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federal register

Friday
May 9, 1997

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WASHINGTON, DC

WHEN: June 17, 1997 at 9:00 am

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Contents

Federal Register

Vol. 62, No. 90

Friday, May 9, 1997

Agricultural Marketing Service
NOTICES
Agency information collection activities:
Proposed collection; comment request, 25583

Agriculture Department
See Agricultural Marketing Service
See Animal and Plant Health Inspection Service
See Farm Service Agency
See Forest Service

Animal and Plant Health Inspection Service
RULES
Exportation and importation of animals and animal products:
Pork from Sonora, Mexico, 25439–25443
Veterinarian accreditation, etc.:
Optional digital signature acceptance on official certificates, forms, records, and reports, 25444–25445
PROPOSED RULES
Plant-related quarantine, foreign:
Unroasted coffee, coffee berries and fruits, etc.; importation into Hawaii and Puerto Rico; prohibition, 25561–25562

Antitrust Division
NOTICES
Competitive impact statements and proposed consent judgments:
Mulkey, Jeff, et al., 25653–25657

Blind or Severely Disabled, Committee for Purchase From People Who Are
See Committee for Purchase From People Who Are Blind or Severely Disabled

Census Bureau
NOTICES
Agency information collection activities:
Proposed collection; comment request, 25587

Centers for Disease Control and Prevention
NOTICES
Hazardous substance training for emergency responses implementation; NIOSH meeting, 25629–25632

Children and Families Administration
NOTICES
Meetings:
President's Committee on Mental Retardation, 25632

Civil Rights Commission
NOTICES
Meetings; State advisory committees:
Connecticut, 25586
West Virginia, 25586–25587

Coast Guard
RULES
Drawbridge operations:
Michigan, 25514
Lifesaving equipment:
Inflatable liferafts, 25525–25557
PROPOSED RULES
Ports and waterways safety:
Delaware Bay approaches; traffic separation scheme, 25576–25578

Commerce Department
See Census Bureau
See Export Administration Bureau
See International Trade Administration

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement list; additions and deletions, 25585–25586

Committee for the Implementation of Textile Agreements
NOTICES
Cotton, wool, and man-made textiles:
Bangladesh, 25589–25590

Commodity Futures Trading Commission
RULES
Commodity Exchange Act:
Bunched orders and account identification; interpretation, 25470–25475
NOTICES
Meetings; Sunshine Act, 25590

Defense Department
See Navy Department
PROPOSED RULES
Federal Acquisition Regulation (FAR):
Affirmative action reform in Federal procurement, 25786–25798
NOTICES
Federal Acquisition Regulation (FAR):
Agency information collection activities—
Proposed collection; comment request, 25800–25801

Defense Nuclear Facilities Safety Board
NOTICES
Meetings; Sunshine Act, 25591

Delaware River Basin Commission
PROPOSED RULES
Ground water protected area in Pennsylvania:
Numerical ground water withdrawal limits for subbasins; hearing, 25569–25572

Education Department
RULES
Postsecondary education:
William D. Ford Federal direct student loan program; correction, 25515
NOTICES
Grants and cooperative agreements; availability, etc.:
Life skills for State and local prisoners program, 25591
National Institute on Disability and Rehabilitation Research—
Research and demonstration projects, etc., 25760–25784

Employment and Training Administration
NOTICES
Adjustment assistance:
Character Suburbanwear, Inc., 25661
Chevron Overseas Petroleum, Inc., 25661
Cluett, Peabody & Co., Inc., 25661–25662
Exide Batteries et al., 25662–25663
Hasbro Manufacturing Services, 25663
J.M. Huber Corp., 25663
Sara Lee Bodywear, 25663
Shaw Pipe, Inc., 25664
Stanley Works, 25664
Systems & Electronics, Inc., 25664–25665
Texas LPG Storage Co., Inc., 25665
Adjustment assistance and NAFTA transitional adjustment assistance:
Earthgrains Co. et al., 25658–25661
NAFTA transitional adjustment assistance:
Parkway Building Systems, Inc., 25665
Stanley Works, 25665

Employment Standards Administration
NOTICES
Minimum wages for Federal and federally-assisted construction; general wage determination decisions, 25665–25667

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Cyfluthrin, 25518–25524
Tolerance processing fees increase, 25524–25525
NOTICES
Environmental statements; availability, etc.:
Agency statements—
Comment availability, 25609–25610
Weekly receipts, 25610–25611
Antarctica; nongovernmental activities, 25611–25613
Pesticides; emergency exemptions, etc.:
Metolachlor, etc., 25613
Superfund; response and remedial actions, proposed settlements, etc.:
Cherokee Resources Sites, NC, 25613–25614

Executive Office of the President
See Management and Budget Office
See Presidential Documents

Export Administration Bureau
RULES
Export administration regulations:
Restructuring, reorganization, and simplification, 25451–25470
NOTICES
National Defense Stockpile; market impact of proposed disposals of excess commodities, 25587–25588

Farm Service Agency
RULES
Farm marketing quotas, acreage allotments, and production adjustments:
Peanuts, 25433–25439

Federal Aviation Administration
RULES
Class D airspace, 25445–25447
Class E airspace, 25448
IFR altitudes, 25448–25451
PROPOSED RULES
Airworthiness directives:
Lockheed, 25565–25566
Saab, 25566–25568
Twin Commander Aircraft Corp., 25563–25565
Class E airspace, 25568–25569
NOTICES
Passenger facility charges; applications, etc.:
Toledo-Lucas County Airport Authority, OH, et al., 25686–25688

Federal Communications Commission
RULES
Radio stations; table of assignments:
Missouri, 25557
NOTICES
Meetings; Sunshine Act, 25616
Reporting and recordkeeping requirements, 25616–25617
Rulemaking proceedings; petitions filed, granted, denied, etc., 25617–25618
Applications, hearings, determinations, etc.:
Sobel, Marc, et al., 25615

Federal Emergency Management Agency
NOTICES
Disaster and emergency areas:
Arkansas, 25618
Kentucky, 25618
Micronesia, 25618–25619
Minnesota, 25619
North Dakota, 25619
South Dakota, 25620
Emergency food and shelter program; national board implementation plan; correction, 25620
Hotel and Motel Fire Safety Act:
National master list, 25620–25628
Senior Executive Service:
Performance Review Board; membership, 25628

Federal Energy Regulatory Commission
NOTICES
Electric rate and corporate regulation filings:
New York State Electric & Gas Corp. et al., 25602–25608
Hydroelectric applications, 25608–25609
Applications, hearings, determinations, etc.:
Algonquin LNG, Inc., 25591
ANR Pipeline Co., 25591–25592
Arkansas Western Pipeline Co., 25592
Black Brook Energy Co., 25592–25593
Cinergy Services, Inc., 25593
Cleveland Electric Illuminating Co., 25593
CNG Transmission Corp., 25593–25594
Colorado Interstate Gas Co., 25594–25595
Competitive Utility Services Corp., 25595
Equitrans, L.P., 25595–25596
Granite State Gas Transmission, Inc., 25596
International Paper Co. et al., 25596
Midwestern Gas Transmission Co., 25597
Mississippi River Transmission Corp., 25597
Montaup Electric Co., 25597
National Fuel Gas Supply Corp., 25597–25598
Natural Gas Pipeline Co. of America, 25598
NorAm Gas Transmission Co., 25598

Northern Border Pipeline Co., 25598
Northern Natural Gas Co., 25598–25599
Ohio Valley Electric Corp. et al., 25599
Ozark Gas Transmission System, 25599
Pacific Northwest Generating Cooperative, 25599–25600
PacifiCorp, 25600
Panhandle Eastern Pipe Line Co., 25600
Sabine Pipe Line Co., 25600
Tennessee Gas Pipeline Co., 25601
Texas Eastern Transmission Corp., 25601
Tuscarora Gas Transmission Co., 25601
Washington Water Power Co., 25601
Watt Works, L.L.C., 25602
Williston Basin Interstate Pipeline Co., 25602

Federal Housing Finance Board
PROPOSED RULES
Federal home loan bank system:
Housing finance and community investment; mission achievement, 25563

Federal Maritime Commission
NOTICES
Agreements filed, etc., 25628–25629

Federal Reserve System
NOTICES
Meetings; Sunshine Act, 25629

Federal Retirement Thrift Investment Board
PROPOSED RULES
Thrift savings plan:
Periodic participant statements; definitions and clarification, 25559–25561
Vesting; definitions and clarification, 25558–25559

Financial Management Service
See Fiscal Service

Fiscal Service
PROPOSED RULES
Electronic benefits transfer;
Financial institutions designation as financial agents, 25572–25576

Food and Drug Administration
RULES
Animal drugs, feeds, and related products:
Semduramicin, 25477
Food additives:
Adjuvants, production aids, and sanitizers—
High-purity furnace black, 25475–25477
Medical devices:
Electrode lead wires and patient cables; performance standard, 25477–25498
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 25632–25633
Food additive petitions:
BetzDearborn, Inc., 25633–25634
Harmonisation International Conference; guidelines availability:
Pharmaceuticals—
Clinical trials; statistical principles, 25712–25726
Good clinical practice; consolidated guideline, 25692–25709
Stability testing for new dosage forms, 25634–25635
Reports; availability, etc.:
Nutrition labeling information study; raw fruit/vegetables and raw fish, 25635–25636

Forest Service
NOTICES
Environmental statements; notice of intent:
Kaibab National Forest, AZ, 25583–25585

General Services Administration
PROPOSED RULES
Federal Acquisition Regulation (FAR):
Affirmative action reform in Federal procurement, 25786–25798
NOTICES
Federal Acquisition Regulation (FAR):
Agency information collection activities—
Proposed collection; comment request, 25800–25801

Health and Human Services Department
See Centers for Disease Control and Prevention
See Children and Families Administration
See Food and Drug Administration
See Health Care Financing Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration

Health Care Financing Administration
NOTICES
Agency information collection activities:
Proposed collection; comment request, 25636

Housing and Urban Development Department
PROPOSED RULES
Public and Indian housing:
Admission and occupancy regulations; Federal regulatory review, 25728–25738
Real Estate Settlement Procedures Act:
Employer payments to employees who make like-provider referrals; exemption and other amendments, 25740–25749
NOTICES
Agency information collection activities:
Proposed collection; comment request, 25639–25640
Grants and cooperative agreements; availability, etc.:
Facilities to assist homeless—
Excess and surplus Federal property, 25640–25647

Interior Department
See Land Management Bureau
See Reclamation Bureau

Internal Revenue Service
RULES
Income taxes:
Arbitrage and related restrictions on tax-exempt bonds; guidance for complying, 25502–25514
Partnership termination, 25498–25502

International Trade Administration
NOTICES
Antidumping duty orders and findings:
Intent to revoke, 25588–25589

Justice Department
See Antitrust Division

NOTICES
Federal procurement; affirmative action reforms proposal; response to comments, 25648–25653

Labor Department
See Employment and Training Administration
See Employment Standards Administration
See Labor Statistics Bureau
See Occupational Safety and Health Administration
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 25657–25658
Burma; forced labor; hearings, 25658
Meetings:
Trade Negotiations and Trade Policy Labor Advisory Committee, 25658

Labor Statistics Bureau
NOTICES
Meetings:
Labor Research Advisory Council, 25667–25668

Land Management Bureau
NOTICES
Meetings:
Resource advisory councils—
Butte District, 25647
Southeastern Oregon, 25647
Public land orders:
Colorado, 25647–25648
Withdrawal and reservation of lands:
Nevada; correction, 25648

Management and Budget Office
RULES
National security information; classification, downgrading, declassification, and safeguarding, 25426–25433

National Aeronautics and Space Administration
PROPOSED RULES
Federal Acquisition Regulation (FAR):
Affirmative action reform in Federal procurement, 25786–25798
NOTICES
Federal Acquisition Regulation (FAR):
Agency information collection activities—
Proposed collection; comment request, 25800–25801
Meetings:
Life and Microgravity Sciences and Applications Advisory Committee, 25671

National Institutes of Health
NOTICES
Meetings:
National Cancer Institute, 25636–25637
National Heart, Lung, and Blood Institute, 25637
National Institute of Environmental Health Sciences, 25637
National Institute on Alcohol Abuse and Alcoholism, 25637–25638
National Institute on Deafness and Other Communication Disorders, 25637
National Library of Medicine, 25638

National Science Foundation
NOTICES
Meetings:
Advanced Scientific Computing Special Emphasis Panel, 25671
Bioengineering and Environmental Systems Special Emphasis Panel, 25671
Civil and Mechanical Systems Special Emphasis Panel, 25671–25672
Computer and Information Science and Engineering Advisory Committee, 25672
Design, Manufacture, and Industrial Innovation Special Emphasis Panel, 25672
Mathematical and Physical Sciences Advisory Committee, 25672–25673

Navy Department
NOTICES
Environmental statements; availability, etc.:
Base realignment and closure—
Naval Air Station Cecil Field, FL, 25590

Nuclear Regulatory Commission
NOTICES
Environmental statements; availability, etc.:
Public Service Electric & Gas Co. et al., 25675–25677
Export and import license applications for nuclear facilities or materials:
ALARON Corp., 25677
Meetings:
Reactor Safeguards Advisory Committee, 25677–25678
Applications, hearings, determinations, etc.:
Sadovsky, Roy, D.V.M., 25673–25675

Occupational Safety and Health Administration
NOTICES
Meetings:
Occupational Safety and Health National Advisory Committee, 25668
State plans; standards approval, etc.:
Puerto Rico, 25668–25671

Office of Management and Budget
See Management and Budget Office

Personnel Management Office
RULES
Federal Employee Travel Reform Act of 1996; implementation:
Location-based pay entitlements; official duty station determinations, 25423–25425
NOTICES
Meetings:
Federal Prevailing Rate Advisory Committee, 25678–25679

Postal Rate Commission
PROPOSED RULES
Practice and procedure:
Market research evidence; foundational requirements clarified, 25578–25582

Postal Service
RULES
Domestic Mail Manual:
Experimental nonletter-size business reply mail categories and fees; implementation standards, 25752–25755

International Mail Manual:
Global package link (GPL) service—
China, 25515–25517
NOTICES
Domestic mail classification and rates, 25756–25757

Presidential Documents
PROCLAMATIONS
Special observances:
Mother's Day (Proc. 6999), 25421

Public Health Service
See Centers for Disease Control and Prevention
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration

Railroad Retirement Board
NOTICES
Privacy Act:
Computer matching programs, 25679

Reclamation Bureau
NOTICES
Central Valley Project Improvement Act:
Friant Division contractors; interim renewal contracts, 25648

Saint Lawrence Seaway Development Corporation
NOTICES
Meetings:
Advisory Board, 25688

Securities and Exchange Commission
NOTICES
Agency information collection activities:
Proposed collection; comment request, 25679–25680
Self-regulatory organizations; proposed rule changes:
American Stock Exchange, Inc., 25682–25683
National Association of Securities Dealers, Inc., 25683–25685
Applications, hearings, determinations, etc.:
Public utility holding company filings, 25680–25682

Social Security Administration
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 25685–25686

Substance Abuse and Mental Health Services Administration
NOTICES
Meetings:
SAMHSA special emphasis panels et al., 25638–25639

Surface Transportation Board
NOTICES
Railroad operation, acquisition, construction, etc.:
Norfolk & Western Railway Co., 25689

Textile Agreements Implementation Committee
See Committee for the Implementation of Textile Agreements

Transportation Department
See Coast Guard
See Federal Aviation Administration
See Saint Lawrence Seaway Development Corporation
See Surface Transportation Board
NOTICES
Aviation proceedings:
Agreements filed; weekly receipts, 25686
Certificates of public convenience and necessity and foreign air carrier permits; weekly applications, 25686

Treasury Department
See Fiscal Service
See Internal Revenue Service
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 25689, 25690

Separate Parts In This Issue

Part II
Department of Health and Human Services, Food and Drug Administration, 25692–25709

Part III
Department of Health and Human Services, Food and Drug Administration, 25712–25726

Part IV
Department of Housing and Urban Development, 25728–25738

Part V
Department of Housing and Urban Development, 25740–25749

Part VI
Postal Service, 25752–25757

Part VII
Department of Education, 25760–25784

Part VIII
Department of Defense, General Services Administration, National Aeronautics and Space Administration, 25786–25798

Reader Aids
Additional information, including a list of public laws, telephone numbers, reminders, and finding aids, appears in the Reader Aids section at the end of this issue.

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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.

3 CFR
Proclamations:
6999 25421

5 CFR
530 25423
531 25423
591 25423
1312 25426
Proposed Rules:
1603 25558
1640 25559

7 CFR
718 25433
729 25433
Proposed Rules:
319 25561

9 CFR
94 25439
160 25444
161 25444

12 CFR
Proposed Rules:
IX 25563

14 CFR
71 (2 documents) 25445, 25448
95 25448
Proposed Rules:
39 (3 documents) 25563, 25565, 25566
71 25568

15 CFR
730 25451
732 25451
734 25451
736 25451
738 25451
740 25451
742 25451
744 25451
746 25451
748 25451
750 25451
752 25451
754 25451
756 25451
758 25451
762 25451
764 25451
768 25451
770 25451
772 25451

17 CFR
1 25470

18 CFR
Proposed Rules:
430 25569

21 CFR
178 25475
558 25477
898 25477

24 CFR
Proposed Rules:
960 25728
966 25728
3500 25740

26 CFR
1 (2 documents) 25498, 25502
301 25498
602 25502

31 CFR
Proposed Rules:
207 25572

33 CFR
117 25514
Proposed Rules:
167 25576

34 CFR
685 25515

39 CFR
20 25515
111 25752
Proposed Rules:
3001 25578

40 CFR
180 (2 documents) 25518, 25524

46 CFR
159 25525
160 25525
199 25525

47 CFR
73 25557

48 CFR
Proposed Rules:
12 25786
14 25786
15 25786
19 25786
33 25786
52 25786
53 25786

Federal Register
Vol. 62, No. 90
Friday, May 9, 1997

Presidential Documents

Title 3—

The President

Proclamation 6999 of May 7, 1997

Mother's Day, 1997

By the President of the United States of America

A Proclamation

As we prepare to enter the 21st century, in the midst of a rapidly changing world, one thing remains constant—the unconditional love between a mother and her child. This love provides us with a cornerstone and sanctuary throughout our entire lives. Mothers nurture, challenge, and instill strong values in their children, find solutions, arbitrate disputes, organize activities, care and teach, influence and lead, give, share, and encourage. Their abiding moral principles shape our families, our communities, and our national life.

Today, mothers face many different challenges—from balancing the responsibilities of home and work, to raising families on their own—while contending with the often daunting challenges of modern society. They do this all while meeting the day-to-day responsibilities of class projects, car payments, and the flu season. And yet, they succeed, determined to protect what is so precious to them and to make brighter futures for themselves, their children, and their Nation.

Each year we welcome the opportunity to set aside a day to acknowledge all that our mothers—whether biological, adoptive, or foster—have given us. It is a time to reflect on all we have gained from their guidance, care, and sacrifice and a time to openly express our gratitude and love. The Congress, by a joint resolution approved May 8, 1914 (38 Stat. 770), has designated the second Sunday in May each year as ''Mother's Day'' and requested the President to call for its appropriate observance.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim May 11, 1997, as Mother's Day. Whether we are able to share this special day with our mothers or are blessed with memories of them, in our hearts they are with us always. I urge all Americans to express their love and respect for their mothers and to observe this day with appropriate ceremonies, activities, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of May, in the year of our Lord nineteen hundred and ninety-seven, and of the Independence of the United States of America the two hundred and twenty-first.

William J. Clinton

[FR Doc. 97–12403
Filed 5–8–97; 8:45 am]
Billing code 3195–01–P

Rules and Regulations

Federal Register
Vol. 62, No. 90
Friday, May 9, 1997

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

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 530, 531, and 591

RIN 3206—AH84

Official Duty Station Determinations for Pay Purposes

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing interim regulations in response to changes made by the Federal Employee Travel Reform Act of 1996 that affect the status of employees who are assigned to work in another location for an extended period. Under this law, employing agencies are authorized to pay certain relocation allowances in lieu of temporary duty travel allowances for employees who perform an extended assignment lasting from 6 to 30 months in another location. These interim regulations clarify that the temporary duty station during such an extended assignment must be treated as the official duty station of the employee for purposes of determining the employee's location-based pay entitlements.

DATES: These regulations are effective on May 9, 1997. Comments must be received on or before July 8, 1997.

ADDRESSES: Comments may be sent or delivered to Donald J. Winstead, Assistant Director for Compensation Policy, Human Resources Systems Service, Office of Personnel Management, Room 6H31, 1900 E Street NW., Washington, DC 20415 (FAX: (202) 606–0824 or EMAIL: payleave@opm.gov).

FOR FURTHER INFORMATION CONTACT: Jeanne Jacobson, (202) 606–2858, FAX: (202) 606–0824, or EMAIL: payleave@opm.gov.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management (OPM) is issuing interim regulations in response to changes made by the Federal Employee Travel Reform Act of 1996 (title XVII of Pub. L. 104–201, September 23, 1996), which took effect on March 22, 1997. Section 1716 of the Act amends subchapter II of chapter 57 of title 5, United States Code, by adding a new section 5737. Section 5737 gives agencies discretionary authority to pay certain limited relocation allowances (including payment of various expenses associated with moving family members and household goods) in lieu of temporary duty travel allowances (including payment of a per diem allowance or actual subsistence expenses) for employees who are assigned from their official duty station to another duty station for an extended period of time. Agencies may pay the limited relocation allowances only for extended assignments lasting (or originally expected to last) from 6 to 30 months. These extended temporary assignments may involve a duty station change accompanied by a position change (e.g., reassignment or promotion), or they may merely involve a duty station change.

These interim regulations address the pay entitlements of Federal employees during one of these extended assignments and make related clarifying changes. Certain Federal employee pay entitlements—e.g., locality pay and nonforeign area cost-of-living allowances—are linked to an employee's official duty station (sometimes referred to as the ''permanent'' duty station). The official duty station is defined as the duty station for the employee's position of record as documented on his or her most recent notification of personnel action. To ensure consistent and equitable treatment of employees, these regulations provide that the employee's temporary duty station in connection with an extended assignment under 5 U.S.C. 5737 must be considered the employee's official duty station for purposes of certain pay programs regulated by OPM. In other words, the employee's position and duty station associated with the extended assignment must be documented by personnel action as the position of record and official duty station for specified pay purposes. Agencies should follow instructions in OPM's Guide to Processing Personnel Actions when documenting the employee's personnel records. Agency remarks should be used where necessary to distinguish the time limitation of the assignment.

Details Versus Assignments

Previously, agencies that assigned employees to long-term assignments away from their current official duty stations had two options: (1) *Detail* the employee to a temporary duty location and pay temporary duty travel allowances in accordance with subchapter I of chapter 57 of title 5, United States Code, or (2) *assign* the employee, in the interest of the Government, to a new official duty station on an indefinite basis and pay appropriate relocation allowances in accordance with subchapter II of that chapter.

When an employee is *detailed*, the employee's official position of record remains the position the employee occupied before the detail, and the employee's official duty station is the duty station associated with that position. If the temporary duty location associated with the detail is away from the employee's official duty station, the employee is entitled to temporary duty travel allowances as provided in subchapter I of chapter 57 of title 5, United States Code. Since the duty station from which the employee is detailed remains the official duty station, his or her pay entitlements would be determined based on that duty station.

When an employee is *assigned* to a new position and/or duty station, the position and duty station associated with that assignment constitute the employee's position of record and official duty station. The job assignment generally takes the form of a reassignment, promotion, or demotion (as those terms are defined in 5 CFR 210.102), resulting in a change in the employee's position of record, but which may or may not involve a duty station change. In some cases, the assignment is merely a change in duty station without a change in the position of record. The official duty station associated with the assignment constitutes the official duty station for purposes of determining (1) the employee's entitlements to the full array

of relocation allowances under subchapter II of chapter 57 of title 5, United States Code, and (2) the employee's entitlements to various forms of location-based payments.

Extended Assignments With a Temporary Change of Duty Station

Section 5737 of title 5, United States Code, now provides agencies a third option—the authority to pay, in lieu of temporary duty travel allowances, a limited set of relocation allowances to employees who are assigned from their current official duty station to a new temporary duty station for an extended period of time (i.e., 6 to 30 months). The limited relocation allowances include payment of travel expenses for the employee and his or her immediate family to and from the assignment location, transportation expenses of the employee's household goods, househunting trip expenses (if appropriate), temporary quarters subsistence expenses (if appropriate), expenses of transporting a privately owned vehicle to and from the new assignment location, expenses of storage of household goods and personal effects, a relocation income tax allowance, expenses of property management services in connection with maintaining a residence at the old duty station as a rental property, and certain other miscellaneous expenses. However, residence transaction allowances, which apply to permanent changes in duty station, are not payable. The General Services Administration (GSA) published Federal Travel Regulation (FTR) (41 CFR chapters 301–304) Amendment 64, Temporary Change of Station, implementing this limited relocation allowance authority on Friday, March 21, 1997. (See 62 FR 13770.) The provisions of FTR Amendment 64 became effective on March 22, 1997. Among other things, the GSA regulations clarify that employees who are relocated under 5 U.S.C. 5737 to perform an extended assignment are entitled to allowances to cover the costs of moving them back to the last permanent official duty station area, even if they separate from Federal service.

Section 5737 did not clearly state how the employee's pay entitlements would be affected by the extended assignment to a new duty station. The OPM regulations published in this notice make several changes to ensure that employees on extended assignments who are paid limited relocation allowances under 5 U.S.C. 5737 are paid the appropriate special salary rate, locality payment, law enforcement officer geographic adjustment, and nonforeign area cost-of-living allowance and/or post differential for the temporary duty station associated with the extended assignment.

As explained in the section titled ''Details Versus Assignments,'' when an employee is temporarily detailed to a new duty location away from his or her official duty station, the employee is entitled to the payment of temporary duty travel allowances and continues to be paid various types of location-based pay based on the position of record and official duty station from which he or she was detailed. In contrast, when an employee receives an extended assignment under 5 U.S.C. 5737, the new duty station associated with the extended assignment is established as the temporary official duty station. Instead of temporary duty travel allowances, the employee is entitled to a limited set of relocation allowances, including many of the same relocation allowances payable to employees assigned to a new official duty station on an indefinite basis. (See subpart C of part 302–1, title 41, Code of Federal Regulations, as added by Federal Travel Regulation Amendment 64, referenced above.) Therefore, the interim regulations provide that employees serving on extended assignments under 5 U.S.C. 5737 must be paid various types of location-based pay based on the temporary official duty station—i.e., in the same manner as employees who are officially stationed in that same pay area on an indefinite basis.

For temporary work in another location expected to last 6 months or more, the employing agency is responsible for determining whether a detail (providing temporary duty travel allowances) or an extended assignment/temporary change of duty station under 5 U.S.C. 5737 (providing limited relocation allowances) would be most appropriate, consistent with the criteria in GSA's Federal Travel Regulation. (See subpart D of part 302–1, title 41, Code of Federal Regulations, as added by Federal Travel Regulation Amendment 64, referenced above.) As explained above, employees' pay entitlements would automatically flow from the approach chosen by the employing agency.

It should be noted that not all temporary assignments involve a change in duty station. In some cases, an employee may be temporarily reassigned or promoted to a new position that is at the same duty station. In these cases, there is no issue as to the payment of relocation allowances, since those allowances only apply when there is a change in duty station. Of course, the duty station for pay purposes would also be unchanged.

In addition, we note that these regulations deal only with the effect that an extended assignment under 5 U.S.C. 5737 has on an employee's official duty station for purposes of making certain pay determinations. They do not address other personnel rules (e.g., reduction-in-force regulations in 5 CFR part 351).

Regulatory Changes

The interim regulations add a new paragraph to 5 CFR 530.303 that clarifies that an employee is covered by a special salary rate schedule based on the employee's position of record and the official duty station for that position, as documented on the employee's most recent notification of personnel action. The new paragraph also provides that, for special salary rate purposes, when an employee is paid limited relocation allowances under 5 U.S.C. 5737, the employee's position of record and official duty station are the position and duty station associated with the extended assignment. The interim regulations also make a similar change in the definitions of *official duty station* in 5 CFR 531.301 and 531.602 for purposes of paying locality-based comparability payments and law enforcement officer geographic adjustments.

The interim regulations add a definition of *official duty station* to 5 CFR 591.201 (consistent with the revised definitions of *official duty station* in 5 CFR 531.301 and 531.602) for purposes of paying nonforeign area cost-of-living allowances and post differentials and change the term ''permanent duty station'' to ''official duty station'' in 5 CFR 591.210(a) to make these terms consistent with those used in the locality pay regulations. The regulations also make conforming changes in § 591.201 and in paragraphs (b)(1), (c), and (f) of § 591.210.

Waiver of Notice of Proposed Rulemaking and of Delay in Effective Date

Pursuant to 5 U.S.C. 553(b)(3)(B), I find that good cause exists for waiving the general notice of proposed rulemaking. Also, pursuant to 5 U.S.C. 553(d)(3), I find that good cause exists to make this rule effective in less than 30 days. As explained in this notice, these regulatory changes are needed to address new situations created by the Federal Employee Travel Reform Act of 1996, which took effect on March 22, 1997. The regulations are necessary to ensure that Federal employees are treated equitably and consistently in

determining their location-based pay entitlements.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

List of Subjects in 5 CFR Parts 530, 531, and 591

Government employees, Law enforcement officers, Reporting and recordkeeping requirements, Travel and transportation expenses, Wages.

U.S. Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM is amending parts 530, 531, and 591 of title 5 of the Code of Federal Regulations as follows:

PART 530—PAY RATES AND SYSTEMS (GENERAL)

1. The authority citation for part 530 continues to read as follows:

Authority: 5 U.S.C. 5305 and 5307; E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316;

Subpart B also issued under secs. 302(c) and 404(c) of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509), 104 Stat. 1462 and 1466, respectively;

Subpart C also issued under sec. 4 of the Performance Management and Recognition System Termination Act of 1993 (Pub. L. 103–89), 107 Stat. 981.

2. In § 530.303, a new paragraph (i) is added to read as follows:

§ 530.303 Establishing and adjusting special salary rate schedules.

* * * * *

(i) The determination regarding whether an employee is covered by a special salary rate schedule is based on the employee's position of record and the official duty station for that position. For purposes of this subpart, the employee's position of record and corresponding official duty station are the position and station documented on the employee's most recent notification of personnel action. For an employee who is authorized to receive relocation allowances under 5 U.S.C. 5737 in connection with an extended assignment, the position and duty station associated with that assignment are the employee's position of record and official duty station.

PART 531—PAY UNDER THE GENERAL SCHEDULE

3. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Pub. L. 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316;

Subpart B also issued under 5 U.S.C. 5303(g), 5333, 5334(a), and 7701(b)(2);

Subpart C also issued under 5 U.S.C. 5304, 5305, and 5553; sections 302 and 404 of FEPCA, Pub. L. 101–509, 104 Stat. 1462 and 1466; and section 3(7) of Pub. L. 102–378, 106 Stat. 1356;

Subpart D also issued under 5 U.S.C. 5335(g) and 7701(b)(2);

Subpart E also issued under 5 U.S.C. 5336;

Subpart F also issued under 5 U.S.C. 5304, 5305(g)(1), and 5553; and E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682;

Subpart G also issued under 5 U.S.C. 5304, 5305, and 5553; section 302 of the Federal Employees Pay Comparability Act of 1990 (FEPCA), Pub. L. 101–509, 104 Stat. 1462; and E.O. 12786, 56 FR 67453, 3 CFR, 1991 Comp., p. 376.

4. In § 531.301, the definition of *official duty station* is revised to read as follows:

§ 531.301 Definitions.

