufacturer or importer, albeit with certain limitations on that authority insofar as class I devices are concerned.

FDA advises, however, that nothing in the final rule requires a manufacturer or importer to submit to FDA information not in the possession of the manufacturer or importer (see §§ 803.24(c) and (e) of the final rule and paragraphs 12, 66, and 81 of this preamble). In any event, under § 820.162 of the CGMP regulations, after a device has been released for distribution, a manufacturer already is required to investigate any failure of a device or any of its components to meet its performance specifications and to establish and maintain a written record of the investigation, including the manufacturer's conclusions and followup. Under § 820.198, a
manufacturer already is required to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications and any complaint pertaining to injury, death, or any hazard to safety and to maintain a written record of the investigation. FDA believes that the information listed in § 803.24(e) which may be required by FDA is information that would be included in the written record of an adequate investigation under § 820.162 or § 820.128. As explained in paragraph 12 of this preamble, importers are not required to review, evaluate, or investigate a reportable event.

70. Many comments argue that reproposed § 803.24(c) should be revised to require in the report only information "to the extent known" by the manufacturer or importer when the report is due. Manufacturers and importers claim that this qualifying phrase is needed because the information necessary to evaluate a complaint often is in the hands of a third party, e.g., a physician or health care institution, that is reluctant to allow a manufacturer or importer access to the information until the third party has completed its own independent investigation, if at all.

FDA disagrees with the comments. FDA believes that the information listed under § 803.24(c) (1), (2), (3), (5), and (9) will be known by the manufacturer or importer and is critical to the agency's ability to initiate any investigation that needs to be conducted. FDA notes that, under the reproposed and final rule, the information listed in § 803.24(c)(4) is required to be submitted only "to the extent known." On its own initiative, FDA has added the following language to final § 803.24(c)(1) "and, to the extent known, the model, catalog, or other identification number or code of the device, and the manufacturing lot or serial number of the device."

71. Many comments argue that manufacturers and importers should be allowed to submit additional information concerning a reportable event at any time, regardless of whether the manufacturer or importer states in the report that additional information will be submitted.

FDA agrees with the comments and advises that it will accept, at any time, additional information submitted by a manufacturer or importer. Unless a manufacturer or importer notifies FDA in the report under final § 803.24(c) that it intends to submit additional information, however, FDA will presume that such information will not be submitted.

72. One comment suggests that reproposed § 803.24(c)(6) be deleted, arguing that a manufacturer or importer always will submit additional information to FDA because the report has placed the matter on public record. Another comment suggests that reproposed § 803.24(c)(6) be modified to state whether the report is complete, not whether additional information will be submitted. Still another comment objects to FDA requesting that a manufacturer or importer specify when the additional information will be submitted, arguing that this information often must be obtained from a third party. According to the comment, FDA should at most request an "estimated time frame."

Section 803.24(c)(6) of the reproposal provided that a medical device report was to "state whether the manufacturer or importer intends to submit additional information, and, if so, when such information will be submitted." According to the preamble, however, § 803.24(c)(6) provided that a medical device report was to "state whether the manufacturer or importer intends to submit additional information, and, if so, when such information will be submitted" (48 FR 24019). The language in the preamble accurately reflected FDA's intent, and the comments responded to that language. Final § 803.24(c)(6) has been modified to be consistent with FDA's intent, as expressed in the preamble to the reproposal.

The agency does not believe that every manufacturer and importer always will submit, on a voluntary basis, additional information. The reason for requiring a statement of a manufacturer's or importer's intent to submit additional information is to assist FDA with the utilization of its resources to investigate reportable events. To reduce the reporting burden on the medical device industry, FDA is providing that manufacturers and importers may submit in the report under final § 803.24(c) a minimal amount of information about a reportable event. In certain instances, however, the protection of the public health will require that FDA initiate its own investigation of an event and may require that the agency obtain more information from the manufacturer or importer about the event. By providing that a manufacturer or importer state in the report under final § 803.24(c) whether it intends to submit additional information and, if so, to declare when such additional information will be submitted, FDA will be better able to determine whether its investigation can proceed on the basis of the report, and, where the manufacturer or importer states that additional information will be submitted, and when, whether it may defer such investigation pending receipt of the additional information. Revising § 803.24(c)(6) to require a statement from a manufacturer or importer about whether the report is complete would not provide FDA with the information it needs to allocate its resources properly.

FDA does not agree with the comment suggesting that FDA should at most request an "expected time frame" for the submission of additional information. Given the seriousness of the events required to be reported, FDA accepts an estimated time frame which the manufacturer or importer could change without notifying FDA.

73. On its own initiative, FDA has added to the final rule new § 803.24(c)(7), which requires that the manufacturer or importer state in the report FDA whether the reported event is occurring more frequently or greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device, if such information is available. FDA needs this information to assist the agency in determining the significance of a reported event and whether to begin its own investigation.

On its own initiative, FDA also is adding to the final rule new § 803.24(e)(7), which provides that, if requested by FDA, the manufacturer or importer shall submit to FDA (1) all the information on the basis of which the manufacturer or importer determined that the reported event is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device; and (2) any evaluation or analysis available to or used by the manufacturer or importer in making this determination. In the final rule, FDA has redesignated reproposed § 803.24(e)(7) through (10) as § 803.24(e)(8) through (11).

74. One comment argues that requiring a manufacturer or importer to submit to FDA any of the evaluations specified in reproposed § 803.24(e)(final § 803.24(e)) would violate a manufacturer's or importer's constitutional rights because such information may be self-incriminating.

These requirements do not violate any privilege against compelled self-incrimination. That privilege attaches only to a person in his or her individual capacity, and is available neither to a collective entity, such as a business enterprise, nor to an individual acting in
FDA has revised § 803.24(e)(3) to

77. Many comments on reproposed § 803.24(e) argue that a request for additional information should be in writing and should state the basis for FDA's conclusion that such information is needed to protect the public health. FDA agrees in part with the comments. In some cases, FDA may conduct an on-site inspection in response to information received about a reportable event. In such cases, section 704(e) of the act and final § 803.31 (c) and (d) require the manufacturer or importer to permit any authorized FDA employee at all reasonable times to have access to and to copy and verify records of reportable events. FDA agrees, however, that a request for additional information under final § 803.24(e) should be in writing and should state the reason or purpose such information being required. The agency has revised § 803.24(e) to provide that any request for additional information under that section will be in writing, will state the reason or purpose for which the information is being requested, and will specify a due date for the submission of the information.

78. Several comments suggest that FDA include in any final rule criteria specifying when FDA will require the submission of additional information. FDA will review each report submitted under final § 803.24(b) and determine on a case-by-case basis whether the protection of the public health requires additional information. FDA believes that the agency needs to acquire some experience under the final rule before the agency can determine whether it is feasible to identify criteria for when additional information will be required under § 803.24(e). At this time, therefore, FDA is rejecting the suggestion.

79. One comment argues that FDA should set a time period after which it will not require additional information under reproposed § 803.24(e). The comments suggest 2 years, which is the retention period for records specified for importers in reproposed § 803.31(b).

FDA disagrees with the comment. Under final § 803.31(d), a manufacturer is required to retain copies of information received concerning a reportable event for a period of 3 years from the date that a report or additional information is submitted to FDA under § 803.24 (b) or (e), or for a period of time equivalent to the design and expected life of the device, whichever is greater (see paragraph 90 of this preamble). For the reasons discussed in paragraph 90 of this preamble, FDA reproposed in § 803.31(b) and is establishing in final § 803.31(b) a 2-year record retention requirement for importers. FDA believes, however, that the agency could reasonably require, at any time, whatever additional information the manufacturer or importer has retained.

80. One comment argues that a manufacturer or importer should have at least 30 days after receiving a request for additional information to submit it. FDA has revised § 803.24(e) in the final rule to provide that an FDA request for additional information will specify a time period for the submission of such information. This time period will depend on a number of factors, including FDA's evaluation/assessment of the risk to health posed by the device. Therefore, FDA is not specifying in the final rule any preset time period within which manufacturers or importers are required to submit additional information.

81. One comment states that the phrase "whether a death or serious injury has occurred" should be deleted from proposed § 803.24(e)(3) because the information has been submitted under § 803.24(c)(4).

FDA disagrees with the comment. The report submitted under § 803.24(c)(4) is required to include only that information known by the manufacturer or importer at the time the report is submitted. FDA recognizes that when a manufacturer or importer submits its report under final § 803.24(b), the manufacturer or importer may not know whether a death or serious injury has, in fact, occurred. For this reason, final § 803.24(c)(4) requires that the manufacturer or importer describe in the report a reportable event "to the extent known" at that time. Under such circumstances, FDA expects that the additional information that the agency may subsequently require under § 803.24(e)(3)] will be more complete and will likely confirm whether a death or serious injury has occurred. This is so because the manufacturer will have had more time to investigate the event in accordance with Part 820 and the importer, although not subject to Part 820 or required under the final rule to investigate the event, will have had more time to conduct a voluntary investigation of the event or obtain more information on the matter from the foreign manufacturer.

Content of a Report

82. Several comments on reproposed § 803.24(e)(5) state that the identity of an individual providing the information to the manufacturer or importer should not be routinely required by FDA.

FDA disagrees with the comment. In some cases, FDA may determine that it
should immediately begin an independent investigation of a reportable event. FDA will need to know the identity of the individual providing the information to the manufacturer or importer to begin such an investigation in a timely manner.

FDA recognizes that under section 519(a)(4) of the act, a rule promulgated under section 519 of the act may not mandate that the identity of any patient be disclosed in records, reports, or information submitted to the agency unless the identification is required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under the act. Given the scope of the final rule, FDA believes that disclosure of the identity of a patient providing information about a reportable event to a manufacturer or importer will be required to enable the agency to determine the safety or effectiveness of the device or to verify a record, report, or other information submitted under the rule. In most cases, however, FDA expects that the person providing the information to the manufacturer or importer will be a person other than a patient.

83. One comment claims that an evaluation may be publicly available and used as an admission against interest in a product liability proceeding. The public availability of information submitted to FDA under the final rule is discussed in paragraphs 43 through 49 of this preamble. Whether an evaluation constitutes an admission against interest is for the courts to decide on a case-by-case basis (see paragraphs 7 and 49a. of this preamble). In any event, FDA needs the evaluations specified in final § 803.24(e) to carry out its statutory mandate to protect the public health.

84. Many comments urge that FDA revise reproposed § 803.24(e)(4), (5), and (6) to require the submission of an evaluation of a reportable event only if the evaluation is prepared for or used by the manufacturer of the device. One comment argues that it is unreasonable to require a manufacturer to submit unsubstantiated evaluations prepared by a third party regarding the manufacturer’s device and submitted to or otherwise obtained by the manufacturer. Another comment suggested that after all information about a reportable event is collected, FDA should make its own determination as to whether the event is device related; FDA should not require the manufacturer to make such a determination.

FDA disagrees in part with the comments. Under §§ 820.162, 820.198, and 820.180 of the CGMP regulations, a manufacturer is required to maintain records of the evaluations referred to in the comments; under section 704(e) of the act, every person required under section 519 of the act to maintain records and every person who is in charge or custody of such records shall, upon request of any authorized FDA employee, permit such employee at all reasonable times to have access to, and to copy and verify, such reports. Final § 803.24(e) merely requires the manufacturer to submit evaluations to FDA rather than to have FDA go to the manufacturing facility to obtain it, and therefore is reasonable.

FDA agrees that it should make its own determination as to whether the reported event is device related. In making its determination, FDA will take into account evaluations prepared for or used by the manufacturer, or prepared by a third party and submitted to or otherwise obtained by the manufacturer. None of these evaluations is required by the final rule; each of them already is required to be made or maintained under §§ 820.162, 820.198, and 820.180, and each of them is required to be submitted to FDA under final § 803.24(e).

85. Several comments request clarification of the term “attributable” in reproposed § 803.24(e)(6) and (7) (final § 803.24(e)(6) and (6)).

FDA advises that the phrase “whether the event described in the medical device report is or is not attributable to the device” means an assessment of whether (1) the device caused or contributed to a death or serious injury or (2) as a result of a recurrence of a malfunction, the device or any other device marketed by the manufacturer or importer is likely to cause a death or serious injury.