* * * * *

Official duty station means the duty station for the law enforcement officer's position of record as indicated on his or her most recent notification of personnel action. For an employee who is authorized to receive relocation allowances under 5 U.S.C. 5737 in connection with an extended assignment, the temporary duty station associated with that assignment is the employee's official duty station.

* * * * *

5. In § 531.602, the definition of *official duty station* is revised to read as follows:

§ 531.602 Definitions.

* * * * *

Official duty station means the duty station for an employee's position of record as indicated on his or her most recent notification of personnel action. For an employee who is authorized to receive relocation allowances under 5 U.S.C. 5737 in connection with an extended assignment, the temporary duty station associated with that assignment is the employee's official duty station.

* * * * *

PART 591—ALLOWANCES AND DIFFERENTIALS

Subpart B—Cost-of-Living Allowance and Post Differential—Nonforeign Areas

6. The authority citation for subpart B of part 591 continues to read as follows:

Authority: 5 U.S.C. 5941; E.O. 10000, 3 CFR, 1943–1948 Comp., p. 792; and E.O. 12510, 3 CFR, 1985 Comp., p. 338.

7. In § 591.201, the definitions of *date of arrival* and *date of departure* are removed and the definition of *official duty station* is added in alphabetical order to read as follows:

§ 591.201 Definitions.

* * * * *

Official duty station means the duty station for an employee's position of record as indicated on his or her most recent notification of personnel action. For an employee who is authorized to receive relocation allowances under 5 U.S.C. 5737 in connection with an extended assignment, the temporary duty station associated with that assignment is the employee's official duty station.

* * * * *

8. In § 591.210, paragraph (a) is amended by removing the word ''permanent'' and adding the word ''official'' in its place; paragraph (c) is amended by removing the words ''a duty station'' and adding the words ''an official duty station'' in their place; paragraph (b)(1) is amended by removing the last sentence and adding a new sentence in its place; and paragraph (f) is revised to read as follows:

§ 591.210 Payment of allowances and differentials.

* * * * *

(b)(1) * * * Allowances and differentials that an employee is receiving in accordance with this subpart at the time of separation or death shall be included in any lump-sum payment for accumulated and current accrued annual leave issued under sections 5551 or 5552 of title 5, United States Code.

* * * * *

(f) Payment of an allowance or differential will begin on the effective date of the change in the employee's official duty station to a duty station within the allowance or differential area or on the effective date of the appointment in the case of local recruitment. Payment of an allowance or differential will cease upon separation or on the effective date of an assignment or transfer to a new official duty station outside the allowance or differential area.

[FR Doc. 97–12089 Filed 5–8–97; 8:45 am]

BILLING CODE 6325–01–P

OFFICE OF MANAGEMENT AND BUDGET

5 CFR Part 1312

RIN 0348–AB34

Classification, Downgrading, Declassification and Safeguarding of National Security Information

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations that set forth the procedures to be followed by the Office of Management and Budget's (OMB) staff regarding the classification, downgrading, declassification and safeguarding of national security information. In addition, this final rule lists OMB staff who are authorized to originally classify information at the top secret and secret level. These regulations also contain the procedures to be used by OMB when other government agencies and the public request that classified information in OMB files be reviewed for possible declassification and release. These procedures also outline how to appeal a decision not to declassify information.

EFFECTIVE DATE: June 9, 1997.

FOR FURTHER INFORMATION CONTACT: Darrell A. Johnson, Deputy Assistant Director for Administration, Office of Management and Budget, at (202) 395–5715.

SUPPLEMENTARY INFORMATION: On September 17, 1996 (61 FR 48855), OMB requested public comment on proposed revisions to its regulations at 5 CFR Part 1312 concerning the classification, downgrading, declassification and safeguarding of national security information. This revision is necessary to ensure conformity with Executive Order 12958 (60 FR 19825, April 20, 1995) and implementing directives issued by the Information Security Oversight Office. OMB proposed to repeal its existing Part 1312 and replace it with a new Part 1312.

No public comments were received in response to the September 1996 proposed rule. No substantive changes have been made to the proposed rule, which is being adopted.

Regulatory Flexibility Act, Unfunded Mandates Reform Act, and Executive Orders 12866 and 12875

For purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the final rule will not have a significant economic effect on a substantial number of small entities; the final rule addresses only the procedures for OMB's classification, downgrading, declassification and safeguarding of national security information. For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Orders No. 12866 and 12875, the final rule will not significantly or uniquely affect small governments, and will not result in increased expenditures by State, local, and tribal governments, or by the private sector, of $100 million or more. The final rule is not a ''major rule'' under 5 U.S.C. Chapter 8; the rule will not have any of the effects set forth in 5 U.S.C. 804(2).

Issued in Washington, DC, April 24, 1997.

Franklin D. Raines

Director.

For the reasons set forth in the preamble, OMB amends 5 CFR Chapter III by revising Part 1312 to read as follow:

PART 1312—CLASSIFICATION, DOWNGRADING, DECLASSIFICATION AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION:

Subpart A—Classification and Declassification of National Security Information

Sec.
1312.1 Purpose and authority.
1312.2 Responsibilities.
1312.3 Classification requirements.
1312.4 Classified designations.
1312.5 Authority to classify
1312.6 Duration of classification.
1312.7 Derivative classification.
1312.8 Standard identification and markings.
1312.9 Downgrading and declassification.
1312.10 Systematic review guidelines.
1312.11 Challenges to classifications.
1312.12 Security Program Review Committee.

Subpart B—Control and Accountability of Classified Information

1312.21 Purpose and authority.
1312.22 Responsibilities.
1312.23 Access to classified information.
1312.24 Access by historical researchers and former Presidential appointees.
1312.25 Storage.
1312.26 Control of secret and confidential material.
1312.27 Top secret control.
1312.28 Transmission of classified material.
1312.29 Destruction.
1312.30 Loss or possible compromise.
1312.31 Security violations.

Subpart C—Mandatory Declassification Review

1312.32 Purpose and authority.
1312.33 Responsibility.
1312.34 Information in the custody of OMB.
1312.35 Information classified by another agency.
1312.36 Appeal procedure.
1312.37 Fees.

Authority: Executive Order 12958, April 20, 1995, 3 CFR, 1995 Comp., p. 333.

Subpart A—Classification and Declassification of National Security Information

§ 1312.1 Purpose and authority.

This subpart sets forth the procedures for the classification and declassification of national security information in the possession of the Office of Management and Budget. It is issued under the authority of Executive Order 12958, (60 FR 19825, 3 CFR, 1995 Comp., P.333), as implemented by Information Security Oversight Office Directive No. 1 (32 CFR part 2001), and is applicable to all OMB employees.

§ 1312.2 Responsibilities.

The effectiveness of the classification and declassification program in OMB depends entirely on the amount of attention paid to it by supervisors and their staffs in those offices and divisions that possess or produce classified material. Officials who originate classified information are responsible for proper assignment of a classification to that material and for the decision as to its declassification. Officials who produce documents containing classified information must determine the source of the classification for that information and must ensure that the proper identity of that source is shown on the document. Custodians of classified material are responsible for its safekeeping and for ensuring that such material is adequately marked as to current classification. Custodians are also responsible for the control of and accounting for all classified material within their area of jurisdiction as prescribed in OMB Manual Section 1030.

(a) *EOP Security Officer.* In cooperation with the Associate Director (or Assistant Director) for Administration, the EOP Security Officer supervises the administration of this section and develops programs to assist in the compliance with the Order. Specifically, he:

(1) Promotes the correct understanding of this section by all employees by providing annual security refresher briefings and ensures that new employees attend initial briefings about overall security procedures and policies.

(2) Issues and keeps current such classification guides and guidelines for review for declassification as are required by the Order.

(3) Conducts periodic reviews of classified documents produced and

provides assistance and guidance where necessary.

(4) Maintains and publishes a current listing of all officials who have been designated in writing to have Top Secret, Secret, and Confidential original classification authority.

(b) *Heads of divisions or offices.* The head of each division or major organizational unit is responsible for the administration of this section within his or her area. Appropriate internal guidance should be issued to cover special or unusual conditions within an office.

§ 1312.3 Classification requirements.

United States citizens must be kept informed about the activities of their Government. However, in the interest of national security, certain official information must be subject to constraints on its dissemination or release. This information is classified in order to provide that protection.

(a) Information shall be considered for classification if it concerns:

(1) Military plans, weapons systems, or operations;

(2) Foreign government information;

(3) Intelligence activities (including special activities), intelligence sources or methods, or cryptology;

(4) Foreign relations or foreign activities of the United States, including confidential sources;

(5) Scientific, technological, or economic matters relating to the national security;

(6) United States Government programs for safeguarding nuclear materials or facilities; or

(7) Vulnerabilities or capabilities of systems, installations, projects or plans relating to the national security.

(b) When information is determined to meet one or more of the criteria in paragraph (a) of this section, it shall be classified by an original classification authority when he/she determines that its unauthorized disclosure reasonably could be expected to cause at least identifiable damage to the national security.

(c) Unauthorized disclosure of foreign government information, including the identity of a confidential foreign source of intelligence sources or methods, is presumed to cause damage to the national security.

(d) Information classified in accordance with this section shall not be declassified automatically as a result of any unofficial or inadvertent or unauthorized disclosure in the United States or abroad of identical or similar information.

§ 1312.4 Classified designations.

(a) Except as provided by the Atomic Energy Act of 1954, as amended, (42 U.S.C. 2011) or the National Security Act of 1947, as amended, (50 U.S.C. 401) Executive Order 12958 provides the only basis for classifying information. Information which meets the test for classification may be classified in one of the following three designations:

(1) *Top Secret.* This classification shall be applied only to information the unauthorized disclosure of which reasonably could be expected to cause exceptionally grave damage to the national security that the original classification authority is able to identify or describe.

(2) *Secret.* This classification shall be applied only to information the unauthorized disclosure of which reasonably could be expected to cause serious damage to the national security that the original classification authority is able to identify or describe.

(3) *Confidential.* This classification shall be applied only to information the unauthorized disclosure of which reasonably could be expected to cause damage to the national security that the original classification authority is able to identify or describe.

(b) If there is significant doubt about the need to classify information, it shall not be classified. If there is significant doubt about the appropriate level of classification, it shall be classified at the lower level.

§ 1312.5 Authority to classify.

(a) The authority to originally classify information or material under this part shall be limited to those officials concerned with matters of national security. The officials listed in this section are granted authority by the Director, OMB, to assign original classifications as indicated to information or material that is originated by OMB staff and relating to the national security of the United States:

(1) Top Secret and below:

(i) Deputy Director.

(ii) Deputy Director for Management.

(iii) Associate Director for National Security and International Affairs.

(iv) Associate Director for Natural Resources, Energy and Science.

(2) Secret and below:

(i) Deputy Associate Director for National Security.

(ii) Deputy Associate Director for International Affairs.

(iii) Deputy Associate Director for Energy and Science.

(b) Classification authority is not delegated to persons who only reproduce, extract, or summarize classified information, or who only apply classification markings derived from source material or from a classification guide.

§ 1312.6 Duration of classification.

(a)(1) When determining the duration of classification for information originally classified under Executive Order 12958, an original classification authority shall follow the following sequence:

(i) He/She shall attempt to determine a date or event that is less than 10 years from the date of original classification, and which coincides with the lapse of the information's national security sensitivity, and shall assign such date or event as the declassification instruction;

(ii) If unable to determine a date or event of less than 10 years, he/she shall ordinarily assign a declassification date that is 10 years from the date of the original classification decision;

(iii) He/She may extend the duration of classification or reclassify specific information for a period not to exceed 10 additional years if such action is consistent with the exemptions as outlined in Section 1.6(d) of the Executive Order. This provision does not apply to information contained in records that are more than 25 years old and have been determined to have permanent historical value under Title 44 United States Code.

(iv) He/She may exempt from declassification within 10 years specific information, which is consistent with the exemptions as outlined in Section 1.6 (d) of the Executive Order.

(2) Extending Duration of Classification. Extensions of classification are not automatic. If an original classification authority with jurisdiction over the information does not extend the date or event for declassification, the information is automatically declassified upon the occurrence of the date or event. If an original classification authority has assigned a date or event for declassification that is 10 years or less from the date of classification, an original classification authority with jurisdiction over the information may extend the classification duration of such information for additional periods not to exceed 10 years at a time. Records determined to be of historical value may not exceed the duration of 25 years.

(b) When extending the duration of classification, the original classification authority must:

(1) Be an original classification authority with jurisdiction over the information.

(2) Ensure that the information continues to meet the standards for classification under the Executive Order.

(3) Make reasonable attempts to notify all known holders of the information. Information classified under prior orders marked with a specific date or event for declassification is automatically declassified upon that date or event. Information classified under prior orders marked with Originating Agency's Determination Required (OADR) shall:

(i) Be declassified by a declassification authority as defined in Section 3.1 of the Executive Order.

(ii) Be re-marked by an authorized original classification authority with jurisdiction over the information to establish a duration of classification consistent with the Executive Order.

(iii) Be subject to Section 3.4 of the Executive Order if the records are determined to be of historical value and are to remain classified for 25 years from the date of its original classification.

§ 1312.7 Derivative classification.

A *derivative classification* means that the information is in substance the same information that is currently classified, usually by another agency or classification authority. The application of derivative classification markings is the responsibility of the person who incorporates, restates, paraphrases, or generates in new form information that is already classified, or one who applies such classification markings in accordance with instructions from an authorized classifier or classification guide. Extreme care must be taken to continue classification and declassification markings when such information is incorporated into OMB documents. The duplication or reproduction of existing classified information is not derivative classification. Persons who use derivative classification need not possess original classification authority.

§ 1312.8 Standard identification and markings.

(a) *Original Classification.* At the time classified material is produced, the classifier shall apply the following markings on the face of each originally classified document, including electronic media:

(1) *Classification Authority.* The name/personal identifier, and position title of the original classifier shall appear on the ''Classified By'' line.

(2) *Agency and Office of Origin.* If not otherwise evident, the agency and office of origin shall be identified and placed below the name on the ''Classified By'' line.

(3) *Reasons for Classification.* Identify the reason(s) to classify. The classifier shall include, at a minimum, a brief reference to the pertinent classification category(ies), or the number 1.5 plus the letter(s) that corresponds to that classification category in Section 1.5 of the Executive Order.

(4) *Declassification instructions.* These instructions shall indicate the following:

(i) The duration of the original classification decision shall be placed on the ''Declassify On'' line.

(ii) The date or event for declassification that corresponds to the lapse of the information's national security sensitivity, which may not exceed 10 years from the date of the original decision.

(iii) When a specific date or event within 10 years cannot be established, the classifier will apply the date that is 10 years from the date of the original decision.

(iv) The exemption category from declassification. Upon determination that the information must remain classified beyond 10 years, the classifier will apply the letter ''X'' plus a brief recitation of the exemption category(ies), or the letter ''X'' plus the number that corresponds to the exemption category(ies) in Section 1.6(d) of the Executive Order.

(v) An original classification authority may extend the duration of classification for successive periods not to exceed 10 years at a time. The ''Declassify On'' line shall be revised to include the new declassification instructions and shall include the identity of the person authorizing the extension and the date of the action.

(vi) Information exempted from automatic declassification at 25 years should on the ''Declassify On'' line be revised to include the symbol ''25X'' plus a brief reference to the pertinent exemption categories/numbers of the Executive Order.

(5) The overall classification of the document is the highest level of information in the document and will be conspicuously placed stamped at the top and bottom of the outside front and back cover, on the title page, and on the first page.

(6) The highest classification of individual pages will be stamped at the top and bottom of each page, to include ''unclassified'' when it is applicable.

(7) The classification of individual portions of the document, (ordinarily a paragraph, but including subjects, titles, graphics) shall be marked by using the abbreviations (TS), (S), (C), or (U), will be typed or marked at the beginning or end of each paragraph or section of the document. If all portions of the document are classified at the same level, this may be indicated by a statement to that effect.

(b) *Derivative Classification.* Information classified derivatively on the basis of source documents shall carry the following markings on those documents:

(1) The derivative classifier shall concisely identify the source document(s) or the classification guide on the ''Derived From'' line, including the agency and where available the office of origin and the date of the source or guide. When a document is classified derivatively on the basis of more than one source document or classification guide, the ''Derived From'' line shall appear as ''Derived From: Multiple Sources''.

(2) The derivative classifier shall maintain the identification of each source with the file or record copy of the derivatively classified document. Where practicable the copies of the document should also have this list attached.

(3) A document derivatively classified on the basis of a source document that is itself marked ''Multiple Sources'' shall cite the source document on its ''Derived From'' line rather than the term ''Multiple Sources''.

(4) The reason for the original classification decision, as reflected in the source document, is not required to be transferred in a derivative classification action.

(5) Declassification instructions shall carry forward the instructions on the ''Declassify On'' line from the source document to the derivation document or the duration instruction from the classification guide. Where there are multiple sources, the longest duration of any of its sources shall be used.

(6) When a source document or classification guide contains the declassification instruction ''Originating Agency's Determination Required'' (OADR) the derivative document shall carry forward the fact that the source document(s) were so marked and the date of origin of the most recent source document (s).

(7) The derivatively classified document shall be conspicuously marked with the highest level of classification of information.

(8) Each portion of a derivatively classified document shall be marked in accordance with its source.

(9) Each office shall, consistent with Section 3.8 of the Executive Order, establish and maintain a database of information that has been declassified.

(c) *Additional Requirements.* (1) Markings other than ''Top Secret'', ''Secret'', and ''Confidential'' shall not be used to identify classified national security information.

(2) Transmittal documents will be stamped to indicate the highest classification of the information transmitted, and shall indicate conspicuously on its face the following or something similar ''Unclassified When classified Enclosure Removed'' to indicate the classification of the transmittal document standing alone.

(3) The classification data for material other than documents will be affixed by tagging, stamping, recording, or other means to insure that recipients are aware of the requirements for the protection of the material.

(4) Documents containing foreign government information shall include the markings ''This Document Contains (country of origin) Information''. If the identity of the specific government must be concealed, the document shall be marked'' This Document Contains Foreign Government Information,'' and pertinent portions marked ''FGI'' together with the classification level, e.g., ''(FGI–C)''. In such cases, separate document identifying the government shall be maintained in order to facilitate future declassification actions.

(5) Documents, regardless of medium, which are expected to be revised prior to the preparation of a finished product—working papers—shall be dated when created, marked with highest classification, protected at that level, and destroyed when no longer needed. When any of the following conditions exist, the working papers shall be controlled and marked in the same manner as prescribed for a finished classified document:

(i) Released by the originator outside the originating activity;

(ii) Retained more than 180 days from the date of origin;

(iii) Filed permanently.

(6) Information contained in unmarked records, or Presidential or related materials, and which pertain to the national defense or foreign relations of the U.S. and has been maintained and protected as classified information under prior orders shall continue to be treated as classified information under the Executive Order and is subject to its provisions regarding declassification.

§ 1312.9 Downgrading and declassification.

Classified information originated by OMB offices will be downgraded or declassified as soon as it no longer qualifies for continued protection under the provisions of the classification guides. Authority to downgrade or declassify OMB-originated information is granted to those authorized to classify (See § 1312.5). Additionally, the Associate Director (or Assistant Director) for Administration is authorized to exercise downgrading and declassification actions up to and including the Top Secret level.

(a) *Transferred material.* Information which was originated by an agency that no longer exists, or that was received by OMB in conjunction with a transfer of functions, is deemed to be OMB-originated material. Information which has been transferred to another agency for storage purposes remains the responsibility of OMB.

(b) *Periodic review of classified material.* Each office possessing classified material will review that material on an annual basis or in conjunction with the transfer of files to non-current record storage and take action to downgrade or declassify all material no longer qualifying for continued protection at that level. All material transferred to non-current record storage must be properly marked with correct downgrade and declassification instructions.

§ 1312.10 Systematic review guidelines.

The EOP Security Officer will prepare and keep current such guidelines as are required by Executive Order 12958 for the downgrading and declassification of OMB material that is in the custody of the Archivist of the United States.

§ 1312.11 Challenges to classifications.

OMB employees are encouraged to familiarize themselves with the provisions of Executive Order 12958 and with OMB Manual Sections 1010, 1020, and 1030. Employees are also encouraged to question or to challenge those classifications they believe to be improper, unnecessary, or for an inappropriate time. Such questions or challenges may be addressed to the originator of the classification, unless the challenger desires to remain anonymous, in which case the question may be directed to the EOP Security Officer.

§ 1312.12 Security Program Review Committee.

The Associate Director (or Assistant Director) for Administration will chair the OMB Security Program Review Committee, which will act on suggestions and complaints about the OMB security program.

Subpart B—Control and Accountability of Classified Information

§ 1312.21 Purpose and authority.

This subpart sets forth procedures for the receipt, storage, accountability, and transmission of classified information at the Office of Management and Budget. It is issued under the authority of Executive Order 12958, (60 FR 19825, 3 CFR, 1995 Comp., P.333), as implemented by Information Security Oversight Office Directive No 1 (32 CFR part 2001), and is applicable to all OMB employees.

§ 1312.22 Responsibilities.

The effective direction by supervisors and the alert performance of duty by employees will do much to ensure the adequate security of classified information in the possession of OMB offices. Each employee has a responsibility to protect and account for all classified information that he/she knows of within his/her area of responsibility. Such information will be made available only to those persons who have an official need to know and who have been granted the appropriate security clearance. Particular care must be taken not to discuss classified information over unprotected communications circuits (to include intercom and closed-circuit TV), at non-official functions, or at any time that it might be revealed to unauthorized persons. Classified information may only be entered into computer systems meeting the appropriate security criteria.

(a) *EOP Security Officer.* In cooperation with the Associate Director (or Assistant Director) for Administration, the EOP Security Officer supervises the administration of this section. Specifically, he/she:

(1) Promotes the correct understanding of this section and insures that initial and annual briefings about security procedures are given to all new employees.

(2) Provides for periodic inspections of office areas and reviews of produced documents to ensure full compliance with OMB regulations and procedures.

(3) Takes prompt action to investigate alleged violations of security, and recommends appropriate administrative action with respect to violators.

(4) Supervises the annual inventories of Top Secret material.

(5) Ensures that containers used to store classified material meet the appropriate security standards and that combinations to security containers are changed as required.

(b) *Heads of Offices.* The head of each division or office is responsible for the

administration of this section in his/her area. These responsibilities include:

(1) The appointment of accountability control clerks as prescribed in § 1312.26.

(2) The maintenance of the prescribed control and accountability records for classified information within the office.

(3) Establishing internal procedures to ensure that classified material is properly safeguarded at all times.

§ 1312.23 Access to classified information.

Classified information may be made available to a person only when the possessor of the information establishes that the person has a valid ''need to know'' and the access is essential to the accomplishment of official government duties. The proposed recipient is eligible to receive classified information only after he/she has been granted a security clearance by the EOP Security Officer. Cover sheets will be used to protect classified documents from inadvertent disclosure while in use. An SF–703 will be used for Top Secret material; an SF–704 for Secret material, and an SF–705 for Confidential material. The cover sheet should be removed prior to placing the document in the files.

§ 1312.24 Access by historical researchers and former Presidential appointees.

(a) The requirements of Section 4.2(a)(3) of Executive Order 12958 may be waived for persons who are engaged in historical research projects, or who previously have occupied policy-making positions to which they were appointed by the President. Waivers may be granted only if the Associate Director (or Assistant Director) for Administration, in cooperation with the EOP Security Officer:

(1) Determines in writing that access is consistent with the interest of national security;

(2) Takes appropriate steps to protect classified information from unauthorized disclosure or compromise, and ensures that the information is safeguarded in a manner consistent with the order; and

(3) Limits the access granted to former Presidential appointees to items that the person originated, reviewed, signed, or received while serving as a Presidential appointee.

(b) In the instances described in paragraph (a) of this section, the Associate Director (or Assistant Director) for Administration, in cooperation with the EOP Security Officer, will make a determination as to the trustworthiness of the requestor and will obtain written agreement from the requestor to safeguard the information to which access is given. He/She will also obtain written consent to the review by OMB of notes and manuscripts for the purpose of determining that no classified information is contained therein. Upon the completion of these steps, the material to be researched will be reviewed by the division/office of primary interest to ensure that access is granted only to material over which OMB has classification jurisdiction.

§ 1312.25 Storage.

All classified material in the possession of OMB will be stored in a GSA-approved container or in vault-type rooms approved for Top Secret storage. Under the direction of the EOP Security Officer, combinations to safes used in the storage of classified material will be changed when the equipment is placed in use, whenever a person knowing the combination no longer requires access to it, whenever the combination has been subjected to possible compromise, whenever the equipment is taken out of service, or at least once a year. Knowledge of combinations will be limited to the minimum number of persons necessary, and records of combinations will be assigned a classification no lower than the highest level of classified information stored in the equipment concerned. An SF–700, Security Container Information, will be used in recording safe combinations. Standard Form–702, Security Container check sheet, will be posted to each safe and will be used to record opening, closing, and checking the container whenever it is used.

§ 1312.26 Control of secret and confidential material.

Classified material will be accounted for by the office having custody of the material. OMB Form 87, Classified Document Control, will be used to establish accountability controls on all Secret material received or produced within OMB offices. No accountability controls are prescribed for Confidential material, but offices desiring to control and account for such material should use the procedures applicable to Secret material. Information classified by another agency shall not be disclosed without that agency's authorization.

(a) *Accountability Control Clerks.* Each division or office head will appoint one person as the Accountability Control Clerk (ACC). The ACC will be the focal point for the receipt, routing, accountability, dispatch, and declassification downgrading or destruction of all classified material in the possession of the office.

(b) *OMB Form 87.* One copy of OMB Form 87 will be attached to the document, and one copy retained in the accountability control file for each active document within the area of responsibility of the ACC. Downgrading or destruction actions, or other actions removing the document from the responsibility of the ACC will be recorded on the OMB Form 87, and the form filed in an inactive file. Inactive control forms will be cut off annually, held for two additional years, then destroyed.

(c) *Working papers and drafts.* Working papers and drafts of classified documents will be protected according to their security classification, but will not be subject to accountability control unless they are forwarded outside of OMB.

(d) *Typewriter ribbons.* Typewriter ribbons, cassettes, and other devices used in the production of classified material will be removed from the machine after each use and protected as classified material not subject to controls. Destruction of such materials will be as prescribed in § 1312.29.

(e) *Reproduction.* Classified material will be reproduced only as required unless prohibited by the originator for the conduct of business and reproduced copies are subject to the same controls as are the original documents. Top Secret material will be reproduced only with the written permission of the originating agency.

§ 1312.27 Top secret control.

The EOP Security Officer serves as the Top Secret Control Officer (TSCO) for OMB. He will be assisted by the Alternate TSCOs in each division/office Holding Top Secret material. The ATSCOs will be responsible for the accountability and custodianship of Top Secret material within their divisions/offices. The provisions of this section do not apply to special intelligence material, which will be processed as prescribed by the controlling agency.

(a) *Procedures.* All Top Secret material produced or received in OMB will be taken to the appropriate ATSCO for receipting, establishment of custodianship, issuance to the appropriate action officer, and, as appropriate, obtaining a receipt. Top Secret material in the custody of the TSCO or ATSCO will normally be segregated from other classified material and will be stored in a safe under his or her control. Such material will be returned to the appropriate ATSCO by action officers as soon as action is completed. OMB Form 87 will be used

to establish custody, record distribution, routing, receipting and destruction of Top Secret material. Top Secret Access Record and Cover Sheet (Standard Form 703) will be attached to each Top Secret document while it is in the possession of OMB.

(b) *Inventory.* The Associate Director (or Assistant Director) for Administration will notify each appropriate OMB office to conduct an inventory of its Top Secret material by May 1 each year. The head of each office will notify the EOP Security Officer when the inventory has been satisfactorily completed. Each Top Secret item will be examined to determine whether it can be downgraded or declassified, and the inventory will be adjusted accordingly. Discrepancies in the inventory, indicating loss or possible compromise, will be thoroughly investigated by the EOP Security Officer or by the Federal Bureau of Investigation, as appropriate. Each ATSCO will retain his/her division's inventory in accordance with the security procedures set forth in this regulation.

§ 1312.28 Transmission of classified material.

Prior to the transmission of classified material to offices outside OMB, such material will be enclosed in opaque inner and outer covers or envelopes. The inner cover will be sealed and marked with the classification, and the address of the sender and of the addressee. The receipt for the document, OMB Form 87, (not required for Confidential material) will be attached to or placed within the inner envelope to be signed by the recipient and returned to the sender. Receipts will identify the sender, the addressee, and the document, and will contain no classified information. The outer cover or envelope will be sealed and addressed with no identification of its contents.

(a) *Transmittal of Top Secret Material.* The transmittal of Top Secret material shall be by personnel specifically designated by the EOP Security Officer, or by Department of State diplomatic pouch, by a messenger-courier system specifically created for that purpose. Alternatively, it shall be taken to the White House Situation Room for transmission over secure communications circuits.

(b) *Transmittal of Secret Material.* The transmittal of Secret material shall be as follows:

(1) Within and between the fifty States, the District of Columbia, and Puerto Rico: Use one of the authorized means for Top Secret material, or transmit by U.S. Postal Service express or registered mail.

(2) Other Areas. Use the same means authorized for Top Secret, or transmit by U.S. registered mail through Military Postal Service facilities.

(c) *Transmittal of Confidential Material.* As identified in paragraphs (a) and (b) of this section, or transmit by U.S. Postal Service Certified, first class, or express mail service within and between the fifty States, the District of Columbia, and Puerto Rico.

(d) *Transmittal between OMB offices and within the EOP complex.* Classified material will normally be hand carried within and between offices in the Executive Office of the President complex by cleared OMB employees. Documents so carried must be protected by the appropriate cover sheet or outer envelope. Top Secret material will always be hand carried in this manner. Secret and Confidential material may be transmitted between offices in the EOP complex by preparing the material as indicated above (double envelope) and forwarding it by special messenger service provided by the messenger center. The messenger shall be advised that the material is classified. Receipts shall be obtained if Top Secret or Secret material is being transmitted outside of OMB. Classified material will never be transmitted in the Standard Messenger Envelope (SF Form 65), or by the Mail Stop system.

§ 1312.29 Destruction.

The destruction of classified material will be accomplished under the direction of the TSCO or the appropriate ATSCO, who will assure that proper accountability records are kept. Classified official record material will be processed to the Information Systems and Technology, Records Management Office, Office of Administration, NEOB Room 5208, in accordance with OMB Manual Section 540. Classified nonrecord material will be destroyed as soon as it becomes excess to the needs of the office. The following destruction methods are authorized:

(a) *Shredding.* Using the equipment approved for that purpose within OMB offices. Shredders will not accommodate typewriter ribbons or cassettes. Shredding is the only authorized means of Destroying Top Secret material.

(b) *Burn Bag.* Classified documents, cassettes, ribbons, and other materials at the Secret level or below, not suitable for shredding, may be destroyed by using burn bags, which can be obtained from the supply store. They will be disposed of as follows:

(1) OEOB. Unless on an approved list for pick-up of burn bags, all other burn bags should be delivered to Room 096, OEOB between 8:00 a.m. and 4:30 p.m. Burn bags are not to be left in hallways.

(2) NEOB. Hours for delivery of burn bag materials to the NEOB Loading Dock Shredder Room are Monday through Friday from 8:00 a.m. to 9:30 a.m.; 10:00 a.m. to 11:00 a.m.; 11:45 a.m. to 1:30 p.m. and 2:00 p.m. to 3:30 p.m. The phone number of the Shredder Room is 395–1593. In the event the Shredder Room is not manned, do not leave burn bags outside the Shredder Room as the security of that material may be compromised.

(3) Responsibility for the security of the burn bag remains with the OMB office until it is handed over to the authorized representative at the shredder room. Accountability records will be adjusted after the burn bags have been delivered. Destruction actions will be recorded on OMB Form 87 by the division TSCO or by the appropriate ATSCO at the time the destruction is accomplished or at the time the burn bag is delivered to the U.D. Officer.