86. Many comments argue that FDA should not require that manufacturers submit the information listed in reproposed § 803.24(e) (7) through (10) (final § 803.24(e)(8) through (11)) and, therefore, that these paragraphs should be deleted from any final rule. The comments state that manufacturers and importers do not make recall decisions for every complaint received. According to the comments, FDA should require that the agency be notified only if a manufacturer or importer has conducted a voluntary recall, and already has collected, pursuant to Part 7, the information listed in reproposed § 803.24(e)(7) through (10).

FDA disagrees with the comments. The final rule does not require a manufacturer or importer to make a recall decision for any complaint received. Under §§ 820.162 and 820.198 of the CGMP regulations, however, a manufacturer is required to make such a decision. Submission of the information specified in final § 803.24(e)(8) through (11) will be necessary, and will be required, whenever FDA determines that the protection of the public health demands that the agency conduct its own investigation of the reported event. Whether FDA will invoke these or any other provisions of final § 803.24(e) will depend on the facts and circumstances surrounding the event.

Under Part 7, reports of recalls are not required to be submitted to FDA, but rather are requested to be submitted voluntarily. In any event, information about recalls initiated in response to reportable events is necessary to enable FDA to take action to protect the public health and for the reasons discussed in paragraphs 5 and 68 of this preamble, FDA may not defer action, including investigation, with respect to every reportable event until after the manufacturer or importer has conducted a recall. FDA notes that if a remedial action is undertaken in response to information that is required to be reported under this rule, and such remedial action includes a significant change or modification to the device, a premarket notification may be required under 21 CFR 807.61.

87. Several comments state that reproposed § 803.24(e)(7) through (10) (final § 803.24(e)(8) through (11)) would require the submission of trade secret or confidential commercial information not generally available to FDA, and argue that such information can be required only for restricted and critical devices. One comment states that information required under reproposed § 803.24(e)(6) (final § 803.24(e)(10)) constitutes sales data, and argues that FDA does not have authority to require such data under section 704(a) of the act (21 U.S.C. 374(a)).

FDA disagrees with the comments, and directs attention to section 704(e) of the act. FDA acknowledges that the second sentence of section 704(a) of the act limits the agency’s authority to examine, during an inspection, records relating to other than restricted devices. However, section 704(e) of the act provides that every person required to maintain records under section 519 of the act, and every person who is in charge or custody of such records, shall permit FDA at all reasonable times to have access to and to copy and verify such records. Section 704(e) of the act does not limit in any way the types of device records maintained under section 519 and 520(g) of the act that FDA may inspect. Moreover, nothing in section 519 of the act or its legislative history...
precludes FDA from requiring the submission of trade secret or confidential commercial information. In addition, sections 301(j) and 520(c) of the act (21 U.S.C. 331(j) and 360(c)), by explicitly protecting from public disclosure trade secret or confidential commercial information obtained under the authority of section 519, are evidence that Congress expected FDA to obtain such information under section 519.

88. One comment argues that the requirement in reproposed § 803.24(e)(10) (final § 803.24(e)(11)) precludes FDA from requiring the public health. FDA does not believe that a change in the language of the final rule is necessary.

Complaint Files

89. One comment suggests that a complaint file requirement for importers is unnecessary because all reports and additional information will be submitted to FDA. FDA disagrees with the comment. The complaint file requirement is necessary to enable FDA to verify the accuracy of any report or additional information submitted to the agency under the final rule. The requirement also is necessary to enable FDA to determine whether, based on the information required to be maintained in the complaint file, an importer is reporting information not in its possession or to submit reports on a periodic basis.

90. One comment argues that the retention period for complaint files should be the same for manufacturers and importers, i.e., for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release by the manufacturer or importer for commercial distribution. FDA disagrees with the comment. The record retention period should begin on the date of the submission to FDA of information about the reportable event. If FDA adopted the record retention period recommended by the comment and, e.g., a reportable event occurred 3 years after the date of release for commercial distribution and within 10 days of the end of the expected life of the device, the manufacturer or importer could dispose of the records concerning the event immediately upon submission of a medical device written report under final § 803.24(b).

Final § 803.31(d) provides that a manufacturer is to retain copies of records of any information, including any written or oral communication, received by the manufacturer concerning a death, serious injury, or device malfunction that requires a report under § 803.24. The manufacturer also is required to retain a copy of any report submitted to FDA under § 803.24(b) and any additional information submitted to FDA under §§ 803.24(e) and 803.24(f). The manufacturer may maintain as part of its complaint file under § 803.31(d) the records referred to in this paragraph. FDA believes that, unlike device manufacturers, importers generally do not maintain scientific or engineering staffs and, therefore, may be unable to determine the period of time equivalent to the design and expected life of the device. Therefore, FDA selected for importers a time period that the agency determined to be reasonable. The 2-year record retention period specified in final § 803.31(b) begins on the date that an importer submits to FDA under § 803.24 (b) or (e) a report or additional information about a reportable event and is the minimal period that a manufacturer is required to retain this type of information under new § 803.31(d).

91. One comment suggests that a manufacturer that also is an importer be permitted to maintain all its complaint files at one location. FDA agrees with the comment. Final § 803.31(c) provides that an importer that also is a manufacturer may maintain the file at the same location as the manufacturer maintains its records under §§ 820.180 and 820.190.

Exemptions From Reporting

92. One comment suggests that FDA include in any final rule a provision noting a possible exemption under section 513(d)(2)(A) of the act (21 U.S.C. 360b(d)(2)(A)) from a requirement of section 519 of the act upon the recommendation of an FDA advisory committee. Two comments suggest that any final rule include a provision for manufacturers or importers to petition for an exemption from reporting in certain situations not already exempted, rather than to use the citizen petition provisions under Part 10.

FDA disagrees with the comments.

There is no need to include in the final rule a provision that duplicates section 513(d)(2)(A) of the act or § 10.30. Section 513(d)(2)(A) speaks for itself, and § 10.30 is adequate for the purpose referred to in the comments. FDA notes that under § 803.24(d), FDA may notify a manufacturer or importer that reports of a particular type of event are no longer required.