(c) *Technical Guidance.* Technical guidance concerning appropriate methods, equipment, and standards for destruction of electronic classified media, processing equipment components and the like, may be obtained by submitting all pertinent information to NSA/CSS Directorate for Information Systems Security, Ft. Meade, Maryland 20755. Specifications concerning appropriate equipment and standards for destruction of other storage media may be obtained from the General Services Administration.

§ 1312.30 Loss or possible compromise.

Any person who has knowledge of the loss or possible compromise of classified information shall immediately secure the material and then report the circumstances to the EOP Security Officer. The EOP Security Officer will immediately initiate an inquiry to determine the circumstances surrounding the loss or compromise for the purpose of taking corrective measures and/or instituting appropriate administrative, disciplinary, or legal action. The agency originating the information shall be notified of the loss or compromise so that the necessary damage assessment can be made.

§ 1312.31 Security violations.

(a) A security violation notice is issued by the United States Secret Service when an office/division fails to properly secure classified information. Upon discovery of an alleged security violation, the USSS implements their

standard procedures which include the following actions:

(1) Preparation of a Record of Security Violation form;

(2) When a document is left on a desk or other unsecured area, the officer will remove the classified document(s) and deliver to the Uniformed Division's Control Center; and

(3) Where the alleged violation involves an open safe, the officer will remove one file bearing the highest classification level, annotate it with his or her name, badge number, date and time, and return the document to the safe, which will then be secured. A description of the document will be identified in the Record of Security Violations and a copy of the violation will be left in the safe.

(b) Office of record. The EOP Security Office shall serve as the primary office of record for OMB security violations. Reports of violations will remain in the responsible individual's security file until one year after the individual departs the Executive Office of the President, at which time all violation reports will be destroyed.

(c) Compliance. All Office of Management and Budget employees will comply with this section. Additionally, personnel on detail or temporary duty will comply with this section, however, their parent agencies will be provided with a copy of any security violation incurred during their period of service to OMB.

(d) Responsibilities for processing security violations. (1) EOP Security Officer. The EOP Security Officer shall provide OMB with assistance regarding Agency security violations. Upon receipt of a Record of Security Violation alleging a security violation, the EOP Security Officer shall:

(i) Prepare a memorandum to the immediate supervisor of the office/division responsible for the violation requesting that an inquiry be made into the incident. Attached to the memorandum will be a copy of the Record of Security Violation form. The receiving office/division will prepare a written report within five working days of its receipt of the Security Officer's memorandum.

(ii) Provide any assistance needed for the inquiry conducted by the office/division involved in the alleged violation.

(iii) Upon receipt of the report of inquiry from the responsible office/division, the EOP Security Officer will:

(A) Consult with the OMB Associate Director (or Assistant Director) for Administration and the General Counsel;

(B) Determine if a damage assessment report is required. A damage assessment will be made by the agency originating the classified information, and will be prepared after it has been determined that the information was accessed without authorization; and

(C) Forward the report with a recommendation to the OMB General Counsel.

(2) Immediate supervisors. Upon receipt of the EOP Security Officer's security violation memorandum, the immediate supervisor will make an inquiry into the alleged incident, and send a written report of inquiry to the EOP Security Officer. The inquiry should determine, and the related report should identify, at a minimum:

(i) Whether an actual security violation occurred;

(ii) The identity of the person(s) responsible; and

(iii) The probability of unauthorized access.

(3) Deputy Associate Directors (or the equivalent) will:

(i) Review and concur or comment on the written report; and

(ii) In conjunction with the immediate supervisor, determine what action will be taken to prevent, within their area of responsibility, a recurrence of the circumstances giving rise to the violation.

(e) Staff penalties for OMB security violations. When assessing penalties in accordance with this section, only those violations occurring within the calendar year (beginning January 1) will be considered. However, reports of all previous violations remain in the security files. These are the standard violation penalties that will be imposed. At the discretion of the Director or his designee, greater or lesser penalties may be imposed based upon the circumstances giving rise to the violation, the immediate supervisor's report of inquiry, and the investigation and findings of the EOP Security Officer and/or the OMB Associate Director (or Assistant Director) for Administration.

(1) First violation:

(i) Written notification of the violation will be filed in the responsible individual's security file; and

(ii) The EOP Security Officer and/or the Associate Director (or Assistant Director) for Administration will consult with the respective immediate supervisor, and the responsible individual will be advised of the penalties that may be applied should a second violation occur.

(2) Second violation:

(i) Written notification of the violation will be filed in the responsible individual's security file;

(ii) The EOP Security Officer and/or the Associate Director (or Assistant Director) for Administration will consult with the respective Deputy Associate Director (or the equivalent) and immediate supervisor and the responsible individual who will be advised of the penalties that may be applied should a third violation occur; and

(iii) A letter of Warning will be placed in the Disciplinary Action file maintained by the Office of Administration, Human Resources Management Division.

(3) Third violation:

(i) Written notification of the violation will be filed in the responsible individual's security file;

(ii) The EOP Security Officer and/or the Associate Director (or Assistant Director) for Administration will consult with the OMB Deputy Director, General Counsel, the respective Deputy Associate Director (or equivalent), and the immediate supervisor and the responsible individual who will be advised of the penalties that may be applied should a fourth violation occur; and

(iii) A Letter of Reprimand will be placed in the Disciplinary Action file maintained by the OA/HRMD.

(4) Fourth violation:

(i) Written notification of the violation will be filed in the responsible individual's security file;

(ii) The EOP Security Officer and/or the Associate Director (or Assistant Director) for Administration will consult with the OMB Director, Deputy Director, General Counsel, the respective Deputy Associate Director (or the equivalent), and immediate supervisor;

(iii) The responsible individual may receive a suspension without pay for a period not to exceed 14 days; and

(iv) The responsible individual will be advised that future violations could result in the denial of access to classified material or other adverse actions as may be appropriate, including dismissal.

Subpart C—Mandatory Declassification Review

§ 1312.32 Purpose and authority.

Other government agencies, and individual members of the public, frequently request that classified information in OMB files be reviewed for possible declassification and release. This subpart prescribes the procedures for such review and subsequent release or denial. It is issued under the authority of Executive Order 12958 (60 FR 19825, 3 CFR, 1995 Comp., p. 333),

as implemented by Information Security Oversight Office Directive No. 1 (32 CFR part 2001).

§ 1312.33 Responsibility.

All requests for the mandatory declassification review of classified information in OMB files should be addressed to the Associate Director (or Assistant Director) for Administration, who will acknowledge receipt of the request. When a request does not reasonably describe the information sought, the requester shall be notified that unless additional information is provided, or the scope of the request is narrowed, no further action will be taken. All requests will receive a response within 180 days of receipt of the request.

§ 1312.34 Information in the custody of OMB.

Information contained in OMB files and under the exclusive declassification jurisdiction of the office will be reviewed by the office of primary interest to determine whether, under the declassification provisions of the Order, the requested information may be declassified. If so, the information will be made available to the requestor unless withholding is otherwise warranted under applicable law. If the information may not be released, in whole or in part, the requestor shall be given a brief statement as to the reasons for denial, a notice of the right to appeal the determination to the Deputy Director, OMB, and a notice that such an appeal must be filed within 60 days in order to be considered.

§ 1312.35 Information classified by another agency.

When a request is received for information that was classified by another agency, the Associate Director (or Assistant Director) for Administration will forward the request, along with any other related materials, to the appropriate agency for review and determination as to release. Recommendations as to release or denial may be made if appropriate. The requester will be notified of the referral, unless the receiving agency objects on the grounds that its association with the information requires protection.

§ 1312.36 Appeal procedure.

Appeals received as a result of a denial, see § 1312.34, will be routed to the Deputy Director who will take action as necessary to determine whether any part of the information may be declassified. If so, he will notify the requester of his determination and make that information available that is declassified and otherwise releasable. If continued classification is required, the requestor shall be notified by the Deputy Director of the reasons thereafter. Determinations on appeals will normally be made within 60 working days following receipt. If additional time is needed, the requestor will be notified and this reason given for the extension. The agency's decision can be appealed to the Interagency Security Classification Appeals Panel.

§ 1312.37 Fees.

There will normally be no fees charged for the mandatory review of classified material for declassification under this section.

[FR Doc. 97–12247 Filed 5–8–97; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Farm Service Agency

7 CFR Parts 718 and 729

RIN 0560–AE82

Amendments to the Peanut Poundage Quota Regulations

AGENCY: Farm Service Agency, USDA.

ACTION: Final rule.

SUMMARY: This final rule adopts, with certain modifications, the interim rule published in the **Federal Register** on July 16, 1996 (61 FR 36997), which set forth regulations for Federal farm peanut poundage quotas. These regulations implement the provisions of the Agricultural Market Transition Act of 1996 (1996 Act) for the 1996 through 2002 crops of peanuts. The amendments adopted in this final rule principally involve the following issues: eliminating the national poundage quota floor; eliminating the undermarketing carryover provisions; establishing temporary seed quota allocations; establishing the ineligibility of certain farms for quota allocation; authorizing the intercounty transfer of farm poundage quotas in all States, subject to certain limitations in some States; eliminating the special allocations of increased quotas for certain Texas counties; establishing new provisions for ''considered produced'' credit with respect to a farm whose quota has been transferred; and other minor clarifying and technical changes.

These regulations are required by the Agricultural Adjustment Act of 1938, as amended (1938 Act). The modifications made in this final rule to 7 CFR part 729 have been made after consideration of public comments.

In addition, this rule makes a technical change concerning the application of special sanctions in connection with certain drug-related offenses.

EFFECTIVE DATE: This final rule is effective May 9, 1997.

FOR FURTHER INFORMATION CONTACT: David Kincannon, Farm Service Agency, United States Department of Agriculture, STOP 0514, 1400 Independence Avenue, SW, Washington, D.C. 20250–2415 or call (202) 720–7914.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule has been determined to be Economically Significant and was reviewed by the Office of Management and Budget (OMB) under Executive Order 12866.

The 1996 Act makes at least six important changes to the peanut program. These changes include the following: (1) elimination of the minimum quota floor, (2) elimination of undermarketings, (3) provisions for unlimited and limited transfer of peanut quota by sale or lease within State in all States, (4) forfeiture of quota for certain nonproducers, (5) no-net-cost to treasury provisions, and (6) lowering the quota price support level.

The final rule contains no changes from the interim rule published in the **Federal Register** on July 16, 1996 that have any discernible budget or economic impact. Differences in this cost benefit assessment and the one prepared for the interim rule reflect new data and projections.

The economic impacts of the peanut program provisions of the 1996 Act include expected reductions in producers' revenue by $1.25 billion from 1996 to 2002, while taxpayers are expected to benefit by avoiding costs of $0.5 billion compared with the FY 1997 baseline. First buyers benefit from lower prices, part of which will be passed on to consumers.

Quota lease and capitalized values of quotas are expected to decline. Quota holders could absorb a loss of about $40 million annually because of reduced leasing rates due to the lower peanut price support. Capitalized value of quotas could decline $200 to $300 million, thus reducing land values and the tax base of rural communities. With increased transferability of quotas under the 1996 Act, the sale and rental market for quotas becomes a State rather than a county market. Values are reduced in more efficient production areas and increased in less efficient areas.

Under no peanut program, producer prices would decline resulting in gains to first buyers of peanuts of $150 to $160 million annually, compared with 1996 provisions. Over the 7-year life of the program, the capitalized gain to first buyers would total about $800 million, assuming a 10 percent capitalization rate. For additional information or to request a copy of the cost benefit assessment, contact: Verner N. Grise at (202) 720–5291.

Executive Order 12988

This final rule has been reviewed in accordance with Executive Order 12988, Civil Justice Reform. The provisions of this final rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. Before any legal action is brought regarding determinations made under the provisions of 7 CFR part 729, the administrative appeal provisions set forth at 7 CFR parts 11 and 780 must be exhausted.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this final rule because the Farm Service Agency (FSA) 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 this rule.

Paperwork Reduction Act

The regulations set forth in this final rule require a new information collection instrument, form FSA–377, Register of Tentative Out of County Peanut Poundage Quota Transfers. The new form necessary to conduct the peanut poundage quota program has been developed, and a notice and request for comments for revising a currently approved information collection was issued in the **Federal Register** on December 24, 1996 (61 FR 67767), and provided for a 60-day comment period. Because the information collection is needed before the regular submission for approval of the information can be submitted to OMB, FSA has submitted to OMB an addendum to the information collection requirements, as set forth in 5 CFR 1320.18 for OMB Control Number 0560–0006, and has requested that OMB authorize emergency processing of the information collection submission.

Environmental Evaluation

It has been determined by an environmental evaluation that this action will have no significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Unfunded Federal Mandates

This rule contains no Federal mandates under the regulatory provisions of Title II of the Unfunded Mandate Reform Act of 1995 (UMRA) for State, local, and tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Small Business Regulatory Enforcement Fairness Act of 1996

To the extent that this rule can be or is considered to be major under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), it has been determined that, pursuant to section 808 of SBREFA, that it is impracticable, unnecessary, and contrary to the public interest to delay the effective date of this rule. That finding has been made on the basis that such a delay would make it impossible to make the changes in this rule effective in time for producers with a substantial interest in production to plant peanuts in a timely fashion with a proper understanding of the rules for quota distribution and for forfeitures. Those matters could have a substantial impact on individual decisions. Different provisions, if needed, can be implemented for subsequent crop years. Accordingly, this rule is effective upon publication in the **Federal Register**.

Federal Assistance Program

The title and number of the Federal Assistance Program, as found in the Catalog of Federal Domestic Assistance, to which this final rule applies are: Commodity Loans and Purchases—10.051.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

National Appeals Division Rules of Procedure

The procedures set out in 7 CFR parts 11 and 780 apply to appeals of adverse decisions made under the regulations adopted in this notice.

Background

Title I of the 1996 Act amended the 1938 Act and the Agricultural Act of 1949, as amended, to provide, for the 1996 through 2002 crops, for a revised peanut poundage quota and peanut price support program.

The statutory provisions for the peanut poundage quota program contained in the 1996 Act were described in the supplementary information section of the interim rule.

Summary of Comments

A total of 42 comments was received in response to the interim rule published in the **Federal Register** on July 16, 1996. The comment period expired on August 15, 1996. The following is a summary, by section, of the comments received:

Section 729.103—Definition of Preliminary Quota

The interim rule defined ''preliminary quota'' to be that farm's quota for the previous year unless the quota is subject to a reduction. There are several statutory provisions calling for reductions for individual farm quota, one being a provision relating to residency and the location of the quota, which is addressed elsewhere in the rule. One comment objected to the references to reductions but since that reference relates to statutory provisions, it has been determined that no modification should be made.

Section 729.204—Temporary Seed Quota Allocation

The 1996 Act allowed for providing a quota in an amount equal to the seed which producers would plant to grow the peanuts and the interim rule provided for a national per acre seeding allowance with small variations made to account for peanut type. A total of six comments addressed this issue. One respondent requested that a temporary seed quota allocation be allowed for peanut acreage of ''volunteer'' peanuts—that is, peanuts which grow wild and are outside the area of the farm's planned cultivation of the crop. The statute and interim rule are clear that the temporary seed quota allocation is to account for seed peanuts actually planted on the farm. Therefore, no modification of the interim rule was made to accommodate this suggestion.

There were five comments about the use of a national seeding rate and the method of determining the amount of seed allocation. Most respondents supported the use of a national seeding rate for determining the amount of seed allocation because it would be less burdensome than other options. One respondent suggested that temporary seed allocations be verified by receipts for seed purchased or records of quota peanuts retained on the farm. No

modification in the regulation is needed to accommodate this suggestion at this time. FSA will monitor seed quota allocations through spot checks to determine whether further action is warranted.

One respondent from Texas suggested that the seeding rate for Virginia-type peanuts in that area should be 115 pounds per acre rather than 110 pounds per acre as provided for in the interim rule, and one respondent from the southeast marketing area suggested the seeding rate for Runner-type peanuts should be 100 pounds per acre rather than 90 pounds per acre as provided for in the interim rule. The seeding rates were based on statistical surveys and the best data available at this time. For that reason, no adjustment has been made in the seed allocation formula provided for in the interim rule. However, FSA will continue to monitor seeding rates and review any studies or data which might indicate a need for seeding rate adjustments.

Section 729.205—Farms Ineligible for Farm Poundage Quota

Provisions of the 1996 Act disallowed quotas for farms that were, as of the end of the 1996 marketing year (August 1, 1997) or thereafter, owned or controlled by: (1) A municipality, airport authority, school, college, refuge or other public entity (other than a university used for research purposes); or (2) a person who is not a producer and resides in another State. To implement the nonresidency provision, the interim rule provided that in the case of corporations and partnerships the forfeiture would not apply if a person (or persons) with a 20-percent interest in the entity had their primary residence in the State where the quota was allocated.

Also, a 3-year grace period was allowed in the interim rule for involuntary acquisitions by foreclosure or otherwise. Further, for situations where the ineligible party held the farm prior to August 1, 1997, the rule provided that the quota would be forfeited as of that date unless there was a sale or transfer of the quota by that date and to that end the interim rule allowed for the parties to complete the paperwork by October 1, 1997. The rule effectively allowed the sale of the future right to the quota to be effective for this purpose rather than simply limit the sale exemption to sales or transfers of existing, operational quotas. For farm acquisitions after August 1, 1997, the rule provided, in accord with the statute, that if an ineligible party bought the farm, the quota would not be forfeited but no quota would be established for the farm involved until the ineligibility was corrected or the quota was sold.

There were 17 comments opposed to the ineligibility of nonresident, nonproducers and of certain public entities for quota allocation. The respondents, representing nonresident, nonproducer quota holders and several resident quota holders opposed this provision on the grounds it unfairly discriminated based on State of residency. Several suggested that the provision is unconstitutional. Aside from losing quota, several expressed concern that the provision adversely impacted the value of their farm as an inheritance because their heirs were residents of another State. Most respondents stated that not living in the State in which the quota was allocated was due to conditions beyond their control, such as family situations, health or other reasons and that the State in which a quota holder resided should have no bearing on a national quota program. One respondent stated that the quota held by public entities provided a source of peanut quotas for younger farmers who were just starting to farm.

The ineligibility provisions are statutory and must be enforced. However, the rules have been amended to provide for corporations and other specially chartered entities such as estates and limited partnerships to be considered residents of the place where they are incorporated or created as well as residents of any State where individuals with at least a cumulative 20-percent interest in the entity reside. The incorporation and creation rule replaces the ''primary place of business'' test that was included in the interim rule and which could have allowed for the maintenance of quotas by entities with no real tie to the State except for the quota itself. Also, with respect to defining who is a ''producer'' of peanuts for purposes of these rules, the final rule provides, as a good faith test, that the would-be producer must have at least a 15-percent interest in the quota peanut crop. A lower amount would suggest that the ''risk'' was incidental to other arrangements. Also, after further review of the statute, the final rule eliminates provisions which would allow for avoidance of the forfeiture by the sale, by October 1, 1997, of the future right to the quota. It has been determined (and the rule has been amended accordingly) that August 1, 1997, should be read as an absolute deadline in that it appears correct to presume that Congress did not contemplate sales of a quota to differ from the historical method of allowing sales only to be made of an existing, established quota—not future rights to a quota. Presumably, if Congress has intended or expected otherwise, there would have been some indication of that intent. On further review, none appears. In special cases of reliance on the previous rule, the Deputy Administrator may consider the granting of relief but it is not expected that there will be cases in which such relief is justified. Otherwise, to avoid forfeiture of the quota, the owner of an ineligible farm with a 1997 peanut quota allocation must: (1) Sell the quota prior to August 1, 1997; (2) beginning with the 1997 crop, produce or share in the production of the quota peanuts on the farm; or (3) consistent with this rule and prior to August 1, 1997, establish residency in the State in which the quota is allocated.

The interim rule provided that schools, colleges and other public entities were ineligible for quota allocation beginning with the 1998 crop. Upon further review of the 1996 Act, the agency has determined that the intent of Congress was to allow public universities to hold the historic research quotas, provided such quotas would continue to be used for experimental and research purposes. Accordingly, § 729.205(a)(1) has been amended.

Section 729.214—Transfer of Quota by Sale, Lease, Owner, or Operator

Until the 1996 Act, quotas could not be transferred across county lines except in States with a small total quota. However, the 1996 Act allows such transfers in all States up to certain percentages of each county's quota and all counties with quotas under a certain amount can have unlimited transfers. Because the demand for transfers could exceed the limits in some counties, the interim rule allowed for lotteries (the need for which could decrease as the allowable percentage increases). The interim rule also noted that the 1996 Act appeared to grant considered produced credit for any out-of-county transfers, if the quota was produced or considered produced on the receiving farm. This, the rule noted, appeared to be different from the rule which the statute seemed to establish for within-county transfers which appeared to be to allow considered produced credit only once every three years. The importance of considered produced credit is that it can help the transferring farm avoid a loss of quotas under the provisions of the 1938 Act which provide for reducing quotas for nonproduction.

A total of 25 respondents commented on several provisions of the interim rule applicable to quota transfers. There were 19 respondents who requested that within-county transfers be treated the same as out-of-county transfers with

respect to protecting the quota on the transferring farm if the quota is produced or considered produced on the receiving farm. One respondent, a regional peanut growers' association, supported the interim regulation's treatment of out-of-county transfers.

On further review of this issue, it has been determined that the interim rule should be amended. The provisions of the 1938 Act which provide for leasing are those in section 358–1. Section 358–1(a)(1)(D) provides that for leases under section 358–1 the transferring farm will receive credit so long as the quota is produced or considered produced on the receiving farm. It was noted, however, with the interim rule, that the provisions of section 358–1(b)(4) continue to provide that where a farm poundage quota was leased to another owner or operator of a farm within the same county, the transferring farm can receive considered produced credit for one year in any 3-year base period. On further review, this appears to be an additional allowance, not a limitation, since the 358–1(b)(4) credit is not tied to actual production or planting on the receiving farm and since there is no actual exclusion of within-county transfers provided for with respect to the allowance in 358b. Nor is there an inherent conflict given the special conditions of 358b. Further, the provisions in section 358–1(b)(3) for removing quotas that are not produced provide that such reductions shall be made on such fair and equitable basis as the Secretary determines to be appropriate. It does not appear equitable or logical to apply a more difficult standard to within-county transfers in light of the 1996 amendments, nor does there appear to be reason to believe at this time that such was Congress' intention.

Accordingly, the regulations have been revised as to within-country transfers. They will receive the same considered produced credit that is available for out-of-county transfers and, in addition, if they have not otherwise received considered produced credit on a spring lease in a 3-year base period, they can receive credit for a transfer for one year of the 3-year base period for a transfer even if the quota was not produced or considered produced on the receiving farm.

There were seven comments which addressed the method of administering the provisions of the 1996 Act with respect to out-of-county sale and lease limitation. One respondent opposed the lottery in favor of prorating the amount eligible for out-of-county transfer among all applicants requesting such transfers. Another respondent favored a first-come, first-granted method for approving such transfers. Five respondents were concerned that, in certain counties, the register of producers requesting to transfer quotas out of county was being filled with producers who had no intention of effecting such transfers, thereby decreasing the likelihood that bona fide requests for out-of-county transfers would be selected in a lottery. Also, in some cases, producers selected by the lottery were unable to secure an agreement for an out-of-county transfer, thereby leaving the maximum transfer percentage unrealized. Suggestions for decreasing the potential for such a possibility included the following: (1) Permitting only those having a valid agreement for sale or lease to be registered for the lottery, (2) allowing alternate selections to transfer if the original lottery picks chose not to transfer out of county, (3) counting only the sales or leases actually transferred out of county toward fulfilling the transfer percentages, and (4) otherwise limiting the lottery to persons who will actually transfer out of county.

In addition, three respondents stated the view that the intent of the law to transfer quotas to those actually producing the quota was being circumvented with the lottery system by the selection of those who made temporary, out-of-county transfers, thereby displacing those who wished to effect permanent transfers. Each of these respondents suggested giving permanent out-of-county transfers priority over temporary transfers.

To allow more flexibility for handling changing circumstances, the rule would allow a method other than a lottery to be used. However, for the immediate crop year, it is expected and planned that a lottery will be used. Some of the distribution problems should be solved by the increasing transfer percentage allowed for in the statute. With respect to permanent transfers, the regulations currently permit priority for transfer by sale and it is anticipated that, beginning with the 1997 crop of peanuts, such priority will be applied.

The agency does not plan to use a *pro rata* distribution method as that would unnecessarily divide up the marketable quota and would complicate the making of a pre-lottery lease agreement. First-come, first-served would in this instance induce a new element of uncertainty and stress with little or no real gain over the current lottery system and would place some farms at a disadvantage to other farms on grounds wholly unrelated to the transfer of the quota. As to failed transfers, the agency plans, effective with the immediate crop year, to provide a method whereby a transferor who fails to complete the transfer is replaced in a timely manner by a substitute transferor.

Three respondents supported the interim rule with respect to prohibiting the transfer to and from the same farm during the same transfer period. One respondent suggested allowing a permanent transfer to the farm and a temporary transfer from the farm for the same period. Another suggested ''easing'' the regulation that prohibits a quota that is permanently transferred to the farm from being permanently transferred from the farm for three years.

It appears on further review of the regulations that the rules do not, as such, forbid a farmer who has recently been the recipient of a permanent quota transfer from then making, in the same year, a temporary transfer, by spring lease, to another farm. Rather, such farms can make those transfers under the same conditions as would apply if the farm which is the transferring farm in the temporary transfer had held the quota for a long period of time prior to that transfer. However, the regulations have been modified to further clarify that a farm cannot, as far as ''spring leases'' are concerned, receive a quota by a temporary transfer and then transfer that quota to another farm by a temporary transfer in the same lease period. That is, the interim rule is amended to make clear that such ''subleasing'' of quotas is not permitted.

The provisions of the regulations restricting permanent transfer to and from a farm are not changed by this rule. However, the rule is amended to clarify the limitations on permanent transfers to and from the same farm during the same year. Further, upon review of the regulations applicable to disposal of a tenant's share of any increased quota, it was determined that applying permanent transfer limitations to such tenant's shares would adversely impact the tenant's ability to sell the quota allocation. Accordingly, the rule is amended to permit the sale of a tenant's share of increased quota without subjecting either the transferring farm or the receiving farm to any of the transfer limitations in part 729.

Section 729.216—National Poundage Quota

One respondent also complained that the Department of Agriculture (USDA) had not allowed for sufficient comment on the particular quota set for 1996 following the enactment of the 1996 Act. The rule does not restrict the time for comment and it is USDA's intent to allow for such comment as is practicable within the time constraints

set by Congress for announcing the quota.

Other Changes and Corrections

1. Definitions

The definition of ''farmers stock peanuts'' is revised to specify that dug peanuts which are not marketed but which are disposed of under supervision of a representative of FSA will not be considered as farmers stock peanuts. This modification is intended to arrive at a more equitable determination of what constitutes actual production for purposes of determinations to be made under the program regulations.

Also, the definition of ''peanuts'' has been revised to track more closely with the peanut regulations in 7 CFR part 1446. This should avoid any possible confusion in the application of terms and rules.

2. Administration

To assist producers who inadvertently fail to meet the final deadline for transferring quotas, this final rule amends the regulations to allow the Deputy Administrator to delegate authority to set guidelines for waivers by the State FSA committees. This action will expedite producer requests for late-filed transfers and help assure that available peanuts may be marketed as quota peanuts.

3. Temporary Seed Quota (TSQ)

Upon review of the interim rule with respect to TSQ allocation and experience gained from the 1996 crop, FSA has determined that a sanction is needed in instances where the TSQ allocation was based on an erroneous acreage certification. Accordingly, when the certified acreage on which the TSQ allocation is made is greater than the acreage determined by FSA to have been planted to peanuts by more than the smaller of 2 percent of the certified acreage or 5 acres, a penalty will be calculated on this difference. When this tolerance is exceeded, the penalty will be determined by multiplying the difference between the certified and determined peanut acreage times the applicable per acre seeding rate used in the calculation of the TSQ times 140 percent of the applicable per pound quota support rate for the crop year involved. The authority for this penalty is found in section 358e of the 1938 Act which allows for penalties for over marketings of quota peanuts. Since such penalties flow from normal regulations applicable to the poundage quota system for peanuts, there does not appear to be a need for new rulemaking on this issue. In addition, in the event of an erroneous certification within the tolerance allowed by the rule, the agency may make corrections in the quota for the farm for the following year and may still assess a penalty in any instances in which such overreporting is chronic or otherwise found to have been a scheme or device to defeat the purposes of the program.

The requirement in § 729.214(f)(2)(iii)(A) that 90 percent of the transferring farm's quota must be planted in order for a fall transfer to be approved is amended by this rule to clarify that the TSQ allocation is not included as part of the farm's effective quota with respect to the 90-percent calculation.

4. Technical Corrections

Section 729.214 contains a reference in paragraph (b)(5)(ii) that was not changed in the interim rule to reflect that the referenced paragraph was redesignated from ''(e)'' to ''(f).'' Also, in paragraph (l) the phrase ''all out-of-county transfers'' was inadvertently included with owner-to-owner and operator-to-operator transfers. The adjustment to production history in this paragraph is applicable only to owner-to-owner and operator-to-operator transfers and, although there were other changes in the interim rule to bring owner and operator transfers under the provisions of the new out-of-county transfer provisions, there was never an intention to adjust the produced credit for out-of-county transfers not involving owner-to-owner and operator-to-operator transfers.

Accordingly, this final rule amends § 729.214(b)(5)(ii) to reflect the correct reference and § 729.214(l) to remove the reference to ''all out-of-county transfers.''

Modification of Part 718

This rule also makes a correction to provisions of 7 CFR 718.11 as promulgated in a rule published in the **Federal Register** on July 18, 1996 (61 FR 37544). That section provides for certain sanctions to apply in the event that a person is involved in certain drug-related offenses and is based on a statutory provision which, by its terms, specifies that the sanctions shall apply to benefits related to commodity production. Section 718.11(b), as promulgated, only applied that limitation literally to (b)(1) of that section whereas the limitation, to matters of commodity production, was intended to apply to (b)(1) through (b)(3). This rule makes that correction and revises the provisions of that section to comport more closely with the language of the statutory provision.

List of Subjects

7 CFR Part 718

Acreage allotments, Authority delegations, Crop insurance requirement, Drug traffic control, Price support programs.

7 CFR Part 729

Peanuts, Penalties, Poundage quotas, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 7 CFR part 718 is amended and the interim rule for 7 CFR part 729, published in the **Federal Register** on July 16, 1996 (61 FR 36997), is adopted as final with changes as set forth below.

PART 718—PROVISIONS APPLICABLE TO MULTIPLE PROGRAMS

1. The authority citation for 7 CFR part 718 is amended to read as follows:

Authority: 7 U.S.C. 1373, 1374, 7201 *et seq.*; 15 U.S.C. 714b and 714c; and 21 U.S.C. 889.

2. Section 718.11 is amended by revising paragraph (b) to read as follows:

§ 718.11 Denial of Benefits.

* * * * *

(b) Any person convicted under Federal or State law of planting, cultivating, growing, producing, harvesting, or storing a controlled substance, as defined in 21 CFR part 1308, shall be ineligible for, with respect to any commodity produced during the same year and the next succeeding four years:

(1) Any price support loan available in accordance with parts 1446 and 1464 of this title;

(2) Any price support or payment made under the Commodity Credit Corporation Charter Act;

(3) A farm storage facility loan made under section 4(h) of the Commodity Credit Corporation Charter Act;

(4) Crop Insurance under the Federal Crop Insurance Act;

(5) A loan made, insured or guaranteed under the Consolidated farm and Rural Development Act or any other provision of law formerly administered by the Farmers Home Administration; or

(6) Any payment made under any Act.

* * * * *

PART 729—PEANUTS

3. The authority citation for 7 CFR part 729 continues to read as follows:

Authority: 7 U.S.C. 1301, 1357 *et seq.*, 1372, 1373, 1375, and 7271.

4. In § 729.103(b), the definition of ''considered produced credit'' is amended by redesignating paragraphs (ii) through (v) as paragraphs (iii) through (vi) respectively, and adding a new paragraph (b)(ii), and the definitions of ''farmers stock peanuts'' and ''peanuts'' are revised to read as follows:

§ 729.103 Definitions.

* * * * *

(b) *Terms.*

* * * * *

*Considered produced credit.** * *

(ii) A peanut poundage quota that was leased and transferred by a transfer agreement that was filed before August 1 of the current year to the extent the quota was produced or considered produced on the receiving farm; provided further, that to the extent that for any base period a farm receives credit under this paragraph, such farm may not receive credit under paragraph (iii) of this definition.

* * * * *

Farmers stock peanuts. Picked or threshed peanuts produced in the United States which have not been changed (except for removal of foreign material, loose shelled kernels, and excess moisture) from the condition in which picked or threshed peanuts are customarily marketed by producers, plus any loose shelled kernels that are removed from farmers stock peanuts before such farmers stock peanuts are marketed.

* * * * *

Peanuts. All peanuts produced, excluding:

(i) Any peanuts which were not dug;

(ii) Any dug peanuts not picked or threshed which are disposed of under the direction and supervision of FSA personnel; and

(iii) Green peanuts.

* * * * *

5. Section 729.104 is amended in paragraph (d)(3) by adding a sentence at the end of the paragraph to read as follows:

§ 729.104 Administration.

* * * * *

(d) * * *

(3) * * * Such authority shall include, but not be limited to, the delegation of the authority to the State FSA committee to, acting in accordance with such instructions as the Deputy Administrator may issue, modify deadlines for the filing of transfer of peanut quotas.

6. Section 729.204 is amended by adding a new paragraph (e) at the end of the section to read as follows:

§ 729.204 Temporary seed quota allocation.

* * * * *

(e) *Penalty for erroneous certification.* If the certified acreage on which the temporary seed quota allocation is made is greater than the acreage determined by FSA to be planted to peanuts by more than the smaller of 2 percent of the certified acreage or 5 acres, the producer shall be assessed a penalty based on this difference. The penalty amount shall be calculated by multiplying the difference between the certified and determined peanut acreage by the applicable per acre seeding rate used in the calculation of the temporary seed quota by 140 percent of the applicable per pound quota support rate for the crop year involved. In addition, a commensurate penalty at the same rate may be assessed in cases within the tolerance allowed by the previous sentence in any instance in which the variance is determined to be due to a scheme or device to defeat the purposes of the program, or is repeated. Further, all errors may in all cases result in a commensurate diminution of the quota allowed the farm for the following year.

7. Section 729.205 is amended:

a. In paragraph (a)(1) after the word ''entities'' by adding, the parenthetical phrase ''(other than a university used for research purposes)'',

b. By revising paragraph (a)(2)(ii), and

c. Redesignating paragraph (c) as paragraph (e), revising paragraph (b), revising the new redesignated paragraph (e), and adding paragraphs (c) and (d) to read as follows:

§ 729.205 Farms ineligible for farm poundage quota.

(a) Ineligible farms. * * *

(2) * * *

(ii) Whose primary domicile, as determined by FSA, in the case of any individual is in a State outside the State in which the quota is allocated or, in the case of an entity, does not qualify under this section to be considered to be a resident of the State in which the quota is allocated.

(b) *Determination of residency and related rules.* (1) For purposes of administering paragraph (a) of this section, an entity may be considered a resident of the State in which the quota is located if:

(i) It is determined that a person or persons with at least a cumulative 20-percent interest in any such entity are individuals whose primary residence is in the State in which the quota is allocated; or

(ii) As determined appropriate by the Deputy Administrator, the corporation or other entity, but not a general partnership or an entity not recognized as a separate and distinct legal entity from its members, has been created under the laws of the State in which the quota is allocated.

(2) For purposes of the provisions of (a)(2)(i) of this section, a person shall not be considered to be a producer of a crop of peanuts unless such person is at risk for at least 15 percent of the proceeds from the marketing of the production of the quota at issue.

(c) *Exemption for involuntary acquisition.* Paragraph (a)(2) of this section shall not apply to any involuntary acquisition of a farm by foreclosure, or otherwise, resulting directly from the conduct of a public business in the State in which the quota is allocated, or an acquisition resulting directly by reason of a death. The exemption for involuntary farm acquisitions allowed under the preceding sentence shall only apply to the establishment of quota in the three crop years immediately following the date of the involuntary acquisition of the quota farm.

(d) *Applicable crop year.* For purposes of applying the rules in paragraph (a) of this section as they regard production, the determination of whether paragraph (a)(2) of this section applies shall be made based on the crop last planted before the date on which the determination is to be made.

(e) *Allocating forfeited quota and sales of quotas subject to paragraph (a).* Except for the exemption for involuntary acquisition in § 729.205(c), beginning in 1997 any farm poundage quota held on or after August 1 of 1997 by an ineligible person as determined under paragraph (a) of this section shall be allocated from the quota farm to other farms in the same State in accordance with § 729.206 of this part; provided, however, that if the ineligibility arises solely because of a purchase of a farm after August 1, 1997, or involves a quota which is acquired because of the expiration of a CRP contract after August 1, 1997, the quota shall not be forfeited but may not be used to market peanuts until the ineligibility is determined by the county committee to have been removed or the quota is sold to an eligible farm. Such reallocations shall be made to the extent practicable but shall take into account those instances in which the regulations call for an ineligibility for quota allocation rather than forfeiture of the quota.

8. Section 729.214 is amended:

a. In paragraph (b)(5)(ii) by removing the words ''paragraph (e)'' and adding in its place the words ''paragraph (f)'';

b. In paragraph (d)(2)(iv) by adding the words ''or other method'' to follow the word ''lot'';

c. In paragraph (e)(1) by removing the words ''result in a transfer'' and adding the words ''result in a temporary transfer'' in its place;

d. In paragraph (f)(1)(iii)(A) by adding to the end of the sentence the words ''prior to adjustment for temporary seed quota allocated to the farm'';

e. In paragraph (l) by removing the words ''and all out-of-county transfers''; and

f. By revising paragraphs (f)(3) (i) and (m) to read as follows:

§ 729.214 Transfer of quota by sale, lease, owner, or operator.

* * * * *

(f) *Other transfer provisions*—* * *

(3) *Permanent transfer of quota from a farm.* * * *

(i) *Permanent transfer of quota to the farm.* For the amount of quota purchased or otherwise permanently transferred to the farm in the current year and during the base period, as adjusted for any increase or decrease in such quota due to adjustment in the national quota during the base period, except that a transfer of a tenant's share of any peanut quota increase shall not be considered for purposes of determinations made under the provisions of this paragraph.

* * * * *

(m) *Considered produced credit.* Quota that is leased and transferred from a farm shall be considered produced on such farm to the extent of considered produced credit set forth in the definition of ''Considered produced credit'' in § 729.103 of this part.

Signed at Washington, D.C., on April 30, 1997.

Bruce R. Weber,

Acting, Administrator Farm Service Agency.

[FR Doc. 97–11788 Filed 5–8–97; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 94–106–6]

RIN 0579–AA71

Importation of Pork from Sonora, Mexico

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations concerning the importation of animal products to allow, under certain conditions, the importation of fresh, chilled or frozen pork from the State of Sonora, Mexico. This change is warranted because it removes unnecessary restrictions on the importation of pork from Sonora, Mexico, into the United States.

EFFECTIVE DATE: July 8, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231, (301) 734–8590.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has promulgated regulations regarding the importation of animals and animal products in order to guard against the introduction into the United States of animal diseases not currently present or prevalent in this country. These regulations are set forth in the Code of Federal Regulations (CFR), title 9, chapter I, subchapter D.

On April 18, 1996, we published in the **Federal Register** a proposed rule (61 FR 16978–17105, Docket No. 94–106–1) to revise the regulations in six different parts of 9 CFR to establish importation criteria for certain animals and animal products based on the level of disease risk in specified geographical regions. In proposing the amendments to the regulations, we stated that we considered the proposed regulatory changes to be consistent with and to meet the requirements of international trade agreements that had recently been entered into by the United States.

We solicited comments concerning our proposal for 90 days ending July 17, 1996. During the comment period, several commenters requested that we extend the period during which we would accept comments. In response to these requests, on July 11, 1996, we published in the **Federal Register** a notice that we would consider comments on the proposed rule for an additional 60 days ending September 16, 1996 (61 FR 36520, Docket No. 94–106–4). During the comment period, we conducted four public hearings at which we accepted oral and written comments from the public. These public hearings (announced in the **Federal Register** on May 6 and May 29, 1996, 61 FR 20190–20191 and 26849–26850, Docket Nos. 94–106–2 and 94–106–3, respectively) were held in Riverdale, MD; Atlanta, GA; Kansas City, MO; and Denver, CO.

We received 113 comments on the proposed rule on or before September 16, 1996. These comments came from representatives of State and foreign governments, international economic and political organizations, veterinary associations, State departments of agriculture, livestock industry associations and other agricultural organizations, importing and exporting associations, members of academia and the research community, brokerage firms, exhibitors, animal welfare organizations, and other members of the public.

Based on our review of the comments received on our proposed rule, it is clear that drafting a final rule in response to recommendations submitted by commenters will require close analysis of numerous and complex issues. However, it is also clear to us that there are a limited number of provisions within the proposal that we can make final at this time. Where these provisions involve trade, we believe that delaying their implementation is unwarranted and not in the best interests of trade relations with other countries. In this final rule we are establishing provisions based on the importation procedures set forth in our proposed rule, described below, to allow the importation, under certain conditions, of fresh, chilled or frozen pork from the State of Sonora, Mexico.

Under the regulations prior to the effective date of this final rule (9 CFR 94.9), the entire country of Mexico was considered to be a country in which hog cholera existed. As part of our proposed rule, we proposed to classify the State of Sonora, Mexico, as a region that presents only a slight risk of introducing hog cholera into the United States. In meeting the criteria for the proposed classification of a ''slight risk'' for hog cholera, Sonora also met all of the criteria currently used to designate countries free of hog cholera, as discussed below. However, due to additional factors, such as the disease status of surrounding regions, we determined that the region of Sonora posed more than a negligible risk of introducing hog cholera into the United States if mitigating measures were not applied to the importation of fresh, chilled or frozen pork from that region. These measures included the requirements that the pork come from swine that were raised and slaughtered in Sonora, and that an authorized official of Mexico certify as to the origin of the pork. Additionally, an authorized official of Mexico would need to certify that the pork had not been in contact

with pork from areas of greater risk than Sonora for hog cholera.

Of the comments we received on our proposed rule, a small number addressed our proposed classification of Sonora, Mexico, and mitigating measures for animal products from that region. Commenters on these issues included United States State departments of agriculture, foreign governmental representatives, foreign industry associations, and other members of the public.

One commenter opposed allowing the importation of fresh pork products from Sonora, stating that the potential danger of introducing hog cholera into the United States would be too great. The commenter did not include any supporting information. We are making no changes based on this comment. In June 1994, the Department received a request from the Chief Animal Health Official in Mexico for recognition of the State of Sonora as a region free of hog cholera under the sanitary and phytosanitary provisions of the North American Free Trade Agreement (NAFTA) and the General Agreement on Tariffs and Trade (GATT). A team of APHIS personnel reviewed this request and conducted a site visit in October 1994, which confirmed the facts of the request from the Mexican government. Based on this site visit and our analysis of data provided to APHIS by Mexico, we consider it appropriate to classify Sonora, Mexico, as a region from which fresh, chilled or frozen pork can be imported with negligible risk, provided the mitigating measures described above are applied.

Several commenters supported the proposed classification of Sonora. Several other commenters stated that the proposed classification of Sonora does not include the final risk analysis necessary for considering Sonora a region of slight risk for hog cholera, and that such information should be published in the regulations. In this final rule, we are allowing the importation of fresh, chilled or frozen pork from Sonora, Mexico. In our proposed rule, we published the criteria we considered in classifying Sonora as a region from which fresh pork could be imported with negligible risk under specified conditions.

Our decision to consider Sonora such a region, made following a 1994 site visit to Sonora and elsewhere in Mexico, was based on analysis of the following factors: (1) That hog cholera virus has not been diagnosed in Sonora, Mexico, since 1985; (2) that there are currently no reported outbreaks of hog cholera in any of the States of Mexico or the United States that adjoin the State of Sonora, Mexico (the last reported outbreak in any of these States occurred in 1990); (3) that vaccination for hog cholera has been prohibited in Sonora since 1989; (4) that adjacent States of Mexico are separated by natural physical barriers or manmade fences; (5) that all border access points from adjacent States of Mexico are controlled to prevent movement of swine or swine products into the State of Sonora; (6) that movements of swine and swine products into the State of Sonora from other States of Mexico are effectively restricted; (7) that the State of Sonora maintains effective passive and active surveillance systems; and (8) that the laws, regulations, policies, and infrastructure in the State of Sonora and the country of Mexico have been reviewed by the Administrator and have been determined to be adequate to detect and rapidly eradicate hog cholera in the event of an outbreak. By meeting the criteria described above in this paragraph in points (1), (2), (6), (7), and (8), Sonora also met the criteria we use under the current regulations to determine a country to be free from hog cholera.

In order to reduce from a slight level to a negligible level the risk of the introduction of hog cholera from Sonora, we proposed to require that fresh pork imported from Sonora not have been in contact with pork from any region classified as having more than a slight risk for hog cholera, and that this be certified to by an authorized official of the Mexican government. This requirement ensures that only fresh pork from Sonora that has not been in contact with pork from regions with a higher risk for hog cholera is imported into the United States. The details of the 1994 on-site evaluation are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

One commenter stated that although the proposed classification of Sonora appears to be valid using qualitative criteria, it is not clear whether the risk classification did or will include a quantitative risk analysis. The commenter stated that because the classification of Sonora was included in the proposed rule, a quantitative risk assessment should not be necessary. In our proposed rule, we based the proposed provisions regarding Sonora on the fact that it met the proposed qualitative criteria as a ''slight risk'' region for hog cholera. Therefore, fresh, chilled or frozen pork could be exported from that region with negligible risk of introducing hog cholera into the United States, provided mitigating measures were met. We are basing the provisions of this final rule on that assessment.

Some commenters objected to our proposal to apply mitigating measures to importations of fresh pork from Sonora. The commenters recommended instead that Sonora be treated simply as a region in which hog cholera is not known to exist. We are making no changes based on these comments. Although, as proposed, we would consider Sonora a region where there is only a a slight risk of introducing hog cholera, we stated that other factors, including vaccination history and adjacency to higher risk areas, require adding certain mitigating measures on fresh pork importations from Sonora. We consider the fact that Sonora is adjacent to other regions of Mexico not considered to be free of hog cholera to create a slight risk of the introduction of hog cholera from fresh pork from Sonora, unless mitigating measures are applied. The slight risk of hog cholera from unmitigated importation of fresh, chilled or frozen pork from Sonora is reduced to a negligible level if an authorized official certifies that the pork came from swine raised and slaughtered in Sonora and that it has not been in contact with pork from areas of greater risk for hog cholera.

One commenter stated that the proposed requirements for the importation of animal products under part 94 do not allow for the importing countries to apply different, but equivalent, risk mitigation measures. The commenter stated that such an omission is contrary to the equivalence principle under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, established under the General Agreement on Tariffs and Trade. We are making no changes based on this comment at this time. In our proposal, we proposed quantitative risk assessment options that would allow different risk mitigation measures. We are currently reviewing the comments we received on these options and will address them in future rulemaking. Additionally, should alternative risk mitigation measures be submitted to APHIS, we will review them carefully and, when appropriate, we will propose changes in the future with regard to the regulatory assessment of their use.

Change to Section 94.15

In § 94.15(b) of the existing regulations, provisions are set forth to allow fresh pork and pork products to transit through the United States for immediate export, even though such pork and pork products are not otherwise allowed entry into the United States. This transiting must take place

under specified conditions, including sealing of the container carrying the pork and pork products with APHIS-approved seals in the region of origin, and movement through the United States under Customs bond. Under the existing regulations, the only fresh pork and pork products that may transit the United States under these conditions must be from either Chihuahua, Sonora, or Yucatan, Mexico. Under this final rule, pork from Sonora that could previously only transit the United States for export under § 94.15 may now also be entered into the United States if the conditions of § 94.20 are met.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget. The analyses required by Executive Order 12866 and the Regulatory Flexibility Act are set forth below.

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), we are required to include in our Regulatory Flexibility Analysis a description of significant alternatives to this rule. In developing this rule, APHIS considered either (1) taking no action on the proposed requirements for the importation of fresh, chilled or frozen pork from Sonora, Mexico, (2) allowing the importation of fresh, chilled or frozen pork from Sonora under conditions different from those proposed, or (3) adopting the proposed conditions.

We rejected the first alternative, because it would retain the restrictions on the importation of fresh, chilled and frozen pork from the entire country of Mexico that are set forth in the existing regulations. Because fresh, chilled, or frozen pork can be imported under specified conditions from Sonora with negligible hog cholera risk, taking no action would not be scientifically defensible and would be contrary to trade agreements entered into by the United States. We also rejected the second alternative, which would allow the importation of fresh, chilled, or frozen pork from Sonora under conditions other than those proposed. In developing the proposed criteria for the importation of such pork, we determined that criteria and mitigating measures less stringent than those proposed would increase the risk of the introduction of hog cholera into the United States to more than a negligible level, and that more stringent conditions would be unnecessarily restrictive. We consider the proposed conditions to be both effective and necessary in reducing to a negligible level the risk of the introduction of hog cholera because of fresh pork imports from Sonora.

Under 5 U.S.C. 604, we are also required to include in this analysis an assessment of comments received on our Initial Regulatory Flexibility Analysis. When we proposed the conditions for the importation of fresh pork from Sonora, Mexico, we did so based on the information available to us from Mexico, USDA sources, an APHIS site visit to Mexico, and scientific literature. We requested comments on the proposed conditions for such importation of fresh pork, along with the rest of the proposed rule. We received and considered comments on the proposed conditions, and discuss our responses to these comments in the ''Supplementary Information'' section, above. After reviewing the comments received, we continue to consider the proposed conditions for the importation of fresh pork from Sonora, Mexico, to be effective in reducing the risk of the introduction of hog cholera to a negligible level, and have determined that it is neither warranted nor necessary to revise those conditions in this final rule.

Anticipated Economic Impacts

Under this rule, fresh, chilled and frozen pork may be imported from Sonora, Mexico. Under the regulations already in effect, pork processed by cooking or curing is allowed to be imported from Mexico under specified conditions. Pork that has not been processed sufficiently to meet the conditions of the existing regulations is considered fresh. Fresh pork is customarily shipped chilled or frozen. This rule change could significantly alter current fresh pork production and exports from Sonora over time, because commercial production in that region is relatively new, and because the United States has imposed restrictions on the importation of swine and fresh pork products from Mexico for over 20 years. Both of these factors make it difficult to make projections on possible future fresh pork production and trade from Sonora. However, based on various assumptions, we expect that fresh pork products from Sonora will be exported to the United States. The most important of these assumptions are the following:

1. Production of live hogs in Sonora will be maintained at the current 1.2 million head level;

2. Thirty-five percent of total hog production will continue to be shipped live out of the region for slaughter and processing elsewhere (currently most of these live animal shipments go to Mexico City, some 1,500 miles away);

3. The remaining 65 percent of hog production will be processed in Sonora, with 14 percent going as specialized pork cuts to Japan; the remaining 86 percent will be available for use in Mexico or shipment to the United States;

4. The U.S. base year is assumed to be 1994. United States marketings of 95.697 million head of slaughter hogs were registered in that year at the average price of $40.03 per hundred weight (CWT), liveweight equivalent (LWE);

5. A low-impact scenario assumes that fresh pork imports from Sonora will represent products from about 67,000 hogs. This level of imports would represent about 10 percent of the pork production of Sonora. Imported Sonora fresh pork would be assumed to substitute perfectly for U.S. pork and displace it. The low-impact scenario also assumes that U.S. hog supply elasticity in the United States is 0.15. Hog demand elasticity is assumed to hold at -0.44 in both the low impact and the high impact scenarios;

6. A high-impact scenario assumes that fresh pork imports from Sonora will represent products from 134,160 hogs. This level of imports would represent about 20 percent of the pork production in Sonora. The high impact scenario assumes that U.S. supply elasticity is 0.075, one-half of the U.S. hog supply elasticity assumed in the low impact scenario. Again, imported fresh pork products would be assumed to substitute perfectly for U.S. pork and displace it.

The future economic impact on U.S. swine producers will depend on demand-side factors, such as consumer acceptance of Mexican fresh pork, but probably most heavily on two supply-side factors: (1) Increases in total Mexican fresh pork production, and (2) the composition of fresh pork shipped from Sonora, Mexico. Mexican export pork supply will also be heavily affected by the long-term exchange rate between the United States and Mexico.

The impact of fresh pork imports is difficult to forecast because of the uncertainty as to how they will substitute for current foreign and/or domestic fresh pork products. For example, certain Mexican fresh pork imports may not affect U.S. producers at all, *i.e.*, they may not substitute for similar U.S.-produced pork, but, rather, completely substitute for and displace similar fresh pork products currently imported from another country. In this analysis, we are assuming that Mexican fresh pork from Sonora will displace a

similar U.S. product, causing U.S. farm prices to decrease by .05 cents to .11 cents per pound, liveweight. This small price decline elicits a corresponding small U.S. producer cutback in production. It is estimated that this cutback could represent .018 to .02 percent of U.S. production.

Impact on U.S. Consumers: Assuming Mexican producers find it in their interest to ship fresh pork from Sonora to the United States, consumer welfare gains of $10.7 million (low impact scenario) to $24.5 million (high impact scenario) annually are possible depending on the volume of fresh pork imports from Sonora and the sensitivity of U.S. pork product supply and demand to Mexican imports. This volume of pork imports could range from 7 million to 15 million pounds of additional retail pork available to U.S. consumers.

Impact on U.S. Livestock Sector: Primary producers of livestock and swine products would be detrimentally affected by fresh pork imports. Producer losses would nearly offset net gains to consumers. A breakdown of the anticipated potential impact on the U.S. livestock sector follows:

1. *Impact on Farrow-to-Finish Swine Operators:* Imports under the low-impact scenario are assumed to represent pork from about 67,000 hogs per year. Barrow and gilt slaughter hog prices would be expected to decrease by about 5 cents per CWT LWE. This lower price would elicit a cut in total U.S. hog production of between 10,000 and 17,000 hogs per year (depending on the supply elasticity assumed). The lower production level at a slightly lower price would reduce producer receipts and nearly offset net gains to consumers.

Under the high-impact scenario, increased imports would be expected to represent pork from about 134,000 hogs per year. Barrow and gilt slaughter hog prices would be expected to decrease by about 11 cents per CWT LWE. This lower price would elicit a cut in total U.S. hog production in the range of 20,000 to 34,000 hogs per year. This lower production level—along with a lower price—would reduce producer receipts by about $24.5 million per year.

Although the aggregate potential producer welfare losses appear substantial, total industry sales and the large number of swine operations would make the per farm producer losses relatively small. In 1992, there were about 191,347 hog and pig farms in the United States, of which it is estimated that about 96.4 percent would be considered ''small'' entities (annual sales of less than $0.5 million, according to Small Business Administration (SBA) size criteria).[1] Total value of hog inventories in December 1992 exceeded $4.147 billion, producing $9.9 billion in sales[2]. Small hog and pig entities maintain over 70 percent of these hog and pig inventories. Historical U.S. data show declining farm numbers (but almost stable production) and persistent competitive pressure on producers to adopt as many ''least-cost'' production methods as possible. Dividing the adjusted aggregate economic impact generated under the two scenarios listed above (low- and high-impact scenarios) by the number of small swine operations would produce drops in net annual farm income of almost $67 and $143, respectively.

2. *Impact on Live-Hog Dealers/Transporters:* Under either the low-impact scenario or the high-impact scenario, the effect on live-hog dealers/transporters is expected to be minimal. Reductions in transporting trips of U.S. hogs would be expected to decline by 86 or 125 trips, respectively, based on either low impact or high impact.[3] The reduction in activity in the high-impact scenario is slight in relation to the estimated 500,000 hauls of U.S. hog shipments in 1994.

Most dealers/transporters are considered ''small'' according to SBA guidelines (that is, sales of less than $12.5 million and employment of fewer than 500 employees). Firms in this industry are assumed to be classified in the general Census category of ''motor freight transportation and warehousing'' (''Standard Industry Classification'' (SIC) 4212 and 4213), with over 10,600 firms in 1992.[4] In SIC 4212 (other local trucking (without storage) of agricultural products), there are 6,203 establishments with $2.197 billion in revenue in 1992 and employment of 26,897 employees. The average firm revenue was $354,183, with employment of 4 to 5 workers. Thus, the average firm in the industry would fall under the SBA category of ''small,'' with sales of less than $12.5 million and fewer than 500 employees. In SIC 4213 (trucking, except local, of agricultural products), there are 4,483 establishments with $3.3 billion in revenue in 1992 and employment of 30,518 employees. The average firm revenue was $736,114, with employment of 6 to 7 workers. Thus, the average firm in the industry would fall under the SBA category of ''small,'' with sales of less than $12.5 million and employment of fewer than 500 employees. More detailed data on the actual distribution of firms by size are not available at this time.

Estimation of the potential impact of this rule on the live-hog dealer/transporter sub-sector is not possible given the available data. Census data on transporters is in a general category with other agricultural product shipments. Thus, it is unclear how important livestock transportation is to a particular ''small'' firm's business. Additional data are also needed on average miles traveled and net returns per trip. The relatively small anticipated reduction in trips suggests that the economic impact on this sub-sector will probably be very small. Further, if we assume that these reductions will fall evenly across all firms, this reduced level of economic activity is not expected to drive any one small livestock dealer/transporter out of business.

3. *Impact on Hog Processing Plants:* As discussed, the reduction in swine marketings is expected to be very small in relation to current marketings. The loss of processing activity generated by the displacement of 17,000 to 34,000 hogs (depending on the assumed levels of imports) would be slight compared with slaughter levels of almost 96 million head in 1994.

The size distribution of firms in this sub-sector makes it difficult to allocate the small losses estimated above across large and small firms. In the past, the desire to cut transportation costs of livestock and livestock products, to gain economies of scale in plant operations, and to shift to newer plants (without existing labor contracts) have led to increased industry concentration in this U.S. sub-sector. The exit of many older, smaller plants and companies has also contributed to increased market concentration. Most firms have multimillion dollar operations made up of new, large, state-of-the-art slaughter and packing plants. In 1992, there were 1,385 meat packing establishments in the United States, down from 1,434 such establishments in 1987[5]. The 1987 data indicate that 88 pork-slaughter companies had more than 20 employees. These companies had

[1] Source: *1992 Census of Agriculture*, Part 51, ''United States Summary and State Data'', Table 50, Pg. 123.

[2] Source: *Agricultural Statistics, 1994*, USDA, Tables 399 (pg. 238) and 392 (pg. 233).

[3] This estimate is based on livestock requirements reported in *Livestock Conservation Institute*, Colorado State University. This reference states that trucks measuring 44 feet long, 92 inches wide and 8 feet high, should be able to handle about 200 head of slaughter hogs.

[4] Census information was obtained from Mr. Dennis Shoemaker, Agricultural Statistician, Bureau of the Census, March 1995.

[5] Source: 1992 Census of Manufacturers, MC92–SUM–1(P), Preliminary Report, Summary Series, pg. 9.

34,300 employees in all, with a payroll of $713.8 million and shipments of pork valued at $11.6 billion.[6]

Summary

Allowing the importation of fresh, chilled or frozen pork from Sonora, Mexico, could lead to some changes in Mexican fresh pork production and trade. Assuming stable production and a relatively ''neutral'' currency regime, diversion of current Mexican fresh pork trade would allow Mexico to make some minor inroads into the U.S. fresh pork market, especially in the U.S. Southwest. Two scenarios examined—a low-impact and a high-impact situation— could produce annual consumer welfare gains of .07 cents to .16 cents per pound retail weight, and producer losses of .05 cents to .11 cents per pound, liveweight. These consumer welfare gains and producer welfare losses will depend mainly on the amount of fresh pork imported, but also on how consumers react to Mexican fresh pork product imports.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been designated by the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, as a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121, 5 U.S.C. 801–808). Therefore, it has been submitted for a 60-day Congressional review in accordance with that Act, and will not become effective until that review period ends.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule (1) preempts all State and local laws that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this rule. The assessment provides a basis for the conclusion that the actions required or authorized by this rule will not present a significant risk of introducing or disseminating hog cholera disease agents into the United States and will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW, Washington, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule have been approved by the Office of Management and Budget (OMB). The assigned OMB control number is 0579–0015.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, APHIS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires APHIS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective, or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that may result in expenditures by State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 94 is amended as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

2. A new § 94.20 is added to read as follows:

§ 94.20 Importation of pork from Sonora, Mexico.

Notwithstanding any other provisions of this part, fresh, chilled or frozen pork from the State of Sonora, Mexico, may be imported into the United States under the following conditions:

(a) The pork is meat from swine that have been raised and slaughtered in Sonora;

(b) The pork has not been in contact with pork from countries other than those listed in § 94.9(a) as countries where hog cholera is not known to exist; and

(c) An authorized official of Mexico certifies on the foreign meat inspection certificate required by § 327.4 of this title that the above conditions have been met.

Done in Washington, DC, this 5th day of May 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–12162 Filed 5–8–97; 8:45 am]

BILLING CODE 3410–34–P

[6] Source: Agricultural Input and Processing Industries, Iowa State University, RD–05, April 1992, pg. 17.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 160 and 161

[Docket No. 96–075–2]

Accredited Veterinarians; Optional Digital Signature

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to accept digital signatures from accredited veterinarians as an additional option for official certificates, forms, records, and reports to the Animal and Plant Health Inspection Service. Before the publication of this document, we required hand written signatures on all such documents. We believe that accepting digital signatures will benefit accredited veterinarians and the industries they serve by reducing the turnaround time for these documents. This action relieves restrictions that appear to be unnecessary.

EFFECTIVE DATE: May 9, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. Joseph S. VanTiem, Senior Staff Veterinarian, National Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1231, (301) 734–7716, or e-mail: jvantiem@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 160 and 161 (the regulations), govern the accreditation of veterinarians. Accredited veterinarians are approved by the Administrator of the Animal and Plant Health Inspection Service (APHIS) to perform certain regulatory tasks to control and prevent the spread of animal diseases throughout the country and internationally. One of these regulatory tasks is preparing official documents including certificates, forms, records, and reports and submitting such documents to APHIS. Before the publication of this document, we required a hand written signature by the accredited veterinarian on all official certificates, forms, records, and reports.

On January 6, 1997, we published in the **Federal Register** (62 FR 597–600, Docket No. 96–075–1) a proposal to amend the regulations by allowing accredited veterinarians the additional option of signing official certificates, forms, records, and reports by use of a digital signature and of transmitting such documents electronically to APHIS.

We solicited comments concerning our proposal for 60 days ending March 7, 1997. We received two comments by that date. They were from industry representatives. Both responses were in favor of our proposal to accept digital signatures from accredited veterinarians.

The commenters both supported our proposal and agreed that the acceptance of digital signatures and electronically transmitted documents will expedite document creation and processing and benefit all parties by saving time and money.

Therefore, based on the rationale set forth in the proposed rule, we are adopting the provisions of the proposal as a final rule without change.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. Immediate implementation of this rule is necessary to provide relief to those persons who are adversely affected by restrictions we no longer find warranted. The current method of delivering certificates is time consuming and expensive. The optional use of digital signatures and electronic transmissions will save both time and money and expedite exports. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We do not have enough data for a comprehensive analysis of the economic impacts of this final rule on small entities. Therefore, in accordance with 5 U.S.C. 601 *et seq.*, we have performed a Final Regulatory Flexibility Analysis, set forth below, regarding the economic effect of this rule on small entities.