93. One comment contends that FDA is required to exempt class I devices under section 519 of the act. FDA disagrees with the comment. Under section 519 of the act, FDA is prohibited from requiring a manufacturer, importer, or distributor of a class I device to maintain for such a device records respecting information not in its possession or to submit reports of information not in its possession, or to submit reports on a periodic basis, unless such reports are necessary to determine if the device should be reclassified or is adulterated or misbranded. Nothing in section 519 of the act or its legislative history bars FDA from applying to manufacturers and importers of class I devices any of the provisions of the final rule. None of those provisions requires such a manufacturer or importer to maintain for its class I devices records respecting information not in its possession or to submit reports of information not in its possession, or to submit reports on a periodic basis.

94. Several comments argue that the reporting requirements in the reproposed rule are broader than the reporting requirements in several current FDA regulations (21 CFR 600.14, 600.170, 640.73, 812.150, 813.153, 1002.20, and 1003.10), which are cited in reproposed § 803.36(a) (1), (2), and (3). The comments contend that unless FDA has found that reporting under those regulations is inadequate, devices subject to those regulations should not be subject to any final medical device reporting rule.

The final rule applies to all manufacturers and importers of marketed devices other than general purpose articles. FDA has decided not to retain the rule in the final rule the exemptions that were included in reproposed § 803.36(a) (1), (2), and (3).
FDA advises that §§ 606.170 and 640.73 do not apply to manufacturers or importers of medical devices. For this reason, the final rule does not duplicate either § 606.170 or § 640.73, and reproposes § 803.36(a)(1) as it referred to §§ 606.170 and 640.73 is unnecessary. Because the final rule applies only to marketed devices, reproposed § 803.36(a)(3), which applied to investigational devices, also is unnecessary.

FDA needs a uniform reporting system for all marketed medical devices which captures, in a timely fashion, information about reportable events under the final rule. Accordingly, FDA is revising §§ 600.14, 1002.20, and 1003.10 to conform them to the final rule by providing that whenever a manufacturer or importer is required to report to FDA (1) under one of these sections and (2) under the final rule, the manufacturer is required to report only under the final rule. By establishing a uniform reporting system, FDA ensures that it will receive, in a prompt and efficient manner, the information it needs to protect the public from hazardous and potentially hazardous devices.

FDA finds for good cause that notice and public procedure are unnecessary in accordance with the Administrative Procedure Act (5 U.S.C. 553(b)(B)), considering the previous opportunities for comment afforded in the rulemaking and the resolution of the issues involved with the rule, as described in this paragraph. The agency, nevertheless, is providing a 30-day period during which it will accept comments on the conforming amendments. If FDA decides on the basis of comments received that any change to the conforming amendments is necessary, it will publish the change in the Federal Register.

FDA has redesignated reproposed § 803.36(b) and (c) as final § 803.36(a) and (b).

95. One comment suggests adding to any final rule exemptions for manufacturers and importers of devices which report to the Center for Drugs and Biologics, in accordance with §§ 310.301, 310.302, or § 431.60(b)(2). This policy applies only to marketed devices, FDA notes that there is not any specific program for manufacturers of dialyzers to report concerning hypersensitivity reactions to those devices.

Economic Assessment

FDA has assessed the economic impact of the final rule in accordance with Executive Order 12291 and concludes that the rule is not a major rule under the criteria included in the Executive Order. The agency also has considered the economic impact upon small business in accordance with the Regulatory Flexibility Act (Pub. L. 96–354) and certifies that there will not be a significant impact upon a substantial number of small medical device manufacturers or importers. FDA estimates that under the final rule, approximately 25,100 medical device reports will be submitted each year. About 2,100 of these reports are expected to be for deaths and serious injuries. The remaining reports would be for device malfunctions which, if they recurred, could cause or contribute to a death or serious injury.

Using data provided by industry, FDA estimates that a cost of $600 for each report involving a death or serious injury will be incurred by the manufacturer or importer. (Even though these reportable events must be investigated by manufacturers under the CGMP regulations, FDA envisions that additional review by manufacturers may be undertaken before submission to FDA of this type of report. FDA also envisions that importers, although not subject to the CGMP regulations, will conduct voluntary investigations of device-related deaths and serious injuries.)

FDA believes that the cost of reports of device malfunctions will be proportional to the concern that the manufacturer or importer has over the potential for death or serious injury presented by the malfunction. FDA estimates that there will be 4,600 reports for which this concern will be the
greatest and for which some additional professional review might be necessary. FDA has assumed that a manufacturer or importer will incur an average cost of $300 for each such report. For the remaining reports of malfunctions, FDA assumes that a manufacturer or importer will incur a cost of only $60 for each report because these reports will entail only cursory review, photocopying, and mailing costs. Other costs attributable to the final rule include the cost of telephone calls for deaths and serious injuries, the cost to importers of establishing and maintaining complaints files, and the cost to manufacturers and importers of retaining records in accordance with final § 803.31. FDA estimates that the total cost of the final rule is approximately $4 million per year.

The agency also has examined the impact of the final rule upon small manufacturers. FDA estimates that most reports submitted under the final rule will be for critical devices within the meaning of Part 820 and that about 43 percent of all establishments manufacturing such devices are small establishments. Also, small establishments typically manufacture only half as many types of medical devices as large establishments. Thus, neglecting differences in sales volume (larger establishments would sell more devices of each type) and assuming that the likelihood of a report on a device made by a small or large establishment would be the same, FDA expects that, at most, 22 percent (43 percent x 0.5) of the anticipated reports under the final rule will be from small establishments.

Therefore, FDA concludes that no more than 22 percent of the anticipated $4 million annual cost of the final rule (less than $0.9 million) should be ascribed to small establishments.

Because there are between 5,000 and 6,000 such establishments subject to the final rule, the average impact on any one small establishment should be less than $200 annually.

Reference

Paperwork Reduction Act of 1980

In accordance with the Paperwork Reduction Act of 1980 and 5 CFR 1320.13(g) of OMB’s regulations implementing the provisions of that act, FDA has submitted the final rule to OMB for approval of the collection of information requirements contained in § 803.24 and 803.31 of the rule. These requirements will not be effective until FDA obtains OMB approval. In accordance with 5 CFR 1320.13(f), prior to November 13, 1984, FDA will publish in the Federal Register a notice of OMB’s decision to approve, modify, or disapprove these requirements.

List of Subjects
21 CFR Part 600
Biologics.

21 CFR Part 603
Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1002
Administrative practice and procedure, Electronic products, Radiation protection, Reporting requirements.

21 CFR Part 1003
Administrative practice and procedure, Defects, Electronic products, Noncompliance, Radiation protection.


PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. Part 600 is amended in § 600.14 by designating the existing text as paragraph (a) and by adding new paragraph (b), to read as follows:

§ 600.14 Reporting of errors.
(a) * * *
(b) Manufacturers of licensed in vitro diagnostic products, and manufacturers of unlicensed in vitro diagnostic products which are required to be registered under Part 607 of this chapter, shall notify the Director in accordance with paragraph (a) of this section. Manufacturers of other in vitro diagnostic products which are required to be registered under Part 807 of this chapter, shall report in accordance with Part 803 of this chapter.

2. By adding new Part 803, to read as follows:

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec. 803.1 Scope.
and is required to register under Part 807.

(c) "Malfunction" means the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for a device. The intended performance of a device refers to the objective intent of the person legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised.

(d) "Manufacturer" means any person who is required to register under Part 807, other than a person who initially distributes a device imported into the United States.

(e) "Person" includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity.

(f) "Information that reasonably suggests" a conclusion means (1) information (such as professional, scientific, or medical facts or opinions) from which a reasonable person would reach the conclusion, and (2) a statement to a manufacturer or importer by a health care professional (e.g., a doctor of medicine, osteopathy, dental surgery, podiatry, or chiropractic, or an optometrist, pharmacist, or a registered nurse, or a hospital administrator), reaching the conclusion.

(g) A "remedial action" is any recall, repair, modification, adjustment, relabeling, destruction, inspection (including patient monitoring), notification, or any other action that is initiated by a manufacturer or importer in response to information that it receives or otherwise becomes aware of and that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(h) A "serious injury" is an injury that (1) is life threatening, (2) results in permanent impairment of a body function or permanent damage to body structure, or (3) necessitates medical or surgical intervention by a health care professional to (i) preclude permanent impairment of a body function or permanent damage to body structure or (ii) relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure. Temporary impairment of a body function or temporary damage to body structure is unanticipated if reference to such impairment or damage is not made in the labeling for the device or, if such reference is made in the labeling for the device, the manufacturer or importer of the device determines that such impairment or damage has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device. Any term defined in section 201 of the Federal Food, Drug, and Cosmetic Act shall have that meaning, unless otherwise defined in this Part.

§ 803.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with Part 20.

(b) Before public disclosure of a report, FDA will delete from the report (1) any information that constitutes trade secret or confidential commercial or financial information under § 20.61; and (2) any personnel, medical, and similar information disclosure of which would constitute a clearly unwarranted invasion of personal privacy under § 20.63; provided, however, that except for the information that constitutes trade secret or confidential commercial or financial information under § 20.61, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

Subpart B—Reports and Records

§ 803.24 Reports by manufacturers and importers.

(a) A manufacturer or importer shall submit to FDA a report containing the information listed in paragraph (c) of this section whenever the manufacturer or importer:

(1) Receives or otherwise becomes aware of oral or written information that reasonably suggests that:

(i) A death or serious injury has occurred and that one of the manufacturer's or importer's marketed devices may have caused or contributed to a death or serious injury; or

(ii) One of the manufacturer's or importer's marketed devices has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(2) Receives or otherwise becomes aware of information:

(i) In the medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices (a) may have caused or contributed to a death or serious injury or (b) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; or

(ii) Through its own research, testing, evaluation, servicing, or maintenance of one of its devices, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, the manufacturer or importer shall report to FDA by telephone as soon as possible, but no later than within 5 calendar days of initial receipt of the information. The manufacturer or importer shall include in the telephone report the information listed in paragraph (c) of this section. The manufacturer or importer shall follow the telephone report with a written report submitted to FDA within 15 working days of initial receipt of the information.

(2) Whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, the manufacturer or importer shall report in writing or by telephone to FDA as soon as the information listed in paragraph (c) of this section has been obtained, but in no event later than 15 working days after initial receipt of the information. The manufacturer or importer shall follow any report made by telephone with a written report submitted to FDA within 15 working days of initial receipt of the information.

(c) A medical device telephone report or written report is required to:
(1) Identify the device, including its brand name and common or usual name and, to the extent known, the model, catalog, or other identification number or code of the device, and the manufacturing lot or serial number of the device.

(2) Identify the manufacturer or, in the case of an imported device, identify the importer and the foreign manufacturer; (3) Identify, by name, address, and telephone number, the individual making the report to FDA.

(4) Describe, to the extent known, the event giving rise to the information received by the manufacturer or importer, including (i) whether any deaths or serious injuries have occurred and (ii) the number of persons who died or were seriously injured. (If the report is required under paragraph (a)(2)(i) of this section, the description of the event shall include a copy of the article;)

(5) Identify, by name and address, the person submitting the information to the manufacturer or importer;

(6) State whether the manufacturer or importer intends to submit additional information, and, if so, when such information will be submitted; and

(7) State whether the reported event has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device, if such information is available.

(d)(1) A manufacturer or importer shall report to FDA as required under this paragraph each time it receives or otherwise becomes aware of information described in paragraph (a) of this section, even if an event of the same or a similar nature has been reported previously to FDA. A medical device report is required under paragraph (a) of this section even if the manufacturer or importer believes that the event that requires a report is due to user error; the failure to service or maintain the device properly, the use of the device beyond its labeled useful life, or any other reason not listed under paragraph (d)(2) or (3) of this section.

(2) Only one medical device report is required under paragraph (a) of this section if the manufacturer or importer becomes aware, from more than one source, of information concerning the same patient and the same event.