Under the Animal Industry Act (21 U.S.C. 112, 113–114a–1, and 115), the Animal Quarantine Acts and the Cattle Contagious Diseases Act (21 U.S.C. 105, 111–113, 120, 121, and 125), the Federal Meat Inspection Act (21 U.S.C. 612 and 613), the Foot-and-Mouth Disease Research Act (21 U.S.C. 113a), and the Horse Protection Act (15 U.S.C. 1828), the Secretary of Agriculture has the authority to promulgate regulations and take measures to prevent the introduction and dissemination of communicable diseases of livestock and poultry. In accordance with the regulations in 9 CFR parts 160, 161, and 162, some veterinarians are accredited by the Federal Government to cooperate with APHIS in controlling and preventing the introduction and dissemination of animal diseases. Accredited veterinarians use their professional training in veterinary medicine to perform certain regulatory tasks. One of these regulatory tasks is preparing official documents, including certificates, forms, records, and reports and submitting such documents to APHIS. Before the publication of this document, only a hand written signature of an accredited veterinarian was acceptable.

We are amending the regulations to allow accredited veterinarians to use digital signatures in place of hand written signatures. Allowing the electronic transmission of signed documents will benefit accredited veterinarians and the industries they serve by eliminating the time-consuming step of physical transmission from the accredited veterinarian to the VS area office and others involved in the process.

An example of a document which accredited veterinarians must sign is an export health certificate. For the poultry industry, VS Form 17–6, Certificate for Poultry or Hatching Eggs for Export, is used as an export health certificate. Before the publication of this document, a VS Form 17–6 was processed as follows: The producer filled out information related to the exportation on the VS Form 17–6 and sent it to the accredited veterinarian; the accredited veterinarian filled out the information about the health of the poultry or eggs on the VS Form 17–6, including any required test information, signed the VS Form 17–6 and sent it to the VS area office; the APHIS veterinarian reviewed and endorsed the VS Form 17–6 and sent it back to the producer, who sent the VS Form 17–6 to the importing country. Throughout this process, there could have been time delays and additional expenses incurred for mailing or special handling to move the certificate from one place to the next.

With the use of digital signatures, the accredited veterinarian can receive, complete, and sign an automated document from the producer. The accredited veterinarian can electronically transmit the signed document to the VS area office. Therefore, this amendment eliminates

the need to pay couriers or package delivery companies and wait for delivery between the producers, accredited veterinarians, and the VS area office.

This rule provides an additional option for signing and submitting official certificates, forms, records, and reports. While not requiring that this option be exercised, there are potential savings for those accredited veterinarians who make use of this option. The delivery costs associated with these documents can vary widely based on the delivery method used. Therefore, we cannot accurately estimate the potential savings. However, we expect that this rule will benefit accredited veterinarians and their clients, whether large or small.

An alternative to this rule was to make no changes in the regulations. We rejected this alternative because accredited veterinarians will not be required to use this alternative signature method.

This rule contains no new information collection or recordkeeping requirements.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

List of Subjects

9 CFR Part 160

Veterinarians.

9 CFR Part 161

Reporting and recordkeeping requirements, Veterinarians.

Accordingly, 9 CFR parts 160 and 161 are amended as follows:

PART 160—DEFINITION OF TERMS

1. The authority citation for part 160 continues to read as follows:

Authority: 15 U.S.C. 1828; 21 U.S.C. 105, 111–114, 114a, 114a–1, 115, 116, 120, 121, 125, 134b, 134f, 612 and 613; 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 160.1, the definitions for *issue* and *sign* are revised and the definition for *approved digital signature* is added, in alphabetical order, to read as follows:

§ 160.1 Definitions.

* * * * *

Approved digital signature. Digital signatures approved by the Administrator for electronic transmission, for example, via a computer. To be approved, a digital signature must be able to verify the identity of the accredited veterinarian signing the document and indicate if the integrity of the data in the signed document was compromised.

* * * * *

Issue. The distribution, including electronic transmission, of an official animal health document that has been signed.

* * * * *

Sign, (Signed). For an accredited veterinarian to put his or her signature in his or her own hand, or by means of an approved digital signature, on a certificate, form, record, or report. No certificate, form, record, or report is signed if:

(1) Someone other than the accredited veterinarian has signed it on behalf of or in the name of the accredited veterinarian, regardless of the authority granted them by the accredited veterinarian; or

(2) If any mechanical device, other than an approved digital signature, has been used to affix the signature.

* * * * *

PART 161—REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

3. The authority citation for part 161 continues to read as follows:

Authority: 15 U.S.C. 1828; 21 U.S.C. 105, 111–114, 114a, 114a–1, 115, 116, 120, 121, 125, 134b, 134f, 612 and 613; 7 CFR 2.22, 2.80, and 371.2(d).

4. In § 161.3 paragraph (j) is revised to read as follows:

§ 161.3 Standards for accredited veterinarian duties.

* * * * *

(j) An accredited veterinarian shall be responsible for the security and proper use of all official certificates, forms, records, and reports; tags, bands, or other identification devices; and approved digital signature capabilities used in his or her work as an accredited veterinarian and shall take reasonable care to prevent the misuse thereof. An accredited veterinarian shall immediately report to the Veterinarian-in-Charge the loss, theft, or deliberate or accidental misuse of any such certificate, form, record, or report; tag, band, or other identification device; or approved digital signature capability.

* * * * *

Done in Washington, DC, this 5th day of May 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–12084 Filed 5–8–97; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AAL–3]

Temporary Establishment of Class D Airspace; Anchorage International Airport, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a temporary Class D airspace area east of the Anchorage International Airport, AK, while Runway 06R/24L is closed for construction and at times for the closure of portions of Runway 32/14. During these closures, heavy or large commercial aircraft will be departing to the east from Runway 06L or arriving from the east to land on Runway 24R. The intended effect of this action is to enhance safety by reducing the possibility of small general aviation aircraft encountering wake turbulence from, or conflicting with, heavy or large aircraft departing or arriving Anchorage International Airport.

DATES: *Effective date:* 0901 UTC, May 22, 1997.

Expiration date: 0901 UTC, September 15, 1997.

FOR FURTHER INFORMATION CONTACT: Robert C. Durand, System Management Branch, AAL–530, Air Traffic Division, Federal Aviation Administration, 222 West 7th Avenue #14, Anchorage, AK 99513–7587; telephone number: (907) 271–5898.

SUPPLEMENTARY INFORMATION:

Background

Normally, heavy or large aircraft depart on Runway 32 to the north and arrive on Runway 06R from the west at Anchorage International Airport. The Anchorage International Airport Manager has informed the Federal Aviation Administration (FAA) that beginning in May 1997, Runway 32 will have a displaced threshold with 9400 feet remaining available for departures until June 1997. Also, Runway 06R/24L will be closed for construction from June 1997 until September 1997. These closures will necessitate that heavy or large aircraft operating to or from Anchorage International Airport arrive from or depart to the east using Runway 24R/06L. Part of this airspace is a transition corridor used by small general aviation aircraft operating under visual flight rules (VFR) to or from Lake Hood, Merrill Field, and Anchorage International airports. The FAA has received notification from the Air Transport Association of America and several airlines (Alaska Airlines, Federal Express, and Northwest Airlines), expressing concerns about heavy or large aircraft departing Runway 06L conflicting with VFR traffic east of Anchorage International Airport.

The Rule

This amendment to part 71 of the Federal Aviation Regulations establishes a Temporary Class D airspace area from the surface to 4,100 feet mean sea level (MSL) east of Anchorage International Airport, AK (see appendix). Pilots operating in this airspace above 1200 feet MSL will be required to be in radio contact with Anchorage Radar Approach Control air traffic controllers. These aircraft will be provided traffic advisories, wake turbulence advisories and safety alerts. Additionally, controllers will provide separation services between special VFR operations and aircraft executing instrument departure/approach procedures from/to the Anchorage International Airport. For those pilots operating at and below 1200 feet MSL, radio communications shall be established and maintained with either Lake Hood or Merrill Airport Traffic Control Towers or Anchorage Approach Control prior to entering this airspace. This action is intended to enhance safety by reducing the possibility of small general aviation aircraft encountering wake turbulence from, or conflicting with, heavy or large aircraft departing or arriving Anchorage International Airport.

Because the circumstances described in this final rule warrant immediate action by the FAA to maintain the safety of flight, the FAA concludes that notice and public procedure under 5 U.S.C. section 553(b) are impracticable and good cause, pursuant to 5 U.S.C. section 553(d), exists for making this amendment effective in less than 30 days.

The coordinates for this airspace docket are based on North American Datum 83. Class D airspace area designations are published in paragraph 5000 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. This Class D airspace area listed in this document will be published subsequently in the Order.

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

Adoption of the Amendment

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

PART 71—[AMENDED]

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 5000—Class D Airspace

* * * * *

AAL AK D Temporary Anchorage, AK [New]

That airspace extending upward from the surface to and including 4,100 feet MSL within a line beginning at the intersection of the New Seward Highway and O'Malley Road, at lat. 61°07′23″ N; long. 149°51′23″ W; thence east to the intersection of O'Malley Road and Lake Otis Park Way at lat. 61°07′23″ N; long. 149°50′03″ W; thence north to the intersection of Lake Otis Park Way and Abbott Road at lat. 61°08′14″ N; long. 149°50′03″ W; thence east to the intersection of Abbott Road and Abbott Loop Road at lat. 61°08′14″ N; long. 149°48′16″ W; thence due north to Tudor Road at lat. 61°10′51″ N; long. 149°48′16″ W; thence west to the intersection of Tudor Road and New Seward Highway at lat. 61°10′51″ N; long. 149°51′38″ W; thence south along the New Seward Highway to the point of beginning.

* * * * *

Issued in Anchorage, AK, April 30, 1997.

Willis C. Nelson,

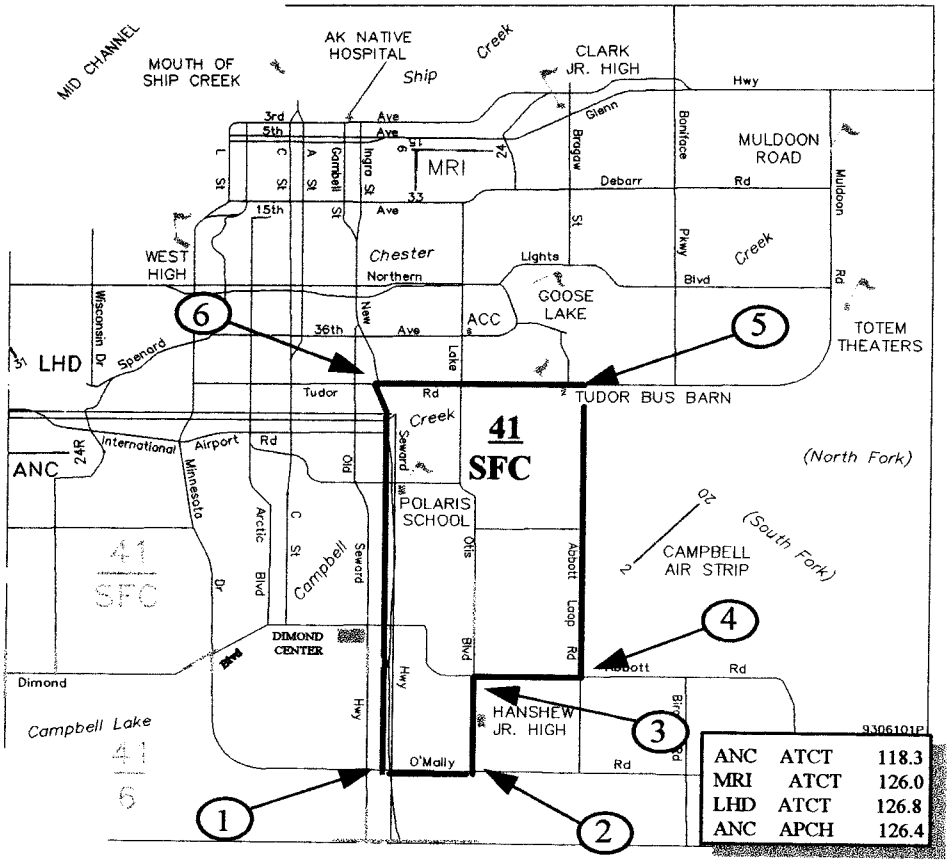
Manager, Air Traffic Division.

Note: This appendix will not appear in the Code of Federal Regulations.

Appendix—Temporary Establishment of Class D Airspace; Anchorage International Airport, Alaska (AK)

BILLING CODE 4910–13–P

Temporary Establishment of Class D Airspace; Anchorage International Airport, Alaska (AK). Docket No. 97-AAL-3



Airspace Description:

1. New Seward Hwy and O'Malley Rd. Lat. 61 07' 23"N; Lg. 149 51' 23"W
2. O'Malley Rd. and Lake Otis Pkwy. Lat. 61 07' 23"N; Lg. 149 50' 03"W
3. Lake Otis Pkwy. and Abbott Rd. Lat. 61 08' 14"N; Lg. 149 50' 03"W
4. Abbott Rd. and Abbott Loop. Rd. Lat. 61 08' 14"N; Lg. 149 48'16"W
5. Imaginary extension of Abbott Loop. Rd. north to where it would intersect Tudor Rd. Lat. 61 10' 51"N; Lg. 149 48' 16"W
6. Tudor Rd. and New Seward Hwy. Lat. 61 10' 51"N; Lg. 149 51' 38"W

[FR Doc. 97–12051 Filed 5–8–97; 8:45 am]
BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 96–AAL–31]

Revision of Class E Airspace; Klawock, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revises Class E airspace at Klawock Airport, AK. The revision of the Global Positioning System (GPS) and creation of a non-directional beacon (NDB) instrument approach to runway (RWY) 1 have made this action necessary. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Klawock Airport, AK.

EFFECTIVE DATE: 0901 UTC, July 17, 1997.

FOR FURTHER INFORMATION CONTACT: Robert van Haastert, System Management Branch, AAL–538, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number: (907) 271–5863; email: Robert.van.Haastert@faa.dot.gov.

SUPPLEMENTARY INFORMATION:

History

On March 4, 1997, a proposal to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the Class E airspace at Klawock was published in the **Federal Register** (62 FR 9720). The revision of the GPS and development of the NDB instrument approach procedures to RWY 1 at Klawock Airport, AK, have made this action necessary.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received, however, the coordinates for the Airport Reference Point were listed incorrectly and should read: 55° 34′ 45″ N, 133° 04′ 34″ W. The Federal Aviation Administration has determined that this change is editorial in nature and will not increase the scope of this rule. Except for the non-substantive change just disclosed, the rule is adopted as written.

The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 of FAA Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996. Paragraph 6005 is incorporated by reference in 14 CFR 71.1 (61 FR 48403; September 13, 1996). The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) revises Class E airspace located at Klawock, AK, to provide controlled airspace extending upward from 700 feet AGL for aircraft executing instrument landing and departing procedures.

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

PART 71—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Klawock, AK [Revised]

Klawock Airport, AK
(lat. 55° 34′ 45″ N, long. 133° 04′ 34″ W)
Klawock NDB/DME
(lat. 55° 34′ 07″ N, long. 133° 04′ 46″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Klawock Airport and 6.5 miles north and 10 miles south of the 243° bearing from the Klawock NDB/DME extending to 16 miles southwest of the NDB/DME; and that airspace extending upward from the 1,200 feet above the surface within 6.7 miles northwest and 9.5 miles southeast of the 039° bearing from the airport extending from the airport to 6.7 miles northeast of the airport and within 6.7 miles northwest and 9.5 miles southeast of the 219° bearing from the airport extending from the airport to 32 miles southwest of the airport and 6.5 miles north and 10 miles south of the 243° bearing from the Klawock NDB/DME beginning 16 miles west of the NDB/DME and extending to 35 miles west of the NDB/DME.

* * * * *

Issued in Anchorage, AK, on April 30, 1997.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 97–12237 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 28904; Amdt. No. 402]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

EFFECTIVE DATE: 0901 UTC, May 22, 1997.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS–420), Technical

Programs Division, Flight Standards Service Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 267–8277.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace.

In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days. The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current.

It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC on April 29, 1997.

David R. Harrington,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, May 22, 1997:

PART 95—IFR ALTITUDES

1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44719, 44721.

2. Part 95 is amended to read as follows:

REVISIONS TO MINIMUM ENROUTE IFR ALTITUDES & CHANGEOVER POINTS

[Amendment 402 effective date, May 22, 1997]

From	To	MEA
§ 95.1001 DIRECT ROUTES—U.S.		
Puerto Rico Routes—Route 11 Is Amended To Read in Part		
Sends, PR FIX	**Varna, PR FIX	*5000
*4300—MOCA		
**5000—MCA VARNA FIX, SW BND		
Varna, PR FIX	San Juan, PR VORTAC	3700
Puerto Rico Routes—Route 12 Is Added To Read		
Mayaguez, PR VOR/DME	Joshe, PR FIX	6000
Joshe, PR FIX	*Varna, PR FIX	6000
*5000—MCA VARNA FIX, SW BND		
Varna, PR FIX	San Juan, PR VORTAC	3700
San Juan, PR VORTAC	JETSS, PR FIX	2000
JETSS, PR FIX	St Thomas, VI VOR/DME	2800
Bahama Routes—10 LIMA Is Amended by Adding		
Islands, BF NDB	Haana, BF FIX	3000
Haana, BF FIX	Marsh Harbour, BF NDB	3000
Marsh Harbour, BF NDB	Governors Harbour, BF NDB	3000
Bahama Routes—53V Is Amended by Adding		
Nassau, BF VOR/DME	Governors Harbour, BF NDB	3000
Bahama Routes—59V Is Amended To Delete		
Nassau, BF VOR/DME	Treasure Cay, BF VOR/DME	2000
Bahama Routes—70V Is Amended By Adding		
Freeport, BF VOR/DME	Marsh Harbour, BF NDB	3500
Marsh Harbour, BF NDB	Nassau, BF VOR/DME	3000

REVISIONS TO MINIMUM ENROUTE IFR ALTITUDES & CHANGEOVER POINTS—Continued

[Amendment 402 effective date, May 22, 1997]

From	To	MEA
§ 95.6001 VOR Federal Airway 1 Is Amended To Read in Part		
Drone, NC FIX *1600—MOCA	Norfolk, VA VORTAC	*2500
Norfolk, VA VORTAC *1700—MOCA	Cape Charles, VA VORTAC	*2500
§ 95.6002 VOR Federal Airway 2 Is Amended To Read in Part		
Buffalo, NY VOR/DME *2400—MOCA	Clung, NY FIX	*6000
§ 95.6014 VOR Federal Airway 14 Is Amended To Read in Part		
Buffalo, NY VOR/DME *3900—MOCA	Geneseo, NY VOR/DME	*6000
§ 95.6061 VOR Federal Airway 61 Is Amended To Read in Part		
Pawnee City, NE VORTAC *4500—MRA **2800—MOCA	*Bowlr, KS FIX	**4000
§ 95.6063 VOR Federal Airway 63 Is Amended To Read in Part		
Bonham, TX VORTAC *2500—MOCA	Mc Alester, OK VORTAC	*3000
§ 95.6067 VOR Federal Airway 67 Is Amended To Read in Part		
Cedar Rapids, IA VOR/DME	Waterloo, IA VORTAC	2900
§ 95.6071 VOR Federal Airway 71 Is Amended To Read in Part		
Topeka, KS VORTAC *2800—MOCA	Pawnee City, NE VORTAC	*4000
Lincoln, NE VORTAC *2600—MOCA	Dwell, NE FIX	*3300
§ 95.6076 VOR Federal Airway 76 Is Amended To Read in Part		
Lubbock, TX VORTAC *7000—MRA	*Welch, TX FIX	5200
Welch, TX FIX	Patts, TX FIX	5200
Patts, TX FIX	Big Spring, TX VORTAC	4700
§ 95.6084 VOR Federal Airway 84 Is Amended To Read in Part		
Buffalo, NY VOR/DME *3900—MOCA	Geneseo, NY VOR/DME	*6000
§ 95.6139 VOR Federal Airway 139 Is Amended To Read in Part		
Pears, NC FIX *5000—MCA SUNNS FIX, SE BND **2000—MOCA	*Sunns, NC FIX	**6000
Sunns, NC FIX	Norfolk, VA VORTAC	2000
Norfolk, VA VORTAC *1700—MOCA	Cape Charles, VA VORTAC	*2500
§ 95.6164 VOR Federal Airway 164 Is Amended To Read in Part		
Bulge, NY FIX *2000—MOCA	Buffalo, NY VOR/DME	*6000
Buffalo, NY VOR/DME *4400—MOCA	Bizon, NY FIX	*6000
Bizon, NY FIX *4500—MOCA	Wellsville, NY VORTAC	*6000
§ 95.6194 VOR Federal Airway 194 Is Amended To Read in Part		
Mc Comb, MS VORTAC	Mizze, MS FIX	*3000

REVISIONS TO MINIMUM ENROUTE IFR ALTITUDES & CHANGEOVER POINTS—Continued

[Amendment 402 effective date, May 22, 1997]

From	To	MEA
*1900—MOCA		
§ 95.6210 VOR Federal Airway 210 Is Amended To Read in Part		
Mingg, OK FIX ..... *2500—MOCA	Okmulgee, OK VOR	*4000
§ 95.6272 VOR Federal Airway 272 Is Amended To Read in Part		
Holle, OK FIX ..... *2500—MOCA	Mc Alester, OK VORTAC	*3000
§ 95.6321 VOR Federal Airway 321 Is Amended To Read in Part		
Abbet, GA FIX	Prest, GA FIX	2600

[FR Doc. 97–12052 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 730, 732, 734, 736, 738, 740, 742, 744, 746, 748, 750, 752, 754, 756, 758, 762, 764, 768, 770, and 772

[Docket No. 970306044–7044–01]

RIN 0694–AB56

Revisions and Clarifications to the Export Administration Regulations

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: On March 25, 1996, the Bureau of Export Administration (BXA) published an interim rule (61 FR 12714) that restructured and reorganized the Export Administration Regulations (EAR). The interim rule clarified the language of the EAR and simplified the application and made the export control regulatory regime more user friendly. This rule amends the EAR by making certain revisions and clarifications and, in some cases, inserts material inadvertently omitted from the March 25 interim rule.

DATES: This rule is effective May 9, 1997.

FOR FURTHER INFORMATION CONTACT: Patricia Muldonian, Office of Exporter Services, Bureau of Export Administration, Telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. This final rule has been determined to be not significant for the purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This rule involves collections of information requirements subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0607–0001, 0607–0018, 0607–1052, 0694–00016, 0694–1017, 0694–0021, 0694–0029, 0694–0058, 0694–0093, 0694–0097, and 0694–0102. This rule also contains collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0694–0050 and 0694–0088. Public reporting burden for these collections of information are estimated to average 30 minutes for 0694–0050 and 45 minutes for 0694–0088 respectively per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information. Send suggestions regarding burden estimates or any other aspect of the data requirements, including suggestions for reducing the burdens to Steve Baker, Bureau of Export Administration, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503, Attention: BXA Desk Officer.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. The provisions of the Administrative Procedure Act requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Patricia Muldonian, Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Foreign trade, Reporting and recordkeeping requirements, Strategic and critical materials.

15 CFR Parts 732, 740, 748, 750, 752, 758 and 768

Administrative practice and procedure, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 734

Administrative practice and procedure, Exports, Foreign trade.

15 CFR Parts 736, 738, 742, 770, and 772

Exports, Foreign trade.

15 CFR Part 744

Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 746

Embargoes, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 754

Exports, Foreign trade, Forests and forest products, Petroleum, Reporting and recordkeeping requirements.

15 CFR Part 756

Administrative practice and procedure, Exports, Foreign trade, Penalties.

15 CFR Part 762

Administrative practice and procedure, Business and industry, Confidential business information, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 764

Administrative practice and procedure, Exports, Foreign trade, Law enforcement, Penalties.

Accordingly, parts 730, 732, 734, 736, 738, 740, 742, 744, 746, 748, 750, 752, 754, 756, 758, 762, 764, 768, 770, and 772 of the Export Administration Regulations (15 CFR Parts 730–799) are amended as follows:

1. The authority citation for 15 CFR Part 730 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 1701 *et seq.;* 10 U.S.C. 7430(e); 18 U.S.C. 2510 *et seq.;* 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004, Sec. 201, Pub. L. 104–58, 109 Stat. 557 (30 U.S.C. 185(s)); 30 U.S.C. 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12867, 58 FR 51747, 3 CFR, 1993 Comp., p. 649; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of August 15, 1995, 3 CFR, 1995 Comp., p. 501; E.O. 12981, 60 FR 62981; Notice of August 14, 1996, 61 FR 42527, August 15, 1996; E.O. 13026, 61 FR 58767, November 18, 1996.

2. The authority citations for 15 CFR Parts 732, 736, 740, 748, 750, 768, 770, and 772 continue to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 1701 *et seq.;* E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; Executive Order 13026, November 15, 1996, 61 FR 58767; Notice of August 15, 1995, 60 FR 42767, August 17, 1995; Notice of August 14, 1996, 61 FR 42527, 3 CFR, 1995 Comp., p. 501.

3. The authority citations for 15 CFR Parts 752, 756, 758, 762, and 764 continue to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 1701 *et seq.;* E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; Notice of August 15, 1995, 60 FR 42767, August 17, 1995; Notice of August 14, 1996, 61 FR 42527, 3 CFR, 1995 Comp., p. 501.

4. The authority citation for 15 CFR Part 734 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of August 15, 1995, 60 FR 42767, August 17, 1995; Notice of August 14, 1996, 61 FR 42527, 3 CFR, 1995 Comp., 501; E.O. 13026, 61 FR 58767, November 19, 1996.

5. The authority citation for 15 CFR Part 738 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 720; 10 U.S.C. 7430(e); 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; Sec. 201, Pub. L. 104–58, 109 Stat. 557 (30 U.S.C. 185(s)); 30 U.S.C. 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; Notice of August 15, 1995, 60 FR 42767, August 17, 1995; Notice of August 14, 1996, 61 FR 42527, 3 CFR, 1995 Comp., 501; E.O. 13026, 61 FR 58767, November 19, 1996.

6. The authority citation for 15 CFR Part 742 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; E.O. 12088, 43 FR 20947, 3 CFR, 1994 Comp., p. 917; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917, E.O. 12938, 59 FR 59099, 3 CFR 1994 Comp., p. 950; Notice of August 15, 1995, 60 FR 42767, August 17, 1995; Notice of August 14, 1996, 61 FR 42527, 3 CFR, 1995 Comp., 501; E.O. 13026, 61 FR 58767, November 19, 1996.

7. The authority citation for 15 CFR Part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12581, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR 1994 Comp., p. 950; Notice of August 15, 1995, 60 FR 42767, August 17, 1995; Notice of August 14, 1996, 61 FR 42527, 3 CFR, 1995 Comp., 501; E.O. 13026, 61 FR 58767, November 15, 1996.

8. The authority citation for 15 CFR Part 746 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 6004; E.O. 12918, 59 FR 28205, 3 CFR Comp., p. 899; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; Notice of August 15, 1995, 60 FR 42767, 3 CFR, 1995 Comp. p. 501; Notice of August 14, 1996, 61 FR 42527, August 15, 1996.

9. The authority citation for 15 CFR Part 754 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7430(e); Sec. 201, Pub. L. 104–58, 109 Stat. 557 (30 U.S.C. 185(s)); 30 U.S.C. 185(u); 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; Notice of August 15, 1995, 60 FR 42767, 3 CFR, 1995 Comp., p. 501; Notice of August 14, 1996, 61 FR 42527, August 15, 1996.

PART 730—[AMENDED]

10. Section 730.9 is amended by revising paragraph (c) to read as follows:

§ 730.9 How the Bureau of Export Administration is organized.

* * * * *

(c) *Technical Advisory Committees.* (1) The Technical Advisory Committees (TACs) provide advice and assistance to BXA from U.S. industry regarding the creation and implementation of export controls. For further information regarding establishment of TACs and other information, see Supplement No. 2 to part 730. Existing TACs include the following:

(i) The Information Systems TAC;

(ii) The Materials TAC;

(iii) The Materials Processing Equipment TAC;

(iv) The Regulations and Procedures TAC;

(v) The Sensors and Instrumentation TAC; and

(vi) The Transportation and Related Equipment TAC.

(2) *For more information.* For information on attending a TAC meeting or on becoming a TAC member, please contact Ms. Lee Ann Carpenter, Director, TAC Unit, OAS-EA/BXA, Room 3886C, U.S. Department of Commerce, Washington, DC 20230; Telephone number: (202) 482–2583. FAX number: (202) 501–8024.

PART 732—[AMENDED]

11. Section 732.1 is amended by revising the introductory text of paragraph (a)(1) to read as follows:

§ 732.1 Steps overview.

(a)(1) *Introduction.* In this part, references to the EAR are references to 15 CFR chapter VII, subchapter C. This part is intended to help you determine your obligations under the EAR by listing logical steps in § 732.2 through § 732.5 of this part that you can take in reviewing these regulations. A flow chart describing these steps is contained in Supplement No. 1 to part 732. By cross-references to the relevant provisions of the EAR, this part describes the suggested steps for you to determine applicability of the following:

* * * * *

12. Section 732.2 is amended:

a. By revising the introductory text immediately following the section heading;

b. By revising paragraph (b)(1);

c. By revising the introductory text to paragraph (d);

d. By revising the phrase ''consider Step 5 regarding'' to read ''consider Step 6 regarding'' in paragraph (d)(3); and

e. By revising the phrase ''Federal Agency or unless publicly available'' to read ''Federal Agency or publicly available.)'' in paragraph (f)(3)(ii).

§ 732.2 Steps regarding scope of the EAR.

Steps 1 though 6 are designed to aid you in determining the scope of the EAR. A flow chart describing these steps is contained in Supplement No. 2 to part 732.

* * * * *

(b) * * *

(1) If your technology or software is publicly available, and therefore outside the scope of the EAR, you may proceed with the export or reexport if you are not a U.S. person subject to General Prohibition Seven. If you are a U.S. person, go to Step 15 at § 732.3(j) of this part. If you are a U.S. person and General Prohibition Seven concerning proliferation activity of U.S. persons does not apply, then you may proceed with the export or reexport of your publicly available technology or software. Note that all U.S. persons are subject to the provisions of General Prohibition Seven.

* * * * *

(d) *Step 4: Foreign-made items incorporating less than the de minimis level of U.S. parts, components, and materials.* This step is appropriate only for items that are made outside the United States and not currently in the U.S. Note that encryption items controlled for EI reasons under ECCN 5A002 or ECCN 5D002 on the Commerce Control List (refer to Supplement No. 1 to part 774 of the EAR) shall be subject to the EAR even if they incorporate less than the de minimis level of U.S. content. Accordingly, the provisions of the EAR concerning de minimis levels are not applicable to encryption items controlled for ''EI'' reasons under ECCNs 5A002, 5D002, or 5E002.

* * * * *

13. Part 732.3 is amended by revising paragraph (h)(2).

§ 732.3 Steps regarding the ten general prohibitions.

* * * * *

(h) * * *

(2) Under License Exception TSU (§ 740.13 of the EAR), operational technology and software (OTS), sales technology (STS), and software updates (SUD) overcome General Prohibition Five (End-Use and End-User) (§ 736.2(b)(5) of the EAR) if all terms and conditions of these provisions are met by the exporter or reexporter.