(3) A medical device report is not required if within the time period specified under paragraph (b) of this section, the manufacturer or importer determines that:

(i) The information received under paragraph (a)(1)(i) of this section is erroneous in that a death or serious injury has not occurred, or

(ii) The information received under paragraph (a)(1)(ii) of this section is erroneous in that the device that is the subject of the information was manufactured or imported by another manufacturer or importer; or

(iii) Although the manufacturer or importer has received or otherwise became aware of information that reasonably suggests that a malfunction has occurred, each of the following applies:

(a) A death or serious injury has not occurred;

(b) The device's labeling sets forth information concerning the potential for death to the type of serious injury that the malfunction may cause or contribute to;

(c) The device's labeling describes the malfunction, and the routine service, repair, or maintenance instructions to correct the malfunction;

(d) The malfunction has occurred or is occurring at or below the frequency and severity stated in the labeling for the device or, if there is not any pertinent statement in the labeling, at or below the frequency and severity that are usual for the device; and

(e) The malfunction does not lead the manufacturer or importer to undertake a remedial action involving any device other than the device product in which the malfunction occurred.

(4) FDA may notify a manufacturer or importer, in writing, that medical device reports of a particular type of event are no longer required.

(e) If FDA determines that the protection of the public health requires information in addition to that included in the medical device report submitted to FDA under paragraph (b) of this section, a manufacturer or importer shall, upon FDA's request, submit such additional information. Any request by FDA under this paragraph will be in writing, state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information. Additional items that may be requested include:

(1) Model, catalog, or other identification number or code of the device.

(2) Manufacturing lot or serial number of the device.

(3) A complete description of the event giving rise to the information received by the manufacturer or importer, including (i) whether any deaths or serious injuries have occurred and (ii) the number of persons who died or were seriously injured. If a complete description is unavailable, the manufacturer or importer shall explain the reason for the unavailability of such description.

(4) Any evaluation of the risk of death or serious injury, including failure analysis, and copies of any laboratory testing or analyses available to or used by the manufacturer or importer.

(5) Any available evaluation by a practitioner, such as a physician or dentist, licensed by law to use or order the use of the device, of the event described in the medical device report.

(6) Any evaluation or other determination available to or used by the manufacturer or importer as to whether the event described in the medical device report is or is not attributable to the device and the basis for such determination.

(7)(1) All the information on the basis of which the manufacturer or importer determined that the reported event has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device; and

(ii) any evaluation or analysis available to or used by the manufacturer or importer in making this determination.

(8) If the manufacturer or importer determines that the event described in the medical device report is attributable to the device, an outline of the plan for remedial action or, if the manufacturer or importer determines that a remedial action is unnecessary, the basis for such determination.

(9) A copy of any proposed remedial action communication and the names and addresses of recipients of the communication.

(10) Information concerning the device's manufacture, e.g., the total number manufactured or the number in the same batch, lot, or equivalent unit of production, the location and date of manufacture, and the device's expiration date, if any.

(11) Information concerning the device's distribution, e.g., the location and number of devices in inventory stock and distribution channels, a list of all consignees, and the dates of distribution.

(Information collection requirements approved by the Office of Management and Budget under number 0910-0209.)

§ 803.31 Complaint files.

(a) An importer shall establish a complaint file and maintain a record of any information, including any written or oral communication, received by the importer concerning a death, serious injury, or device malfunction that requires a report under § 803.24. The file
§ 803.33 Where to submit a report.
(a) Any telephone report required under this part shall be provided to 301-427-7500.
(b) Any written report or additional information required under this part shall be submitted to the Device Monitoring Branch (HFZ-343), Center for Devices and Radiological Health, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910.

§ 803.36 Exemptions from reporting.
A manufacturer or importer otherwise subject to this part is exempt from reporting as required under this part, if the manufacturer or importer:
(a) Is a practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of that individual's professional practice.
(b) Is a person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale or use under an investigational device exemption granted under Part 812 or Part 813.

PART 1002—RECORDS AND REPORTS
3. Part 1002 is amended in § 1002.20 by adding new paragraph (c), to read as follows:

§ 1002.20 Reporting of accidental radiation occurrences.

(c) If a manufacturer is required to report to the Director under paragraph (a) of this section and also is required to report under Part 803 of this chapter, the manufacturer shall report in accordance with Part 803. If a manufacturer is required to report to the Director under paragraph (a) of this section and is not required to report under Part 803, the manufacturer shall report in accordance with paragraph (a) of this section.

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY
4. Part 1003 is amended in § 1003.10 by adding new paragraph (c), to read as follows:

§ 1003.10 Discovery of defect or failure of compliance by manufacturer; notice requirements.

(c) If a manufacturer is required to notify the Secretary under paragraph (a) of this section and also is required to report to the Food and Drug Administration under Part 803 of this chapter, the manufacturer shall report in accordance with Part 803. If a manufacturer is required to notify the Secretary under paragraph (a) of this section and is not required to report to the Food and Drug Administration under Part 803, the manufacturer shall notify the Secretary in accordance with paragraph (a) of this section.

Interested persons may, on or before October 13, 1984, submit to the Dockets Management Branch (address above) written comments regarding the amendments conforming §§ 600.14, 1002.20, and 1003.10 to this final rule. If FDA decides on the basis of comments received that any change to the conforming amendments is necessary, it will publish the change in the Federal Register. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.


Frank E. Young,
Commissioner of Food and Drugs.
Margaret M. Heckler,
Secretary of Health and Human Services.

(Bills and Regulations 4160-01-M)
Part VIII

Office of Management and Budget

Budget Rescissions and Deferrals; Cumulative Report
OFFICE OF MANAGEMENT AND BUDGET

Cumulative Report on Rescissions and Deferrals

September 1, 1984.

This report is submitted in fulfillment of the requirements of section 1014(e) of the Impoundment Control Act of 1974 (Pub. L. 93-344). Section 1014(e) provides for a monthly report listing all budget authority for this fiscal year for which, as of the first day of the month, a special message has been transmitted to the Congress.

This report gives the status as of September 1, 1984 of nine rescission proposals and 65 deferrals contained in the first twelve special messages of FY 1984. These messages were transmitted to the Congress on October 3, November 17, December 14 and December 21, 1983; and January 12, February 1 and 22, March 26, May 8 and 21, June 20, and July 20, 1984.

Rescissions (Table A and Attachment A)

As of September 1, 1984, there were no rescission proposals pending before the Congress. Attachment A shows the history and status of the nine rescissions proposed by the President in 1984.

Deferrals (Table B and Attachment B)

As of September 1, 1984, $1,946.0 million in 1984 budget authority was being deferred from obligation and $10.8 million in 1984 outlays was being deferred from expenditure. Attachment B shows the history and status of each deferral reported during FY 1984.

Information From Special Messages

The special messages containing information on the rescission proposals and deferrals covered by this cumulative report are printed in the Federal Registers listed below:

Vol. 48, FR p. 45730, Thursday, October 6, 1983
Vol. 48, FR p. 53060, Wednesday, November 23, 1983
Vol. 48, FR p. 56720, Thursday, December 22, 1983
Vol. 48, FR p. 57098, Tuesday, December 27, 1983
Vol. 49, FR p. 2076, Tuesday, January 17, 1984
Vol. 49, FR p. 4692, Tuesday, February 7, 1984
Vol. 49, FR p. 7342, Tuesday, February 28, 1984
Vol. 49, FR p. 13096, Monday, April 2, 1984
Vol. 49, FR p. 20234, Friday, May 11, 1984
Vol. 49, FR p. 22032, Thursday, May 24, 1984
Vol. 49, FR p. 26014, Monday, June 26, 1984
Vol. 49, FR p. 30155, Thursday, July 26, 1984

David A. Stockman,
Director, Office of Management and Budget.

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**TABLE A**

STATUS OF 1984 RESCISSIONS

<table>
<thead>
<tr>
<th>Amount (In millions of dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rescissions proposed by the President</td>
</tr>
<tr>
<td>Accepted by the Congress</td>
</tr>
<tr>
<td>Rejected by the Congress</td>
</tr>
<tr>
<td>Pending before the Congress</td>
</tr>
</tbody>
</table>

a/ These amounts were available for obligation between March 28 and August 22, 1984 when the Second Supplemental Appropriations Act (P.L. 98-396) was enacted.

**TABLE B**

STATUS OF 1984 DEFERRALS

<table>
<thead>
<tr>
<th>Amount (In millions of dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferrals proposed by the President</td>
</tr>
<tr>
<td>Routine Executive releases through September 1, 1984 (OMB/Agency Releases of $5,548.2 million and cumulative adjustments of -$86.5 million)</td>
</tr>
<tr>
<td>Overturned by the Congress</td>
</tr>
<tr>
<td>Currently before the Congress</td>
</tr>
</tbody>
</table>

a/ This amount includes $10.8 million in outlays for a Department of the Treasury deferral (O84-16).

Attachments

BILLING CODE 3110-01-M
### Attachment A - Status of Rescissions - Fiscal Year 1984

<table>
<thead>
<tr>
<th>Agency/Bureau/Account</th>
<th>Amount Previously Considered by Congress</th>
<th>Amount Currently before Congress</th>
<th>Date of Message Rescission</th>
<th>Amount Made Available</th>
<th>Date Made Available</th>
<th>Congressional Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT</td>
<td>Public and Indian Housing Programs Payment for operation of Low-Income housing</td>
<td>R84-2</td>
<td>331,431</td>
<td>2-1-84</td>
<td>331,431</td>
<td>3-28-84</td>
</tr>
<tr>
<td>DEPARTMENT OF THE INTERIOR</td>
<td>National Park Service Land acquisition</td>
<td>R84-1</td>
<td>30,000</td>
<td>2-1-84</td>
<td>30,000</td>
<td>3-28-84</td>
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<tr>
<td>DEPARTMENT OF LABOR</td>
<td>Occupational Safety and Health Administration</td>
<td>R84-1</td>
<td>1,700</td>
<td>12-21-83</td>
<td>1,700</td>
<td>3-19-84</td>
</tr>
<tr>
<td>OTHER INDEPENDENT AGENCIES</td>
<td>Corporation for Public Broadcasting Public broadcasting fund</td>
<td>R84-9</td>
<td>20,000</td>
<td>2-1-84</td>
<td>20,000</td>
<td>3-28-84</td>
</tr>
<tr>
<td>Delaware and Susquehanna River Basin Commissions Salaries and expenses, Delaware River Basin Commission</td>
<td>R84-4</td>
<td>19</td>
<td>2-1-84</td>
<td>19</td>
<td>3-28-84</td>
<td></td>
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<tr>
<td>Delaware and Susquehanna River Basin Commissions Salaries and expenses, Susquehanna River Basin Commission</td>
<td>R84-5</td>
<td>24</td>
<td>2-1-84</td>
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<td>3-28-84</td>
<td></td>
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<tr>
<td>Panama Canal Commission Operating expenses</td>
<td>R84-6A</td>
<td>17,750</td>
<td>2-1-84</td>
<td>17,750</td>
<td>3-28-84</td>
<td>P.L. 98-396</td>
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<tr>
<td>Capital outlay</td>
<td>R84-5B</td>
<td>7,625</td>
<td>2-1-84</td>
<td>7,625</td>
<td>3-28-84</td>
<td>P.L. 98-396</td>
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<td>OFF-BUDGET FEDERAL ENTITIES</td>
<td>DEPARTMENT OF AGRICULTURE Rural Electrification Administration Rural electrification and telephone revolving fund</td>
<td>R84-7</td>
<td>197,862</td>
<td>2-1-84</td>
<td>197,862</td>
<td>3-28-84</td>
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<tr>
<td>Rural telephone bank</td>
<td>R84-8</td>
<td>30,000</td>
<td>2-1-84</td>
<td>30,000</td>
<td>3-28-84</td>
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<td>Rescissions, total BA</td>
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<td></td>
<td></td>
<td>636,411</td>
<td>55,375</td>
<td>636,411</td>
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</table>

**NOTE:** Amounts rescinded in the Second Supplemental Appropriations Act (P.L. 98-396) on August 22, 1984 were available between the date of release and the date of enactment.