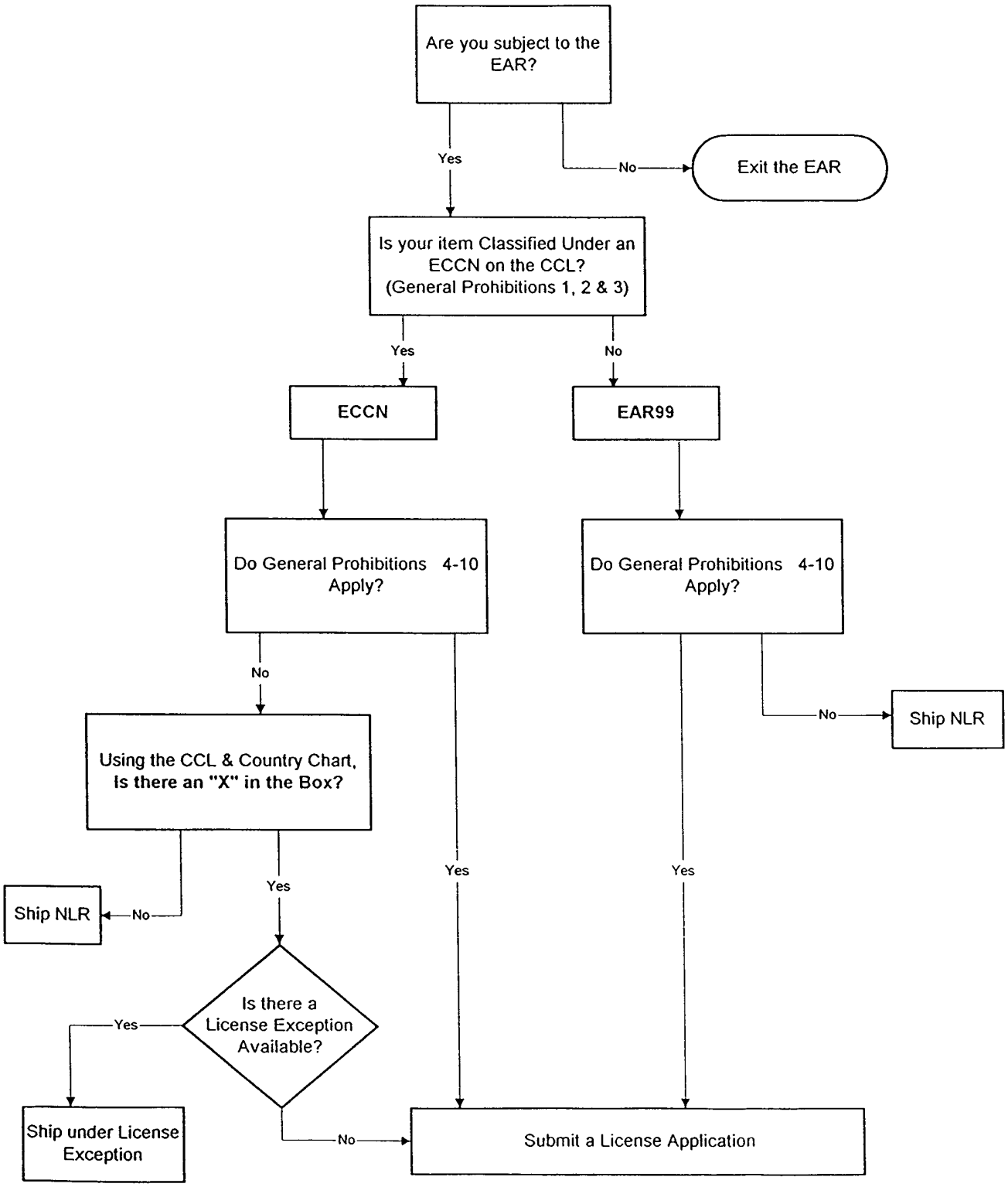
* * * * *

14. In part 732, Supplement No. 1 is redesignated as Supplement No. 3 and a new Supplement No. 1 and a new Supplement No. 2 are added to read as follows:

BILLING CODE 3510–33–P

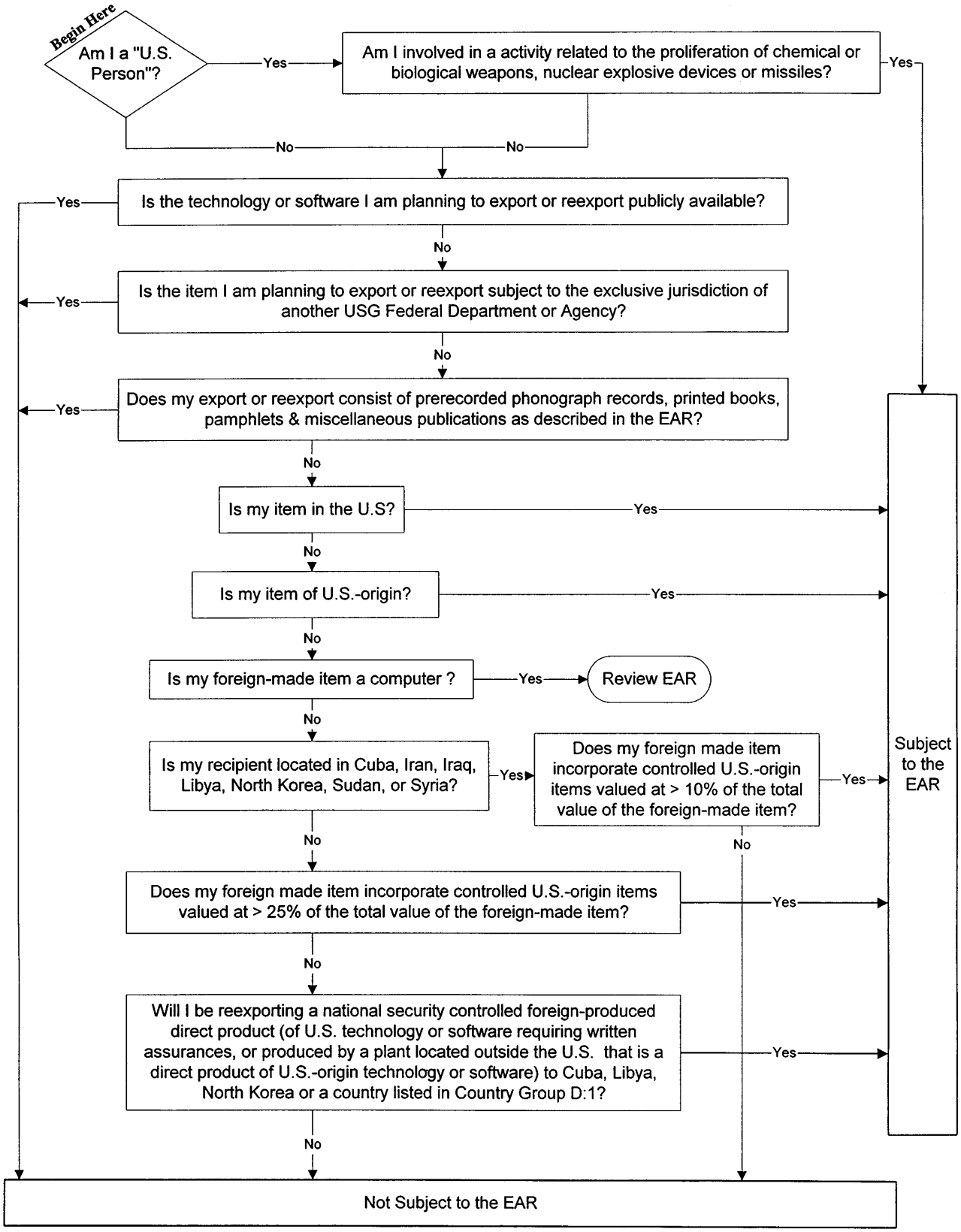
Supplement No. 1 to part 732

DECISION TREE



Supplement No. 2 to Part 732

Am I subject to the EAR?



BILLING CODE 3510–33–C

15. In part 732, newly designated Supplement No. 3 is amended by revising the phrase ''for a validated license'' to read ''for a license'' in paragraph (a)(6).

PART 734—[AMENDED]

16. Section 734.3 is amended by revising paragraph (b)(4) to read as follows:

§ 734.3 Items subject to the EAR.

* * * * *

(b) * * *

(4) Foreign made items that have greater than the *de minimis* U.S. content based on the principles described in § 734.4 of this part.

* * * * *

17. Section 734.4 is amended:

a. By revising the introductory text to paragraph (c);

b. By revising the phrase ''U.S. origin'' to read ''U.S.-origin'' in paragraph (c)(3); and

c. By revising the introductory text to paragraph (d), as follows:

§ 734.4 De minimis U.S. content.

* * * * *

(c) Except as provided in paragraph (a) of this section for certain computers, the following reexports are not subject to the EAR when made to either an embargoed country listed in part 746 of the EAR or to a terrorist-supporting country as described in part 742 of the EAR:

* * * * *

(d) Except as provided in paragraph (a) of this section for certain computers, for all other countries not included in paragraph (b) of this section the following reexports are *not* subject to the EAR:

* * * * *

18. Section 734.8 is amended:

a. By revising the citation reference ''§ 732.10'' to read ''§ 734.11(b)'' in paragraph (a);

b. By revising the citation reference ''§ 732.11'' to read ''§ 734.11'' in paragraph (b)(6); and

c. By revising the citation reference ''§ 734.11'' to read ''§ 734.11(b)'' in paragraph (d)(1).

19. Supplement No. 1 to part 734 is amended:

a. By revising the citation reference ''§ 734.7(d)'' to read ''§ 734.7(a)'' in the ''Answer'' to ''Question B(1)'';

b. By revising the citation reference ''§ 734.7(d)(4)(ii)'' to read ''§ 734.7(a)(4)(ii)'' in the ''Answer'' to ''Question B(3)'';

c. By revising the citation reference ''§ 734.7(d)(4)(iii)'' to read ''§ 734.7(a)(4)(iii)'' in the ''Answer'' to ''Question B(5)''; and

d. By revising the citation reference ''§ 734.7(d)'' to read ''§ 734.7(a)'' in the ''Answer'' to ''Question C(6)''.

20. Supplement No. 2 to part 734 is amended:

a. By revising paragraph (a)(1)(ii);

b. By adding a ''Note'' immediately following paragraph (a)(4), and

c. By revising paragraph (b)(3), as follows:

Supplement No. 2 to Part 734—Calculation of Values for De Minimis Rules

(a) * * *

(1) * * *

(ii) In calculating the U.S. content value, do not include parts, components, or materials that could be exported from the United States to the new country of destination without a license (designated as ''NLR'') or under License Exception GBS (see part 740 of the EAR) or under NLR for items classified as EAR99.

* * * * *

(4) * * *

Note to paragraph (a)—U.S. origin peripheral or accessory devices that are merely rack mounted with or cable connected into foreign equipment are not deemed to be incorporated components even though intended for use with products made abroad. Rather, such items are treated as U.S. items that retain their identity and remain subject to the EAR.

(b) * * *

(3) *Future software sales.* For calculations of U.S.-content in foreign software, you shall include your historic and estimated future software sales in units and value along with the rationale and basis for those estimates in the report. Unlike parts incorporated into commodities, the cost of U.S. software code will be attributed or allocated to the future sales of foreign-made software incorporating the U.S. code, to determine the percentage of U.S. controlled content. In making this calculation for foreign-made software, you must make an estimate of future software sales of that foreign software if it is commingled with or incorporated with the U.S. code. The value of the U.S. code commingled with or incorporated into the foreign made software shall be divided by the total selling price of all foreign-made software units already sold, plus the total selling price of all foreign-made software units estimated for future sales.

* * * * *

PART 736—[AMENDED]

21. Section 736.2 is amended, as follows:

a. By revising paragraph (b)(2)(ii);

b. By revising paragraph (b)(6)(ii); and

c. By revising paragraph (b)(8)(i).

§ 736.2 General prohibitions and determination of applicability.

* * * * *

(b) * * *

(2) * * *

(ii) Each License Exception described in part 740 of the EAR supersedes General Prohibition Two if all terms and conditions of a given License Exception are met by the exporter or reexporter.

* * * * *

(6) * * *

(ii) License Exceptions to General Prohibition Six are described in part 746 of the EAR, on Embargoes and Other Special Controls. Unless a License Exception or other authorization is authorized in part 746 of the EAR, the License Exceptions described in part 740 of the EAR are not available to overcome this general prohibition.

* * * * *

(8) * * *

(i) *Unlading and shipping in transit.* You may not export or reexport an item through or transit through a country listed in paragraph (b)(8)(ii) of this section unless a License Exception or license authorizes such an export or reexport directly to such a country of transit.

* * * * *

PART 738—[AMENDED]

22. Section 738.2 is amended:

a. By adding a new paragraph (d)(1)(iii); and

b. By adding the entry ''SI Significant Items'' following ''XP Computers'' in paragraph (d)(2)(i)(A)

c. By revising paragraph (d)(2)(ii), as follows:

§ 738.2 Commerce Control List (CCL) structure.

* * * * *

(d) * * *

(1) * * *

(iii) The last digit within each entry (e.g., 3A001) is used for the sequential numbering of ECCNs to differentiate between entries on the CCL.

(2) * * *

(ii) *License Exceptions.* This section provides a brief eligibility statement for each ECCN-driven License Exception that may be applicable to your transaction, and should be consulted only AFTER you have determined a license is required based on an analysis of the entry and the Country Chart. The brief eligibility statement in this section is provided to assist you in deciding which ECCN-driven License Exception related to your particular item and destination you should explore prior to submitting an application. The term ''Yes'' (followed in some instances by the scope of Yes) appears next to each available ECCN-driven License Exception. The term ''N/A'' will be noted for License Exceptions that are not available within a particular entry.

If one or more License Exceptions appear to apply to your transaction, you must consult part 740 of the EAR to review the conditions and restrictions applicable to each available License Exception. The list of License Exceptions contained within each ECCN is not an all-exclusive list. Other License Exceptions, not based on particular ECCNs, may be available. Consult part 740 of the EAR to determine eligibility for non-ECCN-driven License Exceptions.

* * * * *

PART 740—[AMENDED]

23. Section 740.1 is amended:

a. By revising paragraph (a);

b. By revising the citation reference ''§ 732.6'' to read ''§ 736.2'' in paragraph (d)(2). [two revisions]; and

c. By revising paragraph (e) to read as follows:

§ 740.1 Introduction.

* * * * *

(a) *Scope.* A ''License Exception'' is an authorization contained in this part that allows you to export or reexport under stated conditions, items subject to the Export Administration Regulations (EAR) that would otherwise require a license under General Prohibition One, Two, or Three, as indicated under one or more of the Export Control Classification Numbers (ECCNs) in the Commerce Control List (CCL) in Supplement No. 1 to part 774 of the EAR. If your export or reexport is subject to General Prohibitions Six for embargoed destinations, refer to part 746 of the EAR to determine the availability of any License Exceptions. Special commodity controls apply to short supply items. License Exceptions for items listed on the CCL as controlled for Short Supply reasons are found in part 754 of the EAR. If your export or reexport is subject to General Prohibition Five, consult part 744 of the EAR. If your export or reexport is subject to General Prohibitions Four, Seven, Eight, Nine, or Ten, then no License Exceptions apply.

* * * * *

(e) *Destination Control Statement.* You may be required to enter an appropriate Destination Control Statement on commercial documents in accordance with Destination Control Statement requirements of § 758.5 and § 758.6 of the EAR.

* * * * *

24. Section 740.2 is amended by revising paragraph (a) to read as follows:

§ 740.2 Restrictions on all License Exceptions.

(a) You may not use *any* License Exception if any one or more of the following apply:

(1) Your authorization to use a License Exception has been suspended or revoked, or your intended export does not qualify for a License Exception.

(2) The export or reexport is subject to one of the ten General Prohibitions, is not eligible for a License Exception, and has not been authorized by BXA.

(3) The item is for surreptitious interception of wire or oral communications, controlled under ECCN 5A980, unless you are a U.S. Government agency (see § 740.11(b)(2)(ii) of this part, Governments (GOV)).

(4) The commodity you are shipping is a specially designed crime control and detection instrument or equipment described in § 742.7 of the EAR and you are not shipping to Iceland, New Zealand, or countries listed in Country Group A:1 (see Supplement No. 1 to part 740), unless the shipment is authorized under License Exception BAG, § 740.14(e) of this part (shotguns and shotgun shells).

* * * * *

25. Section 740.4 is revised to read as follows:

§ 740.4 Shipments to Country Group B countries (GBS).

License Exception GBS authorizes exports and reexports to Country Group B (see Supplement No. 1 to part 740) of those commodities controlled to the ultimate destination for national security reasons and identified by ''GBS—Yes'' on the CCL. License Exception GBS may be used to export or reexport to eligible countries any commodity (but not software) eligible for License Exception CIV.

26. Section 740.9 is amended:

a. By revising the last two sentences of paragraph (a)(2)(i);

b. By revising paragraph (a)(2)(iv);

c. By revising paragraph (a)(2)(viii)(A) introductory text;

d. By revising paragraph (b)(1)(ii); and

e. By revising paragraph (b)(2)(ii)(B), as follows:

§ 740.9 Temporary imports, exports, and reexports (TMP).

* * * * *

(a) * * *

(2) * * *

(i) *Tools of trade.* * * * No tools of trade may be taken to Country Group E:2 and Sudan, only the equipment necessary to commission or service goods may be taken as tools of trade to Country Group D:1. (See Supplement No. 1 to part 740.)

* * * * *

(iv) *Inspection and calibration.* Commodities to be inspected, tested, calibrated or repaired abroad may be exported or reexported to all destinations under this section, except Country Group E:2, Sudan or Syria.

* * * * *

(viii) *News media.* (A) Commodities necessary for news-gathering purposes (and software necessary to use such commodities) may accompany ''accredited'' news media personnel (i.e., persons with credentials from a news gathering or reporting firm) to Country Groups D:1 or E:2, or Sudan (see Supplement No. 1 to part 740) if the commodities:

* * * * *

(b) * * *

(1) * * *

(ii) Items may not be exported to Country Group E:2 or Sudan under this section.

* * * * *

(2) * * *

(ii) * * *

(B) Exports to Country Group E:2 or Sudan (see Supplement No. 1 to part 740); or

* * * * *

27. Section 740.11 is amended by revising paragraphs (b)(2)(iii) and (b)(2)(iv) to read as follows:

§ 740.11 Governments and international organizations (GOV).

* * * * *

(b) * * *

(2) * * *

(iii) *Items for official use within national territory by agencies of cooperating governments.* This provision is available for all items consigned to and for the official use of any agency of a cooperating government within the territory of any cooperating government, except:

(A) Commercial communications satellites controlled under 9A004 and hot section technology for the development, production or overhaul of commercial aircraft engines controlled under 9E003.a.1 through a.12, and .f, and related controls;

(B) Computers with a CTP greater than 10,000 MTOPS when destined for Argentina, Hong Kong, South Korea, Singapore or Taiwan;

(C) Items identified on the Commerce Control List as controlled for missile technology (MT), chemical and biological warfare (CB), or nuclear nonproliferation (NP) reasons;

(D) Regional stability items controlled under Export Control Classification

Numbers (ECCNs) 6A002, 6A003, 6D102, 6E001, 6E002, 7D001, 7E001, 7E002, and 7E101 as described in § 742.6(a)(1) of the EAR; or

(E) Encryption items controlled for EI reasons as described in the Commerce Control List.

(iv) *Diplomatic and consular missions of a cooperating government.* This provision is available for all items consigned to and for the official use of a diplomatic or consular mission of a cooperating government located in any country in Country Group B (see Supplement No. 1 to part 740), except:

(A) Commercial communications satellites controlled under 9A004 and hot section technology for the development, production or overhaul of commercial aircraft engines controlled under 9E003.a.1 through a.12, and .f, and related controls;

(B) Computers with a CTP greater than 10,000 MTOPS when destined for Argentina, Hong Kong, South Korea, Singapore or Taiwan;

(C) Items identified on the Commerce Control List as controlled for missile technology (MT), chemical and biological warfare (CB), or nuclear nonproliferation (NP) reasons;

(D) Regional stability items controlled under Export Control Classification Numbers (ECCNs) 6A002, 6A003, 6D102, 6E001, 6E002, 7D001, 7E001, 7E002, and 7E101 as described in § 742.6(a)(1) of the EAR; or

(E) Encryption items controlled for EI reasons as described in the Commerce Control List.

* * * * *

28. Section 740.12(b)(1) is amended by revising the phrase ''exports by groups'' to read ''exports or reexports by groups''.

29. Section 740.13 is amended by revising paragraph (d)(3)(i) to read as follows:

§ 740.13 Technology and software—unrestricted (TSU).

* * * * *

(d) * * *

(3) * * *

(i) *Destinations.* ''Mass market'' software is available to all destinations except Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria.

* * * * *

30. Section 740.14 is amended:

a. By revising paragraph (a);

b. By revising the introductory text to paragraph (b); and

c. By revising the last two sentences of paragraph (d) to read as follows:

§ 740.14 Baggage (BAG).

(a) *Scope.* This License Exception authorizes individuals leaving the United States and crew members of exporting or reexporting carriers to take to any destination, as personal baggage, the classes of commodities and software described in this section.

(b) *Eligibility.* Individuals leaving the United States may export or reexport any of the following commodities or software to any destination or series of destinations. Crew members may export or reexport only commodities and software described in paragraphs (b)(1) and (b)(2) of this section to any destination.

* * * * *

(d) *Special provision: unaccompanied baggage.* * * * However, commodities controlled for CB, MT, NS, or NP may not be exported under this License Exception to Country Groups D:1, D:2, D:3, D:4, E:2, or Sudan. (See Supplement No. 1 to part 740.)

* * * * *

31. Section 740.16 is amended:

a. By revising paragraph (a)(2);

b. By revising paragraph (a)(3)(ii); and

c. By adding a new paragraph (j), as follows:

§ 740.16 Additional permissive reexports (APR).

* * * * *

(a) * * *

(2) The commodities being reexported are not controlled for NP, CB, MT, SI, or CC reasons; and

(3) * * *

(ii) A country in Country Group D:1 (National Security) (see Supplement No. 1 to part 740), other than Cambodia or Laos, and the commodity being reexported is controlled for national security reasons.

* * * * *

(j) Reexports of items controlled by NP Column 1 (see Supplement No. 1 to part 774 of the EAR) to, among, and from countries described in Country Group A:4 (see Supplement No. 1 to part 740), except:

(1) Reexports from countries that are not identified in Country Group A:1 of items that are controlled for NS reasons to destinations in Country Group D:1; and

(2) Reexports to destinations in Country Group E:2 and Country Group D:2.

32. Supplement No. 1 to part 740 is amended:

a. In Country Group B to add ''Rwanda'' and ''Serbia and Montengro'' in alphabetical order;

b. In Country Group D by removing the reference under the ''Country'' heading for ''South Africa'' and by removing the corresponding ''x'' under the heading ''[D:3] Chemical & Biological''; and

c. In Country Group E by removing the reference under the ''Country'' heading for ''Serbia and Montengro'' and by removing the corresponding ''x'' under the heading ''UN Embargo''.

PART 742—[AMENDED]

33. Section 742.1 is amended:

a. By revising the phrase ''maintains controls under EAA section 6(j) of the EAA'' to read ''maintains controls under section 6(j) of the EAA'' in the third sentence of paragraph (d); and

b. By revising the citation reference ''§ 742.3(b)(3)'' to read ''§ 742.2(b)(3)'' in paragraph (f).

34. Section 742.2 is amended:

a. By revising paragraph (a)(1)(ii);

b. By revising paragraph (a)(2)(iii) introductory text;

c. By revising paragraph (a)(3)(ii); and

d. By revising the phrase ''individual license applications:'' to read ''license applications:'' in paragraph (b)(2), as follows:

§ 742.2 Proliferation of chemical and biological weapons.

(a) * * *

(1) * * *

(ii) Technology (ECCNs 1E001 and 1E391) for the production and/or disposal of microbiological commodities described in paragraph (a)(1)(i) of this section.

(2) * * *

(iii) Technology (ECCNs 1E001 and 1E391) for the production and/or disposal of chemical precursors described in ECCN 1C350, and technology (ECCNs 1E001 and 1E350) involving the following for facilities designed or intended to produce chemicals described in 1C350:

* * * * *

(3) * * *

(ii) Technology (ECCNs 2E001, 2E002 and 2E301) for development, production, or use of the commodities covered in ECCNs 2B350, 2B351 and 2B352.

* * * * *

35. Section 742.7 is amended:

a. By revising paragraph (a)(1);

b. By revising paragraph (a)(2); and

c. By revising paragraph (a)(3) to read as follows:

§ 742.7 Crime Control.

(a) * * *

(1) Crime control and detection instruments and equipment and related technology and software identified in the appropriate ECCNs on the CCL under CC Column 1 in the Country Chart column of the ''License Requirements'' section. A license is required to countries listed in CC

Column 1 (Supplement No. 1 to part 738 of the EAR). Items affected by this requirement are identified on the CCL under the following ECCNs: 0A982, 0A983, 0A984, 0A985, 0E984, 1A984, 3A980, 3A981, 3D980, 3E980, 4A003 (for fingerprint computers only), 4A980, 4D001 (for fingerprint computers only), 4D980, 4E001 (for fingerprint computers only), 4E980, 6A002 (for police-model infrared viewers only), 6E001 (for police-model infrared viewers only), and 9A980.

(2) Shotguns with a barrel length greater than or equal to 24 inches, identified in ECCN 0A984 on the CCL under CC Column 2 in the Country Chart column of the ''License Requirements'' section regardless of end-user to countries listed in CC Column 2 (Supplement No. 1 part 738 of the EAR).

(3) Shotguns with a barrel length greater than or equal to 24 inches, identified in ECCN 0A984 on the CCL under CC Column 3 in the Country Chart column of the ''License Requirements'' section only if for sale or resale to police or law enforcement entities in countries listed in CC Column 3 (Supplement No. 1 part 738 of the EAR).

* * * * *

36. Section 742.9 is amended by revising paragraph (b)(1)(iv) to read as follows:

§ 742.9 Anti-terrorism: Syria.

(b) * * *

(1) * * *

(iv) All aircraft (powered and unpowered), helicopters, engines, and related spare parts and components. These are items controlled to any destination for national security reasons and items controlled to Syria for anti-terrorism purposes. Such items contain an NS Column 1, NS Column 2, or AT Column 1 in the Country Chart column of the ''License Requirements'' section of an ECCN on the CCL. Note that, consistent with the general rule that applies to computing U.S. parts and components content incorporated in foreign made products, all aircraft-related items that require a license to Syria will be included as controlled U.S. content, except for ECCNs 6A990, 7A994, and 9A994, for purposes of such licensing requirements.

* * * * *

37. Supplement No. 1 to part 742 is amended:

a. By revising paragraph (9)(ii); and

b. By revising paragraph (9)(iii), to read as follows:

Supplement No. 1 to Part 742—Nonproliferation of Chemical and Biological Weapons

* * * * *

(9) * * *

(ii) Equipment and materials (for producing biological agents) described in ECCNs 1C351, 1C352, 1C353, 1C354, and 2B352; and

(iii) Technology (for the development, production, and use of equipment described in ECCNs 1C351, 1C352, 1C353, 1C354, 2B350, 2B351, and 2B352) described in ECCNs 2E001, 2E002, and 2E301.

* * * * *

PART 744—[AMENDED]

38. Section 744.2 is amended by revising the citation reference ''§ 740.12(a) and (b)'' to read ''§ 740.13(a) and (b)'' (2 revisions), in paragraph (c).

39. Section 744.3 is amended by removing the phrase ''to any destination, including Canada,'' in paragraph (a).

40. Section 744.4 is amended by removing the phrase ''to any destination, including Canada,'' in paragraph (a).

41. Section 744.5 is amended by removing the phrase ''to any destination, including Canada,'' in paragraph (a).

42. Section 744.6 is amended:

a. By revising paragraph (a)(1)(i); introductory text and

b. By revising paragraph (e), as follows:

§ 744.6 Restrictions on certain activities of U.S. persons.

(a) * * *

(1) * * *

(i) No U.S. person as defined in paragraph (c) of this section may, without a license from BXA, export, reexport, or transfer to or in any country any item where that person knows that such items:

* * * * *

(e) *License review standards.* Applications to engage in activities otherwise prohibited by this section will be denied if the activities would make a material contribution to the design, development, production, stockpiling, or use of nuclear explosive devices, chemical or biological weapons, or of missiles.

43. Supplement No. 1 to part 744 is removed and reserved.

44. Supplement No. 3 to part 744 is amended by adding the country ''Canada'' in alphabetical order.

PART 746—[AMENDED]

45. Section 746.1 is amended:

a. By revising the introductory paragraph;

b. By revising paragraph (b); and

c. By revising the first sentence of paragraph (c), as follows:

§ 746.1 Introduction.

In this part, references to the EAR are references to 15 CFR chapter VII, subchapter C. This part implements broad based controls for items and activities subject to the EAR imposed to implement U.S. government policies. Two categories of controls are included in this part.

* * * * *

(b) *Rwanda.* The second category of controls that apply to Rwanda are supplemental to the controls described in the Country Chart in part 738 of the EAR. Such controls are listed under each affected ECCN on the CCL in part 774 of the EAR.

(c) This part also contains descriptions of controls maintained by the Office of Foreign Assets Control in the Treasury Department and by the Office of Defense Trade Controls in the Department of State. * * *

* * * * *

46. Section 746.2 is amended, as follows:

a. By revising paragraph (a)(1); and

b. By revising the phrase ''Supplement No. 3 to part 734'' to read ''Supplement No. 2 to part 734'' in paragraph (b)(3)(ii).

§ 746.2 Cuba.

(a) * * *

(1) *License Exceptions.* You may export or reexport without a license if your transaction meets all the applicable terms and conditions of any of the following License Exceptions. To determine the scope and eligibility requirements, you will need to turn to the sections or specific paragraphs of part 740 of the EAR (License Exceptions). Read each License Exception carefully, as the provisions available for embargoed countries are generally narrow.

(i) Temporary exports and reexports (TMP) by the news media (see § 740.9(a)(2)(viii) of the EAR).

(ii) Operation technology and software (TSU) for legally exported commodities (see § 740.13(a) of the EAR).

(iii) Sales technology (TSU) (see § 740.13(b) of the EAR).

(iv) Software updates (TSU) for legally exported software (see § 740.13(c) of the EAR).

(v) Parts (RPL) for one-for-one replacement in certain legally exported commodities (see § 740.10(a) of the EAR).

(vi) Baggage (BAG) (see § 740.14 of the EAR).

(vii) Governments and international organizations (GOV) (see § 740.11 of the EAR).

(viii) Gift parcels and humanitarian donations (GFT) (see § 740.12 of the EAR).

(ix) Items in transit (TMP) from Canada through the U.S. (see § 740.9(b)(1)(iv) of the EAR).

(x) Aircraft and vessels (AVS) for certain aircraft on temporary sojourn (see § 740.15(a) of the EAR).

(xi) Permissive reexports of certain spare parts in foreign-made equipment (see § 740.16(h) of the EAR).

* * * * *

47. Section 746.3 is amended by revising paragraph (a)(1) to read as follows:

§ 746.3 Iraq.

(a) * * *

(1) *License Exceptions.* You may export or reexport without a license if your transaction meets all the applicable terms and conditions of one of the following License Exceptions. Read each License Exception carefully, as the provisions available for embargoed countries are generally narrow.

(i) Baggage (BAG) (see § 740.14 of the EAR).

(ii) Governments and international organizations (GOV) (see § 740.11 of the EAR).

* * * * *

48. Section 746.4 is amended:

a. By revising paragraph (b);

b. By revising paragraph (c)(3) introductory text;

c. By redesignating paragraph (e) as paragraph (d); and

d. By redesignating paragraph (f) as paragraph (e), as follows:

§ 746.4 Libya.