### Attachment B - Status of Deferrals - Fiscal Year 1984

| Agency/Bureau/Account | Amount Transmitted Original | Amount Transmitted Subsequent Change | Date of Message Cumulative Congressionally Required Congressional Action Cumulative Adjustments Amount Deferred as of 9-1-84 |
|-----------------------|-----------------------------|-------------------------------------|-----------------------------|------------------|---------------------|---------------------|-------------------|
| FUNDS APPROPRIATED TO THE PRESIDENT | | | | | | | |
| Appalachian Regional Development Programs Appalachian regional development programs | 10,000 | | 10-3-84 | 10,000 | |
| International Security Assistance Foreign military sales credit | 1,315,000 | | 1-12-84 | -1315000 | 0 |
| Economic support fund | 303,000 | | 12-14-83 | -2766931 | 0 |
| Military assistance | 162,000 | | 1-12-84 | 10,000 | 426,970 | 0 |
| DEPARTMENT OF AGRICULTURE | | | | | | | |
| Soil Conservation Service Watershed and flood prevention operations | 8,130 | | 2-1-84 | 8,130 | |
| Forest Service Construction | 10,014 | | 2-1-84 | 10,014 | |
| Timber salvage sales | 6,211 | | 10-3-84 | 1950 | 13,471 | 55,850 | |
| Expenses, brush disposal | 12,398 | | 1-12-84 | 55,850 | |
| DEPARTMENT OF COMMERCE | | | | | | | |
| International Trade Administration Participation in U.S. expositions | 550 | | 1-12-84 | 550 | | | |
| National Oceanic & Atmospheric Administration Promote and develop fishery products and research pertaining to American fisheries | 33,600 | | 10-3-83 | -33600 | 0 | |
### Attachment B - Status of Deferrals - Fiscal Year 1984

<table>
<thead>
<tr>
<th>Agency/Bureau/Account</th>
<th>Amount Transmitted</th>
<th>Cumulative OMB/Agency Releases</th>
<th>Congressional Action</th>
<th>Amount Deferred as of 9-1-84</th>
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<tbody>
<tr>
<td><strong>DEPARTMENT OF DEFENSE - MILITARY</strong></td>
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<tr>
<td>Operation and Maintenance</td>
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<tr>
<td>Environmental restoration, defense..... 084-33</td>
<td>75,000</td>
<td>1-12-84</td>
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<td>Military Construction</td>
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<td>Military construction, all services..... 084-5</td>
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<td>10-3-83</td>
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<td>Family Housing, Defense</td>
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<td>Family housing, Air Force.............. 084-6</td>
<td>53,000</td>
<td>10-3-83</td>
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<td><strong>DEPARTMENT OF DEFENSE - CIVIL</strong></td>
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<td>Wildlife Conservation, Military Reservations</td>
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<td>Wildlife conservation................. 084-7</td>
<td>777</td>
<td>10-3-83</td>
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<td><strong>DEPARTMENT OF EDUCATION</strong></td>
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<td>Office of Postsecondary Education</td>
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<td>Higher education.................... 084-38</td>
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<td><strong>DEPARTMENT OF ENERGY</strong></td>
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<td>Atomic Energy Defense Activities</td>
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<td>Atomic energy defense activities...... 084-62</td>
<td>1,050</td>
<td>6-70-84</td>
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<td>Energy Programs</td>
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<td>General science and research activities..... 084-63</td>
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<td>6-70-84</td>
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<td>Energy supply, research and development activities..... 084-39</td>
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<td>2-1-84</td>
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<td>Uranium supply and enrichment activities..... 084-8</td>
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<td>10-3-83</td>
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<td>Fossil energy research and development..... 084-21</td>
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<td>6-20-84</td>
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### Attachment 8 - Status of Deferrals - Fiscal Year 1984

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### Attachment B - Status of Deferrals - Fiscal Year 1984

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Notes: Deferral 084-25 was reported as part of 084-21 in the second special message. In the third special message the deferral was reported separately and adjusted upward slightly.

Of the amount deferred as 084-25, $26 million was transferred to Fossil energy research and development pursuant to the 1984 Interior and Related Agencies Appropriations Act.

All of the above amounts represent budget authority except one general revenue sharing deferral (084-16) of outlays only.

The Soil Conservation Service deferral was erroneously transmitted as 084-36 in the sixth special message. It has been renumbered as 084-49.
Federal Register
Vol. 49, No. 180
Friday, September 14, 1984

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

### CFR PARTS AFFECTED DURING SEPTEMBER

#### 3 CFR

**Administrative Orders:**

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#### 5 CFR

**Presidential Determinations:**

- No. 84-13 of September 8, 1984

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**Proposed Rules:**

- Ch. XIV of 35096

#### 7 CFR

**Proposed Rules:**

- Ch. XIV of 35929

#### 9 CFR

**Proposed Rules:**

- 112 of 35022
- 113 of 35022
- 114 of 35022
- 307 of 35782
- 308 of 35507
- 310 of 35782
- 318 of 35507
- 320 of 35507
- 327 of 35507
- 381 of 35507
- 10 9 CFR

**Proposed Rules:**

- 2 of 35747
- 40 of 35611
- 50 of 35747
- 205 of 35502
- 590 of 35302

#### 12 CFR

**Proposed Rules:**

- 3 of 34838
- 6 of 35784
- 701 of 35957

#### 14 CFR

**Proposed Rules:**

- 39 of 35079-35083, 35612-35622
- 71 of 34813, 34814, 35623, 35624, 35764-35766

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**FEDERAL REGISTER PAGES AND DATES, SEPTEMBER**

- 34799-35000
- 35001-35070
- 35071-35330
- 35331-35462
- 35463-35508
- 35609-35740
- 35741-35926
- 35927-35604
- 35605-35858
LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last List September 5, 1984.
# Code of Federal Regulations

Revised as of April 1, 1984

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A cumulative checklist of CFR issuances appears every Monday in the Federal Register in the Reader Aids section. In addition, a checklist of current CFR volumes, comprising a complete CFR set, appears each month in the LSA (List of CFR Sections Affected).

Order Form


Order No.__________________

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Total charges $ Fill in the boxes below.

Credit Card No. ____________________________

Expiration Date __________/__________

For Office Use Only.

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Please send me the Code of Federal Regulations publications I have selected above.

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