* * * * *

(b) *License requirements.*

(1) *Exports.* OFAC and BXA both require a license for virtually all exports (including transshipments) to Libya. Except as noted in paragraph (b) of this section or specified in OFAC regulation, you may not use any BXA License Exception or other BXA authorization to export or transship to Libya. You will need a license from OFAC for all direct exports and transshipments to Libya except those eligible for the following BXA License Exceptions:

(i) Baggage (BAG) (see § 740.14 of the EAR).

(ii) Governments and international organizations (GOV) (see § 740.11 of the EAR).

(iii) Gift parcels (GFT) (see § 740.12(a) of the EAR).

(2) *Reexports.* You will need a license from BXA to reexport any U.S.-origin item from a third country to Libya, any foreign-manufactured item containing U.S.-origin parts, components or materials, as defined in § 734.2(b)(2) of the EAR, or any national security-controlled foreign-produced direct product of U.S. technology or software, as defined in § 734.2(b)(3) of the EAR, exported from the U.S. after March 12, 1982. You will need a license from BXA to reexport all items subject to the EAR (see part 734 of the EAR) to Libya, except:

(i) Food, medicines, medical supplies, and agricultural commodities;

(ii) Reexports eligible for the following License Exceptions (read each License Exception carefully, as the provisions available for embargoed countries are generally narrow):

(A) Temporary exports and reexports (TMP): reexports by the news media (see § 740.9(a)(2)(viii) of the EAR).

(B) Operation technology and software (TSU) for legally exported commodities (see § 740.13(a) of the EAR).

(C) Sales technology (TSU) (see § 740.13(b) of the EAR).

(D) Software updates (TSU) for legally exported software (see § 740.13(c) of the EAR).

(E) Parts (RPL) for one-for-one replacement in certain legally exported commodities (§ 740.10(a) of the EAR).

(F) Baggage (BAG) (§ 740.14 of the EAR).

(G) Aircraft and vessels (AVS) for vessels only (see § 740.15(c)(1) of the EAR).

(H) Governments and international organizations (GOV) (see § 740.11 of the EAR).

(I) Gift parcels and humanitarian donations (GFT) (see § 740.12 of the EAR).

(J) Permissive reexports of certain spare parts in foreign-made equipment (see § 740.16(h) of the EAR).

(c) * * *

(3) Notwithstanding the presumptions of denial in paragraphs (c)(2) (i) through (iii) of this section, licenses will generally be issued for items not included in paragraphs (c)(2) (iv) through (vii) of this section when the transaction involves:

* * * * *

49. Section 746.5 is amended by revising paragraphs (a)(1) and (b)(1) to read as follows:

§ 746.5 North Korea.

(a) * * *

(1) *License Exceptions.* You may export without a license if your transaction meets all the applicable terms and conditions of any of the License Exceptions specified in this paragraph. To determine scope and eligibility requirements, you will need to turn to the sections or specific paragraphs of part 740 of the EAR (License Exceptions). Read each License Exception carefully, as the provisions available for embargoed countries are generally narrow.

(i) Temporary exports and reexports (TMP) by the news media (see § 740.9(a)(2)(viii) of the EAR).

(ii) Operation technology and software (TSU) for legally exported commodities (see § 740.13(a) of the EAR).

(iii) Sales technology (TSU) (see § 740.13(b) of the EAR).

(iv) Software updates (TSU) for legally exported software (see § 740.13(c) of the EAR).

(v) Parts (RPL) for one-for-one replacement in certain legally exported commodities (§ 740.10(a) of the EAR).

(vi) Baggage (BAG) (§ 740.14 of the EAR).

(vii) Aircraft and vessels (AVS) for fishing vessels under governing international fishery agreements and foreign-registered aircraft on temporary sojourn in the U.S.[1] (see § 740.15(a) and (b)(1) of the EAR).

(viii) Governments and international organizations (GOV) (see § 740.11 of the EAR).

(ix) Gift parcels and humanitarian donations (GFT) (see § 740.12 of the EAR).

(x) Permissive reexports of certain spare parts in foreign-made equipment (see § 740.16(h) of the EAR).

* * * * *

(b) *Licensing policy.* * * *

(1) BXA will review on a case-by-case basis applications for export of donated human-needs items listed in Supplement No. 2 to part 740 of the EAR that do not qualify for the humanitarian donation provisions of License Exception GFT (see § 740.12(b) of the EAR). Such applications include single transactions involving exports to meet emergency needs.

* * * * *

PART 748—[AMENDED]

50. Section 748.3 is amended:

a. By revising the phrase ''limited to 5 items'' to read ''limited to six items'' in paragraph (b)(1); and

b. By revising paragraph (b)(2), as follows:

[1] Export of U.S. aircraft on temporary sojourn or vessels is prohibited, 44 CFR Ch. IV, Part 403 ''Shipping restrictions: North Korea (T–2).''

§ 748.3 Classification and Advisory Opinions.

* * * * *

(b) * * *

(2) When submitting a Classification Request, you must complete Blocks 1 through 5, 14, 22(a), (b), (c), (d), and (i), 24, and 25 on Form BXA–748P. You must provide a recommended classification in Block 22(a) and explain the basis for your recommendation based on the technical parameters specified in the appropriate ECCN in Block 24. If you are unable to determine a recommended classification for your item, include an explanation in Block 24, identifying the ambiguities or deficiencies that precluded you from making a recommended classification.

* * * * *

51. Section 748.9 is amended:

a. By adding a new paragraph (a)(7);

b. By revising paragraph (b)(1)(ii);

c. By revising paragraph (b)(2)(ii); and

d. By revising paragraph (c)(2).

§ 748.9 Support documents for license applications.

(a) * * *

(7) The license application is submitted to export or reexport software or technology, except for software or technology subject to national security controls destined for Bulgaria, Czech Republic, Hungary, Poland, Romania, or Slovakia.

(b) * * *

(1) * * *

(ii) If no, your transaction may require a Statement by Ultimate Consignee and Purchaser. Read the remainder of this section beginning with paragraph (c) of this section, then proceed to § 748.11 of the EAR.

(2) * * *

(ii) If no, your transaction may require a Statement by Ultimate Consignee and Purchaser. Read the remainder of this section beginning with paragraph (c) of this section, then proceed to § 748.11 of the EAR.

(c) * * *

(2) *License applications supported by Ultimate Consignee and Purchaser statements*. These types of license applications may be submitted upon receipt of a facsimile or other legible copy of the original statement provided that the applicant receives the manually-signed original within 60 days from the date the original is signed by the ultimate consignee.

* * * * *

52. Section 748.10 is amended:

a. By revising paragraph (b)(1); and

b: By revising paragraph (b)(3) introductory text, as follows:

§ 748.10 Import and End-User Certificates.

* * * * *

(b) * * *

(1) Any commodities on your license application are controlled for national security (NS) reasons, or you have software or technology that is controlled for NS reasons and is destined for Bulgaria, Czech Republic, Hungary, Poland, Romania, or Slovakia.

(2) * * *

(3) Your license application involves the export of commodities and software classified in a single entry on the CCL, the total value of which exceeds $5,000.

* * * * *

53. Section 748.11 is amended by revising paragraph (e)(1)(ii) to read as follows:

§ 748.11 Statement by Ultimate Consignee and Purchaser.

* * * * *

(e) * * *

(1) * * *

(ii) *Multiple*. This statement is to be considered a part of every license application submitted by [name and address of applicant] until two years from the date this statement is signed.

* * * * *

54. Section 748.12 is amended by revising paragraph (b) to read as follows:

§ 748.12 Special provisions for support documents.

* * * * *

(b) *Reexports*. If a support document would be required for an export from the United States, the same document would be required for reexport to Country Group D:1 and E:2 (see Supplement No. 1 to part 740 of the EAR).

* * * * *

55. Section 748.13 is amended by revising the first sentence of paragraph (a)(1) to read as follows:

§ 748.13 Delivery Verification (DV).

(a) * * *

(1) BXA may request the licensee to obtain verifications of delivery on a selective basis. * * *

* * * * *

56. Supplement No. 1 to part 748 is amended:

a. By revising the introductory text;

b. By revising Block 5;

c. By revising the heading of Block 6;

d. By revising the phrase ''box'' to read ''Block'' in Block 9;

e. By revising Block 10;

f. By revising Block 11;

g. By revising Block 14;

h. By revising Blocks 16 through 21;

i. By revising the introductory text and paragraphs (b) through (f) of Block 22;

j. By revising Block 24; and

k. By revising Block 25, as follows:

Supplement No. 1 to Part 748—BXA–748P, BXA–748P–A; Item Appendix, and BXA–748P–B; End-User Appendix; Multipurpose Application Instructions

All information must be legibly typed within the lines for each Block or Box, except where a signature is required. Enter only one typed line of text per Block or line. Where there is a choice of entering telephone numbers or facsimile numbers, and you wish to provide a facsimile number instead of a telephone number, identify the facsimile number with the letter ''F'' immediately after the number (e.g., 022–358–0–123456F). If you are completing this form to request classification of your item, you must complete Blocks 1 through 5, 14, 22(a), (b), (c), (d), and (i), 24, and 25 only.

* * * * *

Block 5: Type of Application. *Export*. If the items are located within the United States, and you wish to export those items, mark the Box labeled ''Export'' with an (X). *Reexport*. If the items are located outside the United States, mark the Box labeled ''Reexport'' with an (X). *Classification*. If you are requesting BXA to classify your item against the Commerce Control List (CCL), mark the Box labeled ''Classification Request'' with an (X). *Special Comprehensive License*. If you are submitting a Special Comprehensive License application in accordance with the procedures described in part 752 of the EAR, mark the Box labeled ''Special Comprehensive License'' with an (X).

Block 6: Documents submitted with Application. * * *

* * * * *

Block 10: Resubmission Application Control Number. If your original application was returned without action (RWA), provide the Application Control Number. This does not apply to applications returned without being registered.

Block 11: Replacement License Number. If you have received a license for identical items to the same ultimate consignee, but would like to make a modification that is not excepted in § 750.7(c) of the EAR, to the license as originally approved, enter the original license number and complete Blocks 12 through 25, where applicable. Include a statement in Block 24 regarding what changes you wish to make to the original license.

* * * * *

Block 14: Applicant. Enter the applicant's name, street address, city, state/country, and postal code. Provide a complete street address. P.O. Boxes are not acceptable. Refer to § 748.5(a) of this part for a definition of ''applicant''. If you have marked ''Export'' in Block 5, you must include your company's Employer Identification Number unless you are filing as an individual or as an agent on behalf of the exporter. The Employee Identification Number is assigned by the Internal Revenue Service for tax identification purposes. Accordingly, you should consult your company's financial officer or accounting division to obtain this number.

Block 15: * * *

Block 16: Purchaser. Enter the purchaser's complete name, street address, city, country,

postal code, and telephone or facsimile number. Refer to § 748.5(c) of this part for a definition of ''purchaser''. If the purchaser is also the ultimate consignee, enter the complete name and address. If your proposed transaction does not involve a separate purchaser, leave Block 16 blank.

Block 17: Intermediate consignee. Enter the intermediate consignee's complete name, street address, city, country, postal code, and telephone or facsimile number. Provide a complete street address, P.O. Boxes are not acceptable. Refer to § 748.5(d) of this part for a definition of ''intermediate consignee''. If this party is identical to that listed in Block 16, enter the complete name and address. If your proposed transaction does not involve use of an intermediate consignee, enter ''None''. If your proposed transaction involves more than one intermediate consignee, provide the same information in Block 24 for each additional intermediate consignee.

Block 18: Ultimate Consignee. This Block must be completed if you are submitting a license application. Enter the ultimate consignee's complete name, street address, city, country, postal code, and telephone or facsimile number. Provide a complete street address, P.O. Boxes are not acceptable. The ultimate consignee is the party who will actually receive the item for the end-use designated in Block 21. Refer to § 748.5(e) of this part for a definition of ''ultimate consignee''. A bank, freight forwarder, forwarding agent, or other intermediary may not be identified as the ultimate consignee. Government purchasing organizations are the sole exception to this requirement. This type of entity may be identified as the government entity that is the actual ultimate consignee in those instances when the items are to be transferred to the government entity that is the actual end-user, provided the actual end-user and end-use is clearly identified in Block 21 or in the additional documentation attached to the application.

If your application is for the reexport of items previously exported, enter the new ultimate consignee's complete name, street address, city, country, postal code, and telephone or facsimile number. Provide a complete street address, P.O. Boxes are not acceptable. If your application involves a temporary export or reexport, the applicant should be shown as the ultimate consignee in care of a person or entity who will have control over the items abroad.

Block 19: End-User. Complete this Block only if the ultimate consignee identified in Block 18 is not the actual end-user. If there will be more than one end-user, use Form BXA–748P–B to identify each additional end-user. Enter each end-user's complete name, street address, city, country, postal code, and telephone or facsimile number. Provide a complete street address, P.O. Boxes are not acceptable.

Block 20: Original Ultimate Consignee. If your application involves the reexport of items previously exported, enter the original ultimate consignee's complete name, street address, city, country, postal code, and telephone or facsimile number. Provide a complete street address, P.O. Boxes are not acceptable. The original ultimate consignee is the entity identified in the original application for export as the ultimate consignee or the party currently in possession of the items.

Block 21. Specific End-Use: This Block must be completed if you are submitting a license application. Provide a complete and detailed description of the end-use intended by the ultimate consignee and/or end-user(s). If you are requesting approval of a reexport, provide a complete and detailed description of the end-use intended by the new ultimate consignee or end-user(s) and indicate any other countries for which resale or reexport is requested. If additional space is necessary, use Block 21 on Form BXA–748P–A or B. Be specific—vague descriptions such as ''research'', ''manufacturing'', or ''scientific uses'' are not acceptable.

Block 22: For a license application, you must complete each of the sub-blocks contained in this Block. If you are submitting a classification request, you need not complete Blocks (e), (f), (g), and (h). If you wish to export, reexport, or have BXA classify more than one item, use Form BXA–748P–A for additional items.

(a) * * *

(b) CTP. You must complete this Block only if your application involves a digital computer or equipment containing a digital computer as described in Supplement No. 2 to this part. Instructions on calculating the CTP are contained in a Technical Note at the end of Category 4 in the CCL.

(c) Model Number. Enter the correct model number for the item.

(d) CCATS Number. If you have received a classification for this item from BXA, provide the CCATS number shown on the classification issued by BXA.

(e) Quantity. Identify the quantity to be exported or reexported, in terms of the ''Unit'' identified for the ECCN entered in Block 22(a). If the ''Unit'' for an item is ''$ value'', enter the quantity in units commonly used in the trade.

(f) Units. The ''Unit'' paragraph within each ECCN will list a specific ''Unit'' for those items controlled by the entry. The ''Unit'' must be entered on all license applications submitted to BXA. If an item is licensed in terms of ''$ value'', the unit of quantity commonly used in the trade must also be shown on the license application. This Block may be left blank on license applications only if the ''Unit'' for the ECCN entered in Block 22(a) is shown as ''N/A'' on the CCL.

* * * * *

Block 24: Additional Information. Enter additional data pertinent to the application as required in the EAR. Include special certifications, names of parties of interest not disclosed elsewhere, explanation of documents attached, etc. Do not include information concerning Block 22 in this space.

If your application represents a previously denied application, you must provide the Application Control Number from the original application.

If you are requesting BXA to classify your product, use this space to explain why you believe the ECCN entered in Block 22(a) is appropriate. This explanation must contain an analysis of the item in terms of the technical control parameters specified in the appropriate ECCN. If you have not identified a recommended classification in Block 22(a), you must state the reason you cannot determine the appropriate classification, identifying anything in the regulations that you believe precluded you from determining the correct classification.

If additional space is necessary, use Block 24 on Form BXA–748P–A or B.

Block 25: You, as the applicant or duly authorized agent of the applicant, must manually sign in this Block. Rubber-stamped or electronic signatures are not acceptable. If you are an agent of the applicant, in addition to providing your name and title in this Block, you must enter your company's name in Block 24. Type both your name and title in the space provided.

57. Supplement No. 2 to part 748 is amended:

a. By revising the introductory text of paragraph (d) and the NOTE following it;

b. By revising the introductory text of paragraph (e);

c. By revising the introductory text of paragraph (g)(1);

d. By revising paragraph (g)(2)(i);

e. By revising paragraph (o)(3)(i); and

f. By revising the introductory text of paragraph (p), as follows:

Supplement No. 2 to Part 748—Unique License Application Requirements

* * * * *

(d) *Gift parcels; consolidated in a single shipment.* If you are submitting a license application to export multiple gift parcels for delivery to individuals residing in a foreign country, you must include the following information in your license application.

Note: Each gift parcel must meet the terms and conditions described for *gift parcels* in License Exception GFT (see § 740.12(a) of the EAR).

* * * * *

(e) *Intransit through the United States.* If you are submitting a license application for items moving intransit through the United States that do not qualify for the *intransit* provisions of License Exception TMP (see § 740.9(b)(1) of the EAR), you must provide the following information with your license application:

* * * * *

(g) * * *

(1) *Statement requirement.* If a license is required to export or reexport items described in § 742.3 or § 744.4 of the EAR, or any other item (except those controlled for short supply reasons) where the item is intended for a nuclear end-use, prior to submitting a license application, you must obtain a signed written statement from the end-user certifying the following:

* * * * *

(2) * * *

(i) In Block 7, place an (X) in the box titled ''Nuclear Certification'';

* * * * *

(o) * * *

(3) * * *

(i) *Technology controlled for national security reasons.* If you are submitting a license application to export technology controlled for national security reasons to a country *not* listed in Country Group D:1 or E:2 (see Supplement No. 1 to part 740 of the EAR), upon request, you must provide BXA a copy of the written letter from the ultimate consignee assuring that, unless prior authorization is obtained from BXA, the consignee will not knowingly reexport the technology to any destination, or export the direct product of the technology, directly or indirectly, to a country listed in Country Group D:1 or E:2 (see Supplement No. 2 to part 740 of the EAR). If you are unable to obtain this letter of assurance from your consignee, you must state in your license application why the assurances could not be obtained.

* * * * *

(p) *Temporary exports or reexports.* If you are submitting a license application for the temporary export or reexport of an item (not eligible for the *temporary exports and reexports* provisions of License Exception TMP (see § 740.9(a) of the EAR)) you must include the following certification in Block 24:

* * * * *

58. In Supplement No. 4 to part 748, the IC/DV Authorities column for ''China, PRC People's Republic of'' is amended by revising the phrase ''Telephone: 553031'' to read ''Telephone: 651–97–355''.

59. In Supplement No. 4 to part 748, the IC/DV Authorities column for ''Italy'' is amended by revising the phrase ''Div. III, Rome'' to read ''Div. III, Rome or:'' and revising the phrase ''import where takes place'' to read ''where import takes place''.

60. Supplement No. 5 to part 748 is amended by revising paragraph (a)(6)(vii) to read as follows:

Supplement No. 5 to Part 748—U.S. Import Certificate and Delivery Verification Procedure

(a) * * *

(6) * * *

(vii) Reexport or transshipment of items after delivery to U.S. Items imported into the U.S. under the provisions of a U.S. International Import Certificate may not be reexported to any destination under the *intransit* provisions of License Exception TMP (see § 740.9(b)(1) of the EAR). However, all other provisions of the EAR applicable to items of domestic origin shall apply to the reexport of items of foreign origin shipped to the U.S. under a U.S. International Import Certificate.

* * * * *

PART 750—[AMENDED]

61. Section 750.1 is revised to read as follows:

§ 750.1 Scope.

In this part, references to the EAR are references to 15 CFR chapter VII, subchapter C. This part describes the Bureau of Export Administration's (BXA) process for reviewing your application for a license and the applicable processing times for various types of applications. Information related to the issuance, denial, revocation, or suspension of a license or license application is provided along with the procedures on obtaining a duplicate or replacement license, the transfer of a license and shipping tolerances available on licenses. This part also contains instructions on obtaining the status of any pending application.

62. Section 750.4 is amended:

a. By revising the first sentence of paragraph (b)(1); and

b. By revising the phrase ''terrorist supporting'' to read ''terrorist-supporting'' in paragraph (b)(6) introductory text, as follows:

§ 750.4 Procedures for processing license applications.

* * * * *

(b) * * *

(1) *Agreement by the applicant to the delay.* BXA may request applicants to provide additional information in support of their license application, respond to questions arising during processing, or accept proposed conditions or riders on their license application. * * *

* * * * *

63. Section 750.5 is amended by revising paragraph (a) to read as follows:

§ 750.5 Status of pending applications and other requests.

(a) *Information available.* You may contact BXA for status of your pending Classification Request, Advisory Opinion, or license application. For Advisory Opinion requests, telephone (202) 482–4905 or send a fax to (202) 219–9179. For license applications and Classification Requests, telephone BXA's System for Tracking Export License Applications (''STELA'') at (202) 482–2752. STELA is an automated voice response system, that upon request via any standard touch-tone telephone, will provide you with up to the minute status on any application pending at BXA. Press ''0'' on your keypad for online instructions or ''9'' for the letter ''Z''. Requests for status may be made only by the applicant or the applicant's agent.

* * * * *

64. Section 750.7 is amended:

a. By revising the phrase ''approved by the BXA,'' to read ''approved by BXA,'' in paragraph (a); and

b. By revising the parenthetical phrase ''(See § 748.5(g) of the EAR)'' to read ''(see § 748.4(h) of the EAR)'' in paragraphs (g) introductory text and (g)(1).

65. Section 750.10(c) is amended by revising the phrase ''pending notification by the BXA'' to read ''pending notification by BXA''.

PART 752—[AMENDED]

66. Section 752.1(a)(1) is amended by revising the phrase ''described in part 734 of the EAR.'' to read ''described in part 736 of the EAR.''.

67. Section 752.3 is amended by revising paragraphs (a)(2) and (a)(3) to read as follows:

§ 752.3 Eligible items.

(a) * * *

(2) Items controlled by ECCNs 1C351, 1C352, 1C353, 1C354, 1C991, 1E001, 1E350, 1E391, 2B352, 2E001, 2E002, and 2E301 on the CCL controlled for CB reasons;

(3) Items controlled by ECCNs 1C350, 1C995, 1D390, 2B350, and 2B351 on the CCL that can be used in the production of chemical weapons precursors and chemical warfare agents, to destinations listed in Country Group D:3 (see Supplement No. 1 to part 740 of the EAR);

* * * * *

68. Section 752.5 is amended:

a. By revising the introductory text of paragraph (c)(8)(i);

b. By revising the introductory text and certification of paragraph (c)(8)(ii); and

c. By revising the introductory text of paragraph (c)(8)(iii) to read as follows:

§ 752.5 Steps you must follow to apply for an SCL.

(c) * * *

(8) * * *

(i) *Temporary exports.* Proposed consignees that plan to exhibit or demonstrate items in countries other than those in which they are located or are authorized under an SCL, an approved Form BXA–752, or a License Exception provision described in § 740.8(a)(2)(iii) of the EAR may obtain permission to do so by including the following additional certification on company letterhead, and attaching it to Form BXA–752.

* * * * *

(ii) *Chemicals and chemical equipment certification.* If you are requesting authority to export chemicals or chemical equipment eligible for the

SCL, you must obtain a signed written statement on company letterhead from the proposed consignee(s) and end-user(s) (except those located in Country Group A:3) (see Supplement No. 1 to part 740 of the EAR) certifying the following:

No chemicals or chemical equipment received under this Special Comprehensive License will be transferred, resold, or reexported to a destination that requires a license, unless the new end-user has been approved by the Bureau of Export Administration, and in no case will the items be retransferred, resold, or reexported to a party who is not the end-user.

(iii) *Nuclear nonproliferation certification.* If you are requesting the export or reexport under the EAR of items controlled for nuclear nonproliferation reasons described in § 744.2(a) of the EAR, prior to submitting an SCL application, you must obtain a signed written statement on company letterhead from the proposed consignee(s) and end-user(s) certifying the following:

* * * * *

69. Section 752.6 is amended by revising paragraph (b)(1) to read as follows:

§ 752.6 Reexports.

* * * * *

(b) * * *

(1) Transferring, reselling, or reexporting under your SCL any chemicals or chemical equipment identified with the letters ''CB'' in the applicable ''Reason for Control'' paragraph on the CCL (see Supplement No. 1 to part 774 of the EAR); and

* * * * *

70. Section 752.9 is amended by revising the introductory text of paragraph (a)(2) to read as follows:

§ 752.9 Action on SCL applications.

(a) * * *

(2) *Extension of validity period.* You may request an extension of your valid SCL for an additional four years, but such requests must be received by BXA at least 30 days prior to the expiration of your SCL. If approved, Form BXA–748P and your letter requesting an extension will be validated and returned to you, extending the validity period for four years. No further extensions will be approved. A new application and support documentation is required at the end of that eight-year period. To apply for an extension, complete Form BXA–748P by completing Blocks 1, 2, 3, and 4. In addition, mark ''Special Comprehensive License'' in Block 5, place an ''x'' in ''Letter of Explanation'' in Block 6, and mark ''other'' in Block 8. Include your SCL number in Block 9, and indicate in Block 24 that you are requesting an extension to your SCL. Submit the completed Form BXA–748P and a statement on your company letterhead indicating:

* * * * *

71. Section 752.10 is revised to read as follows:

§ 752.10 Changes to the SCL.

(a) *General information.* Certain changed circumstances regarding the SCL require prior approval from BXA before you make such changes, while others require only notification to BXA. Changes and notifications of license holder information must be initiated by submitting Form BXA–748P. Changes and notifications of consignee information must be initiated by submitting Form BXA–752.

(b) *Changes requiring prior written approval from BXA.* The following circumstances require prior written approval by BXA. Such requests must be submitted by the SCL holder, and changes are not effective until BXA approves the request. Upon approval of a change described in this paragraph, BXA will return to the SCL holder a validated copy of the request, indicating any changes that may have been made to your request, or any special conditions that may have been imposed.

(1) *Change of SCL holder company name.* You must submit to BXA Form BXA–748P, Multipurpose Application, for any change in the name of the SCL holder company. Complete Blocks 1, 2, 3, and 4. Mark ''Special Comprehensive License'' in Block 5, and ''other'' in Block 8. In Block 9, include your SCL number. Briefly indicate the purpose of the change in Block 24 (i.e., a change in company name). Enter the new information in the relevant Blocks, and complete Block 25. The SCL holder must send a copy of the validated Form BXA–748P to each approved consignee, and advise them to attach the copy of the validated form to their validated Form BXA–752.

(2) *Change in consignee name or address.* You must submit to BXA Form BXA–752, Statement by Consignee in Support of Special Comprehensive License, when requesting a change in consignee name, or if the consignee moves out of the country. The consignee must complete Block 3, mark ''change an existing consignee'' and provide the new consignee information in Block 4. In Block 9, explain change of address from ''Address A'' to ''Address B''. Also, complete Block 10 and the SCL holder signature Block information.

(3) *Addition of new consignee.* You must submit to BXA Form BXA–752 for requests to add consignees to an SCL. Complete Form BXA–752 in accordance with the instruction in Supplement No. 3 to this part, marking ''Add a New Consignee'' in Block 3. Use Block 9 to describe the proposed consignee's role in the activities authorized by the SCL. Form BXA–752 is not required if the proposed new consignee is a foreign government agency and the items will not be reexported. If Form BXA–752 is not required, the SCL holder may submit the request to add the foreign government agency to the SCL on company letterhead. You must include the proposed consignee's complete street address.

(4) *Change in reexport territories.* You must submit to BXA Form BXA–752 and Form BXA–752–A to add a country to a consignee's approved reexport territory. Upon approval of change in reexport territory, BXA will return to the SCL holder two validated copies of Form BXA–752 and Form BXA–752–A, Reexport Territories, along with any special conditions that may have been imposed.

(i) *Form BXA–752.* Complete Block 3 by marking ''Change an Existing Consignee''. In Block 4, enter the consignee name and consignee number. In Block 5, enter the SCL number. In Block 9, enter ''to add a country to the reexport territory''. Complete Block 10 and the SCL holder signature block information.

(ii) *Form BXA–752–A.* Complete Blocks 2 and 3. Mark each country that you are adding to your reexport territory.

(5) *Adding items to your SCL.* The following procedures apply to requests to add items to your SCL. Upon approval, BXA will send you a validated Form BXA–748P and, if applicable, Form BXA–748P–A. The SCL holder must send a copy of each validated form to all applicable consignees and attach a copy to their Form BXA–752.

(i) *Adding one item.* You must submit to BXA Form BXA–748P to request the addition of a single item to your SCL. Complete Blocks 1, 2, 3, and 4. Mark an ''x'' in the ''Special Comprehensive License'' box in Block 5, and ''other'' in Block 8. Include your SCL number in Block 9. In Block 24, enter ''add ECCN''. Complete items (a) and (j) in Block 22 and in Block 25.

(ii) *More than one item.* You must submit to BXA Form BXA–748P and Form BXA–748P–A to request to add more than one item to your SCL. Complete Form BXA–748P according to the instructions in paragraph (b)(5)(i) of this section. In Block 24, insert the phrase ''add ECCNs on attached From BXA 748P–A. Complete Block 1 on Form BXA–748P–A by including the

''Application Control Number'' (found on Form BXA–748P). Complete Block 21 and 24, if needed, to describe any special circumstances (i.e., the new item will only be exported to specific consignees and will not be reexported).

(6) *Changes to add end-users.* You must submit to BXA Form BXA–752 and Form BXA–748P–B to add or change end-users to consignee authorizations. When you request multiple ''types of requests'' (i.e., additions or changes) on a single Form BXA–752; you must specify in Block 9, the type of request for each end-user. Example: end-user XXX is to be ''added'' and end-user AAA is to be ''changed'' from ''end-user AAA'' to ''end-user ABA''.

(i) *Form BXA–752.* On Form BXA–752, complete Block 3.B, ''change an existing consignee''. Include the consignee number in Block 4. Include the SCL number in Block 5. In Block 9 insert the phrase ''To add an end-user'' or the phrase ''To change an end-user''. Complete Block 10 and include the SCL holder signature block information.

(ii) *Form BXA–748P–B.* On Form BXA–748–B, complete Blocks 1 and 19. In Block 21, cite the end-user requirement or condition (i.e., end-user XXX is requested in compliance with § 752.5(c)(8)(ii) of this part, which requires prior authorization to reexport chemicals under the SCL). Also, list the items (by ECCN and by description) that each end-user will receive and for what purpose, if approved by BXA.

(c) *Changes that do not require prior approval from BXA.* The following changes regarding your SCL do not require prior approval from BXA, however, such changes must be submitted on the appropriate forms no later than 30 days after the change has occurred. BXA will validate the forms, and return one copy to you for your records.

(1) *Change of SCL holder address, export contact information, or total value of license.* You must submit to BXA Form BXA–748P, Multipurpose Application, for any change in the SCL holder's address, export contact information, or total value of the license. Complete Blocks 1, 2, 3, and 4. Mark ''Special Comprehensive License'' in Block 5, and ''other'' in Block 8. In Block 9, include your SCL number. Briefly indicate the purpose of the change in Block 24. Enter the new information in the relevant Blocks. Complete Block 25. The SCL holder must send a copy of the validated Form BXA–748P to each approved consignee, and advise each approved consignee to attach the copy of the validated form to their validated Form BXA–752.

(2) *Deletion of consignees.* You must submit to BXA Form BXA–752 if you remove a consignee from your SCL. Complete Block 3.C. Indicate your consignee number in Block 4 and your SCL case number in Block 5. Explain the reason for the action in Block 9. Complete Block 10 and the SCL holder signature information. You must notify all remaining consignees if any consignee is no longer eligible to receive items under the SCL.

(3) *Changes in ownership or control of the SCL holder or consignee.*—(i) *SCL holder.* You must notify BXA of changes in ownership or control by submitting to BXA Form BXA–748P. Complete Blocks 1, 2, 3 and 4, mark ''Special Comprehensive License'' in Block 5. Mark and ''x'' in ''other'' in Block 8 and indicate the SCL number in Block 9. Include the SCL holder information number in Block 14, and describe the change in Block 24, indicating the circumstances necessitating the change (i.e., mergers), and changes in persons who have official signing authority. Also complete Block 25.

(ii) *Consignee.* You must notify BXA of changes in ownership or control of the consignee company by submitting to BXA Form BXA–752. Complete Block 1. Mark and ''x'' in ''change an existing consignee'' in Block 3.B, and complete Blocks 4 and 5. In Block 9, describe the change, indicating the circumstances necessitating the change (i.e., mergers), and changes in persons who have official signing authority. Complete Block 10 and the SCL holder signature block information.

(iii) *Transfers and SCLs after control changes.* Note that under § 750.10(a) of the EAR you may not transfer a license—including a Special Comprehensive License—except with the prior written approval of BXA. In addition, BXA reserves the right to modify, revoke, or suspend an SCL in the event of a change in control of the previously approved SCL holder or consignee(s). In reviewing requests to transfer an SCL or consignee authority under an SCL and in reviewing changes in control of an SCL holder or approved consignee, BXA will consider the reliability of the new parties.

(4) *Remove reexport territories.* If you remove a country from a consignee's approved reexport territory, you must submit to BXA Form BXA–752 and Form BXA–752–A. You cannot add and delete countries on the same forms. Upon review of the change in reexport territory, BXA will return to the SCL holder two validated copies of Form BXA–752 and Form BXA–752–A.

(i) *Form BXA–752.* Complete Block 1. Complete Block 3 by marking ''change an existing consignee''. In Block 4, enter the consignee name and consignee number. In Block 5, enter the SCL number. Complete Block 10 and the SCL holder signature block information.

(ii) *Form BXA–752–A.* Complete Blocks 1, 2, 3, and 5. Mark each country that you are removing from the reexport territory with an ''x''. Mark an ''x'' in ''Other Specify'' and insert ''delete''.

(5) *Remove items from your SCL.* The following procedures apply if you remove an item from your SCL. After review of the change by BXA, BXA will send you a validated Form BXA–748P and Form BXA–748P–A, if applicable. The SCL holder must send a copy of each validated form to all applicable consignees and attach a copy to their BXA–752.

(i) *Removing one item.* You must submit to BXA Form BXA–748P if you remove a single item from your SCL. Complete Blocks 1, 2, 3 and 5. Mark ''Special Comprehensive License'' in Block 5 and mark ''other'' in Block 8. Include your SCL number in Block 9. State ''delete ECCN'' in Block 24. Complete items (a) and (j) in Block 22 and Block 25.

(ii) *Removing more than one item.* You must submit to BXA Form BXA–748P and Form BXA 748P–A if you remove more than one item from your SCL. Complete Form BXA–748P according to the instructions in paragraph (a)(5)(i) of this section, except in Block 24, state ''delete ECCNs on attached BXA–748P–A''. Complete Form BXA 748P–A by including the ''application control number'' (found on Form BXA–748P) in Block 1. Complete items (a) and (j) in Block 22 for each item you are removing from your SCL.

(6) *Remove end-users from your SCL.* You must submit to BXA Form BXA–752 if you remove end-users from consignee authorizations. (Use Form BXA–748P–B, if additional space is needed.) After review by BXA, BXA will return to the SCL holder two validated copies of Form BXA–752 and Form BXA–748P–B, which will include any special instructions that may be necessary. You must send one copy of Forms BXA–752 and BXA–748P to the relevant consignee.

(i) *Form BXA–752.* On Form BXA–752, complete Block 1 and 3.B, ''change an existing consignee''. Include the consignee number in Block 4. Include the SCL case number in Block 5. In Block 9, include the phrase ''to remove an end-user(s)'' followed by the name/address information. Complete Block 10 and the SCL holder signature Block information.

(ii) *Form BXA–748P–B.* If there was not enough space on Form BXA–752,

Block 9, you may continue the information on Form BXA–748P–B, in Block 24. Complete the information in Block 1. Do not complete Block 19. Block 19 is only used to add end-users.

(d) *Changes made by BXA*. If BXA revises or adds an ECCN to the CCL, or a country's eligibility already covered by the SCL changes, BXA will publish the change in the **Federal Register**. The SCL holder is responsible for immediately complying with any changes to the scope of the SCL.

72. Section 752.11 is amended by revising paragraph (c)(13)(i) to read as follows:

§ 752.11 Internal Control Programs.

* * * * *

(c) * * *

(13) * * *

(i) The signs of potential diversion that you should take into consideration include, but are not limited to, the following:

(A) The customer or purchasing agent is reluctant to offer information about the end-use (or end-user) of a product.

(B) The product's capabilities do not fit the buyer's line of business; for example, a small bakery places an order for several sophisticated lasers.

(C) The product ordered is incompatible with the technical level of the country to which the product is being shipped. For example, semiconductor manufacturing equipment would be of little use in a country without an electronics industry.

(D) The customer has little or no business background. For example, financial information unavailable from normal commercial sources and corporate principals unknown by trade sources.

(E) The customer is willing to pay cash for a very expensive item when the terms of the sale call for financing.

(F) The customer is unfamiliar with the product's performance characteristics but still wants the product.

(G) Routine installation, training or maintenance services are declined by the customer.

(H) Delivery dates are vague, or deliveries are planned for out-of-the-way destinations.

(I) A freight forwarding firm is listed as the product's final destination.

(J) The shipping route is abnormal for the product and destination.

(K) Packaging is inconsistent with the stated method of shipment or destination.

(L) When questioned, the buyer is evasive or unclear about whether the purchased product is for domestic use, export, or reexport.

(M) Customer uses only a ''P.O. Box'' address or has facilities that appear inappropriate for the items ordered.

(N) Customer's order is for parts known to be inappropriate, or for which the customer appears to have no legitimate need (e.g., there is no indication of prior authorized shipment of system for which the parts are sought).

(O) Customer is known to have, or is suspected of having unauthorized dealings with parties and/or destinations in ineligible countries.

* * * * *

73. Section 752.15 is amended by revising the first sentence of paragraph (b) to read as follows:

§ 752.15 Export clearance.

* * * * *

(b) *Destination control statement.* The SCL holder and consignees must enter a destination control statement on all copies of the bill of lading or air way-bill, and the commercial invoice covering exports under the SCL, in accordance with the provisions of § 758.6 of the EAR. * * *

74. Supplement No. 1 to part 752 is revised to read as follows:

Supplement No. 1 to Part 752—Instructions for Completing Form BXA–748P, Multipurpose Application for Requests for Special Comprehensive Licenses

All information must be legibly typed within the lines for each Block or box, except where a signature is required. Where there is a choice of entering a telephone or telefacsimile number, and you chose a telefacsimile number, identify the number with the letter ''F'' immediately following the number.

Complete Blocks 1, 2, 3 and 4 according to the instructions in Supplement No. 1 to part 748 of the EAR.

Block 5: Type of Application. Enter an ''x'' in the Special Comprehensive License box.

Block 6: Documents Submitted with Application. Enter an ''x'' in the appropriate boxes to indicate which forms are attached.

Block 7: Documents on File with Applicant. Leave blank.

Block 8: Special Comprehensive License. Complete by entering an ''x'' in the appropriate boxes to indicate which forms are attached.

Block 9: Special Purpose. This block should only be completed when requesting changes to an approved SCL.

Block 10: Resubmission Application Control Number. Leave blank.

Block 11: Replacement License Number. This Block should be completed by previous special license holders. If you have had a special license in the past, enter that license number (i.e., V #, SS #, DL #, or SF #). A new SCL number will be assigned upon approval of your SCL application.

Block 12: Items Previously Exported. Leave blank.

Block 13: Import/End-User Certificate. Leave blank.

Block 14: Applicant. Complete according to the instructions in Supplement No. 1 to part 748 of the EAR.

Block 15: Other Party Authorized to Receive License. Complete, if applicable, according to the instructions in Supplement No. 1 to part 748 of the EAR.

Block 16: Purchaser. Leave blank.

Block 17: Intermediate Consignee. Leave blank.

Block 18: Ultimate Consignee. Leave blank.

Block 19: End-User. Leave blank.

Block 20: Original Ultimate Consignee. Leave blank.

Block 21: Specific End-Use. Leave blank.

Block 22: For one item, complete sub-blocks (a) through (j). For multiple items, complete Form BXA 748P–A.

Block 23: Total Application Dollar Value. Enter the projected total dollar value of all transactions you anticipate making throughout the entire validity period of the SCL.

Block 24: Additional Information. Enter additional data pertinent to the transaction.

Block 25: Signature. Complete according to the instructions in Supplement No. 1 to part 748 of the EAR.

75. Supplement No. 2 to part 752 is amended by revising Block 21 to read as follows:

Supplement No. 2 to Part 752—Instructions For Completing Form BXA–748P–A, ''Item Annex''

* * * * *

Block 21: Continuation of Specific End-Use Information. Complete as necessary to fully describe the transaction(s).

* * * * *

76. Supplement No. 3 to part 752 is revised to read as follows:

Supplement No. 3 to Part 752—Instructions on Completing Form BXA–752 ''Statement by Consignee In Support of Special Comprehensive License''

All information must be legibly typed within the lines for each Block or Box, except where a signature is required.

Block 1: Application Control No. Enter the ''Control No.'' that is pre-printed on Form BXA–748P, Multipurpose Application. You may obtain this information from the applicant.

Block 2: Consignee ID Number. Leave blank.

Block 3: Type of Request. For new applications, leave blank.

Block 4: Consignee Information. Enter the complete address where the consignee is located. A Post Office (P.O.) Box alone is NOT acceptable, but may be included in this Block 4 for mailing purposes, along with a complete address. If records required by § 752.12 of this part and part 762 of the EAR are maintained/stored at a separate address, indicate the address in Block 9. In the absence of a complete address, Form BXA–752 will be returned without action.

Block 5: U.S. Exporter Information. Enter the complete address of the U.S. exporter.

Leave the SCL Case No. box blank for new applications and enter the SCL Case No. for ''change'' actions.

Block 6: Description of Items. Provide a summary description of the items proposed for import and reexport under the SCL. Firms that will not receive the entire range of items under a particular ECCN identified on Form BXA–748P–A should describe only the items they will receive under the SCL. In some instances, consignee approval will be contingent on the nature of the item requested.

Block 7: Consignee's Business and Relationships.

(i) Item (a): Identify the nature of your company's principal business as it affects the disposition of items to be imported and reexported under this license by including the appropriate letter choice(s) from the following: (a) manufacturer, (b) distributor, (c) assembler, (d) sales agent, (e) warehouse, (f) service facility, or (g) other. For other, provide an explanation in Block 9.

(ii) Item (b): Indicate the relationship between your company and the applicant's company by providing the appropriate letter choice(s) from the following: (a) wholly-owned subsidiary, (b) independent company, (c) joint venture company, (d) controlled-in-fact affiliate, (e) contractor/subcontractor, or (f) other. For other, provide an explanation in Block 9.

(iii) Item (c): Enter the number of years of relationship between your company and the applicant company.

(iv) Item (d): Enter the estimated dollar volume of sales or other transactions with the SCL holder during the last twelve month period before submission of the application for an SCL.

(v) Item (e): Enter an estimated dollar volume proposed under this application for the validity period of the SCL.

Block 8: Disposition or Use of Items.

(i) Item (a): Complete this Block if your company is requesting involvement in end-user activities that involves importing items for the company's own use (e.g., as capital equipment).

(ii) Item (b): Complete this Block if your company is requesting involvement in end-user activities that incorporates items received under the SCL into a new end-product that results in a change of identity of the U.S.-item (e.g., U.S.-origin semiconductor devices are included in a foreign-origin test instrument). Under Block 9, Additional Information, describe the new end-product more specifically and state how and to what extent the U.S.-origin items will be used. Complete and attach Form BXA–752–A, Reexport Territories.

(iii) Item (c): Complete this Block if your company is requesting authorization to reexport items for service and/or repair. Complete and attach Form BXA–752–A. If you plan to reexport to end-users that require prior approval by BXA, also complete and attach Form BXA–748P–B, End-User Appendix.

(iv) Item (d): Complete this Block if your company plans to retransfer/resell within the country of import. State the end-use of your customers. If you plan to retransfer to end-users that require prior approval by BXA, complete and attach Form BXA–748P–B, End-User Appendix.

(v) Item (e): Complete this Block if your company plans to reexport. Complete and attach Form BXA–752–A. If you plan to reexport to end-users that require prior approval by BXA, complete and attach Form BXA–748P–B, End-User Appendix.

(vi) Item (f): This item should be completed for ''other'' activities that are not defined in Block 8 paragraphs (a) through (e). Describe the proposed activities fully in Block 9 or in a letter submitted with this Form, and complete and submit Form BXA–752–A, indicating the countries to which the products derived from these activities will be exported.

Block 9: Additional Information. In addition to any information that supports other Blocks, indicate whether your company is an active consignee under any other license issued by BXA. Indicate the license and consignee numbers.

Block 10: Signature of Official of Ultimate Consignee. Include an original signature. The authority to sign Form BXA–752 may not be delegated to any person whose authority to sign is not inherent in his/her official position with the company. The signing official must include their official title with their signature. All copies must be co-signed by the applicant in the SCL holder signature block and submitted with the application to BXA.

77. Supplement No. 4 to part 752 is revised to read as follows:

Supplement No. 4 to Part 752—Instructions for Completing Form BXA–752–A, Reexport Territories

All information must be legibly typed within the lines for each Block or Box.

Block 1: Application Control No. Insert the application control No. from the relevant Form BXA–748P.

Block 2: SCL License No. Leave blank for new SCL applications. For changes to existing SCLs, include the original SCL number.

Block 3: Consignee No. Leave blank for new SCL applications. For changes to existing SCLs, include the consignee number that was provided on the original license.

Block 4: Continuation of BXA–752 Question No. Mark an ''x'' in the box next to each country you wish to select. See § 752.4 of this part for countries that are not eligible for the SCL. You may request a country that is not included on Form BXA–752-A by marking an ''x'' in the ''other'' box and including the country name.

78. Supplement No. 5 to part 752 is revised to read as follows:

Supplement No. 5 to Part 752—Instructions for Completing Form BXA–748–B, End-User Appendix

All information must be legibly typed within the lines for each Block or Box.

Block 1: Application Control No. Insert the application control No. from the relevant Form BXA–748P.

Block 19: End-user. Enter each end-user's complete name, street address, city, country, postal code and telephone or facsimile number. Post Office (P.O.) Boxes are not acceptable.

Block 21: Continuation of Specific End-Use Information. Include any additional information that may help BXA in reviewing and making a determination on your application, such as the special safeguards that will be implemented to prevent diversion.

Block 24: Continuation of Additional Information. Enter additional data pertinent to the transaction as required by part 752. Enter the consignee name and complete address of the consignee responsible for the end-user(s) (i.e., recordkeeping and ICP screening, etc.).

PART 754—[AMENDED]

79. Section 754.6 is amended by revising paragraph (c) to read as follows:

§ 754.6 Registration of U.S. agricultural commodities for exemption from short supply limitations on export.

* * * * *

(c) *Mailing address.* Submit applications pursuant to the provisions of section 7(g) of the EAA to: Bureau of Export Administration, U.S. Department of Commerce, P.O. Box 273, Washington, D.C. 20044.

80. Section 754.7 is amended by revising paragraph (d) to read as follows:

§ 754.7 Petitions for the imposition of monitoring or controls on recyclable metallic material; Public hearings.

* * * * *

(d) *Mailing address.* Submit petitions pursuant to section 7(c) of the EAA to: Bureau of Export Administration, U.S. Department of Commerce, P.O. Box 273, Washington, D.C. 20044.

PART 756—[AMENDED]

81. Section 756.1 is amended by revising the third sentence of paragraph (a) to read as follows:

§ 756.1 Introduction.

(a) * * * Any person directly and adversely affected by an administrative action taken by the Bureau of Export Administration (BXA) may appeal to the Under Secretary for reconsideration of that administrative action. * * *

* * * * *

82. Section 756.2 is amended by revising paragraph (b)(4)(ii), to read as follows:

§ 756.2 Appeal from an administrative action.

* * * * *

(b) * * *

(4) * * *

(ii) *Evidence.* The rules of evidence prevailing in courts of law do not apply, and all evidentiary material deemed by

the Under Secretary to be relevant and material to the proceeding, and not unduly repetitious, will be received and considered.

* * * * *

PART 758—[AMENDED]

83. Section 758.1 is amended:

a. By revising paragraph (b)(2);

b. By revising the first sentence of paragraph (d)(2)(vi);

c. By revising paragraph (e)(1)(i)(A);

d. By revising paragraph (e)(1)(i)(C); and

e. By revising the phrase ''''No License Required'' of the applicable'' to read ''''No License Required'', or the applicable'' in paragraph (f)(2)(ii).

§ 758.1 Export clearance requirements.

* * * * *

(b) * * *

(2) Forwarding agent as licensee. If the forwarding agent is appointed at the suggestion of a foreign buyer, the seller may insist that the agent apply for the export license. See § 748.5(a)(1) of the EAR which defines parties to a transaction.

* * * * *

(d) * * *

(2) * * *

(vi) *Software and technology.* If you are exporting software or technology, the export of which is authorized under the License Exceptions in § 740.6 or § 740.13 of the EAR, you do not need to make any notation on the package.

* * *

* * * * *

(e) * * *

(1) * * *

(i) * * *

(A) Any shipment, other than a shipment made under a license issued by BXA, to any country in Country Group B (see Supplement No. 1 to part 740 of the EAR) or to the People's Republic of China if the shipment is valued at $2,500 or less per Schedule B Number (or other number acceptable to the Foreign Trade Division, Bureau of the Census). The Schedule B number of an item is shown in the current edition of the *Schedule B, Statistical Classification of Domestic and Foreign Commodities Exported from the United States.* In paragraph (e) of this section, ''shipment'' means all items classified under a single Schedule B number (or other number acceptable to the Foreign Trade Statistics Division, Bureau of the Census), shipped on the same carrier, from one exporter to one importer. The Foreign Trade Statistics Regulations of the Bureau of the Census (15 CFR part 30) shall govern the valuation of items when determining whether a shipment meets the $2,500 threshold of this paragraph.

(B) * * *

(C) Any shipment made under any other exception to the SED requirements found in Subpart B of the Bureau of the Census' Foreign Trade Statistics Regulations.

* * * * *

84. Section 758.2(c) is amended by revising the term ''OEXS'' to read ''BXA''.

85. Section 758.3 is amended:

a.–b. By revising the introductory text of paragraph (f)(1);

c. By revising paragraph (g);

d. By revising paragraph (h)(1);

e. By revising the introductory text of paragraph (m)(3)(ii)(C);

f. By revising paragraph (m)(3)(iii); and

g. By revising paragraph (o)(2), as follows:

§ 758.3 Shipper's Export Declaration (SED).

* * * * *

(f) * * *

(1) *General.* Except as described in paragraph (f)(2) of this section, more than one item may be listed on the same SED provided they are contained in one shipment on board a single carrier and are going from the same exporter to the same consignee. Even if some of the items are being shipped under authority of a license and others under a License Exception or the ''No License Required'' (NLR) provisions of the EAR (as described in § 758.1(a) of this part), they may still be shown on one SED. For the second and subsequent authorizations used, the applicable license number and expiration date, License Exception symbol, or the symbol NLR must be shown along with the descriptions (including quantity, if required, Schedule B number or other number acceptable to the Foreign Trade Division, Bureau of the Census, and value) to which each authorization applies must be shown under each of the properly aligned line item descriptions. The following apply for notations made on the SED:

* * * * *

(g) *Schedule B number and item description.* (1) *Schedule B number.* You must enter the Schedule B number (or other number acceptable to the Foreign Trade Division, Bureau of the Census), as shown in the current edition of Schedule B, *Statistical Classification of Domestic and Foreign Commodities Exported from the United States,* in the designated column of the SED or other number acceptable to the Foreign Trade Division, Bureau of the Census regardless of whether the shipment is being exported under authority of a license issued by BXA, a License Exception described in part 740 of the EAR, or the ''No License Required'' (NLR) provisions of the EAR as described in § 758.1(a) of this part.

(2) *Item description for exports under a license*—(i) *General.* If your export is being made under the authority of a license issued by BXA, you must enter the item description shown on the license on the SED. However, if part of the description on the license is underlined, you need place only the underlined portions on the SED. The item description on the license will be stated in CCL terms, which may be inadequate to meet Census Bureau requirements. In this event, the item description you place on the SED must be given enough additional detail to permit verification of the Schedule B number (or other number acceptable to the Foreign Trade Division, Bureau of the Census) (e.g., size, material, or degree of fabrication).

(ii) *Distinguishing characteristics or specifications.* If a commodity classification in Schedule B (or other schedule acceptable to the Foreign Trade Division, Bureau of the Census) has instructions such as ''specify by name'', ''state species'', etc., you must furnish that information in the column of the SED provided for the commodity description. When a single SED covers more than one item classifiable under a single classification carrying the ''specify by name'' or similar requirement, you must enter each item separately in this column. However, if more than five items are involved, all classifiable under one Schedule B number or ''other number acceptable to the Foreign Trade Division, Bureau of the Census'' only the five items of greatest value in the classification need be shown separately. Separate quantities, values, and shipping weights for individual items are not required in either case.

(3) *Item description for License Exception shipments or shipments for which no license is required.* For items that may be exported under authority of a License Exception, or under the NLR provisions of the EAR (as described in § 758.1(a) of this part), you must enter a description in sufficient detail to permit review by the U.S. Government and verification of the Schedule B number or ''other number acceptable to the Foreign Trade Division, Bureau of the Census'' entered on the SED.

(h) * * *

(1) *Exports under the authority of a license issued by BXA.* You must show the license number and expiration date, the Export Control Classification

Number (ECCN) and the item description, in the designated spaces of a SED covering an export under a license issued by BXA (the space for the item description on the SED form may be headed ''commodity description''). If you intend to include other items on the SED that may be exported under a License Exception, or under the ''No License Required'' (NLR) provisions of the EAR (as described in § 758.1(a) of this part) you must show the License Exception or NLR symbol, along with the specific description (quantity, Schedule B number or ''other number acceptable to the Foreign Trade Division, Bureau of the Census'', value) of the item(s) to which the authorization applies in the designated spaces on the SED continuation sheet.

* * * * *

(m) * * *

(3) * * *

(ii) * * *

(C) For intransit shipments of items of U.S.-origin eligible for the *intransit* provisions of License Exception TMP (see § 740.9(b) of the EAR), enter the following statement:

* * * * *

(iii) The items must be described in terms of Schedule B, including the appropriate Schedule B number or ''other number acceptable to the Foreign Trade Division, Bureau of the Census''.

* * * * *

(o) * * *

(2) *Applicability.* Approved parties may file monthly SEDs with the Bureau of the Census for export to destinations in Country Groups B and D (see Supplement No. 1 to part 740 of the EAR).

* * * * *

86. Section 758.7(b)(6) is amended by revising the phrase ''both customs officials'' to read ''both Customs officials'' in the third sentence.

PART 762—[AMENDED]

87. Section 762.3(a)(7) is amended by revising the phrase ''Parking material'' to read ''Packing material''.

PART 764—[AMENDED]

88. Section 764.2 is amended by revising paragraph (f) to read as follows:

§ 764.2 Violations.

* * * * *

(f) *Possession with intent to export illegally.* No person may possess any item controlled for national security or foreign policy reasons under sections 5 or 6 of the EAA:

(1) With intent to export or reexport such item in violation of the EAA, the EAR, or any order, license or authorization issued thereunder; or

(2) With knowledge or reason to believe that the item would be so exported or reexported.

* * * * *

90. Section 764.3 is amended:

a. By revising paragraph (b)(1);

b. By revising paragraph (b)(2)(i);

c. By revising paragraph (b)(2)(ii); and

d. By revising paragraph (b)(2)(iii), as follows:

§ 764.3 Sanctions.

* * * * *

(b) * * *

(1) *General.* Except as provided in paragraph (b)(2) of this section, whoever knowingly violates or conspires to or attempts to violate the EAA, EAR, or any order or license issued thereunder, shall be fined not more than five times the value of the exports or reexports involved or $50,000, whichever is greater, or imprisoned not more than five years, or both.

(2) *Willful violations.* (i) Whoever willfully violates or conspires to or attempts to violate any provision of the EAA, the EAR, or any order or license issued thereunder, with knowledge that the exports involved will be used for the benefit of, or that the destination or intended destination of items involved is, any controlled country or any country to which exports or reexports are controlled for foreign policy purposes, except in the case of an individual, shall be fined not more than five times the value of the export or reexport involved or $1,000,000, whichever is greater; and, in the case of an individual, shall be fined not more than $250,000, or imprisoned not more than 10 years, or both.

(ii) Any person who is issued a license under the EAA or the EAR for the export or reexport of any items to a controlled country and who, with knowledge that such export or reexport is being used by such controlled country for military or intelligence gathering purposes contrary to the conditions under which the license was issued, willfully fails to report such use to the Secretary of Defense, except in the case of an individual, shall be fined not more than five times the value of the exports or reexports involved or $1,000,000, whichever is greater; and in the case of an individual, shall be fined not more than $250,000, or imprisoned not more than five years or both.

(iii) Any person who possesses any item with the intent to export or reexport such item in violation of an export control imposed under sections 5 or 6 of the EAA, the EAR, or any order or license issued thereunder, or knowing or having reason to believe that the item would be so exported or reexported, shall, in the case of a violation of an export control imposed under section 5 of the EAA (or the EAR, or any order or license issued thereunder with respect to such control), be subject to the penalties set forth in paragraph (b)(2)(i) of this section and shall in the case of a violation of an export control imposed under section 6 of the EAA (or the EAR, or any order or license issued thereunder with respect to such control), be subject to the penalties set forth in paragraph (b)(1) of this section.

* * * * *

91. Section 764.5 is amended:

a. By revising paragraph (c)(4)(ii);

b. By amending paragraph (c)(7), as follows:

i. By revising the phrase ''Facsimile: (617) 835–6039'' to read ''Facsimile: (617) 565–6039'' under the paragraph for ''Boston Field Office'';

ii. By revising the phrase ''Facsimile: (214) 729–9299'' to read ''Facsimile: (214) 767–9299'' under the paragraph for ''Dallas Field Office'';

iii. By revising the phrase ''Facsimile: (714) 791–9103'' to read ''Facsimile: (714) 251–9103'' under the paragraph for ''Los Angeles Field Office''; and

iv. By revising the phrase ''Facsimile: (718) 370–8226'' to read ''Facsimile: (718) 370–0826'' under the paragraph for ''New York Field Office''.

§ 764.5 Voluntary self-disclosure.

* * * * *

(c) * * *

(4) * * *

(ii) Any relevant documents not attached to the narrative account must be retained by the person making the disclosure until OEE requests them, or until a final decision on the disclosed information has been made. After a final decision, the documents should be maintained in accordance with the recordkeeping rules in part 762 of the EAR.

* * * * *

PART 768—[AMENDED]

92. Section 768.1(d) is amended by revising the phrase ''Kyrgystan'' to read ''Kyrgyzstan'' under the definition for ''Controlled countries''.

PART 770—[AMENDED]

93. Section 770.2 is amended:

a. By revising the phrase ''their original identify'' to read ''their original identity'' in paragraph (g)(3);

b. By revising the phrase ''Slovak Republic'' to read ''Slovakia'' in the introductory text of paragraph (k); and

c. By revising the phrase ''N-Methyl-3-piperidonol'' to read ''N-Methyl-3-piperidinol'' in paragraph (k)(26).

94. Section 770.3(c)(1) is amended:

a. By revising the phrase ''is subject to the EAR is the same manner'' to read ''is subject to the EAR in the same manner''; and

b. By revising the phrase ''described at § 732.4 of the EAR.'' to read ''described in § 734.4 of the EAR.''.

95. Section 770.3 is further amended:

a. By revising the phrase ''described at § 732.4 of the EAR.'' to read ''described in § 734.4 of the EAR.'', in paragraph (c)(2);

b. By revising paragraph (d)(1)(i)(B);

c. By revising paragraph (d)(1)(ii); and

d. By revising paragraph (d)(2)(ii), as follows:

§ 770.3 Interpretations related to exports of technology and software to destinations in Country Group D:1.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) Can we send an engineer (with knowledge and experience) to the customer site to perform the installation or repair, under the provisions of License Exception TSU for operation technology and software described in § 740.13(a) of the EAR, if it is understood that he is restricted by our normal business practices to performing the work without imparting the knowledge or technology to the customer personnel?

(ii) *Answer 1.* Export of technology includes release of U.S.-origin data in a foreign country, and ''release'' includes ''application to situations abroad of personal knowledge or technical experience acquired in the United States.'' As the release of technology in the circumstances described here would exceed that permitted under the License Exception TSU for operation technology and software described in § 740.13(a) of the EAR, a license would be required even though the technician could apply the data without disclosing it to the customer.

(2) * * *

(ii) *Answer 2.* (A) Provided that this is your normal training, and involves technology contained in your manuals and standard instructions for the exported equipment, and meets the other requirements of License Exception TSU for operation technology and software described in § 740.13(a), the training may be provided within the limits of those provisions of License Exception TSU. The location of the training is not significant, as the export occurs at the time and place of the actual transfer or imparting of the technology to the customer's engineers.

(B) Any training beyond that covered under the provisions of License Exception TSU for operation technology and software described in § 740.13(a), but specifically represented in your license application as required for this customer installation, and in fact authorized on the face of the license or a separate technology license, may not be undertaken while the license is suspended or revoked.

PART 772—[AMENDED]

96. Part 772 is amended:

a. By revising the citation reference ''§ 748.4'' to read § 748.5'' in the definition for ''Applicant'';

b. By revising the phrase ''perform (a) specific function'' to read ''perform a specific function'' in the definition for ''Assembly'';

c. By revising the definition for ''CCL Group'';

d. By revising the definition for ''Category'';

e. By revising the phrase ''application for International Import Certificate; International Import Certificate; Delivery Verification Certificate'' to read ''application for International Import Certificate; Delivery Verification Certificate'' in the definition for ''Export control document'';

f–g. By revising the definition of ''Required'';

h. By revising the phrase ''Mixed sequence manipulation'' to read ''Fixed sequence manipulation'' as it appears in paragraph (b) to the Note under the definition for ''Robot'';

i. By revising the phrase ''commodities, Software, technology'' to read ''commodities, software, technology'' in the definition for ''Subject to the EAR'';

j. By revising the phrase ''by low of elongation'' to read ''by low elongation'' in the definition for ''Superplastic forming''; and

k. By revising the citation reference ''§ 748.4(b)(5)'' to read ''§ 748.5(e)'', in the definition for ''Ultimate Consignee''.

PART 772—DEFINITIONS OF TERMS

* * * * *

CCL Group. The Commerce Control List (CCL) is divided into 10 categories. Each category is subdivided into five groups, designated by the letters A through E: (A) Equipment, assemblies and components; (B) Test, inspection and production equipment; (C) Materials; (D) Software; and (E) Technology. See § 738.2(b) of the EAR.

* * * * *

Category. The Commerce Control List (CCL) is divided into ten categories: (0) Nuclear Materials, Facilities and Equipment, and Miscellaneous; (1) Materials, Chemicals, ''Microorganisms'', and Toxins; (2) Materials Processing; (3) Electronics Design, Development and Production; (4) Computers; (5) Telecommunications and Information Security; (6) Sensors; (7) Navigation and Avionics; (8) Marine; (9) Propulsion Systems, Space Vehicles, and Related Equipment. See § 738.2(a) of the EAR.

* * * * *

''Required''. As applied to ''technology'' or ''software'', refers to only that portion of ''technology'' or ''software'' which is peculiarly responsible for achieving or extending the controlled performance levels, characteristics or functions. Such ''required'' ''technology'' or ''software'' may be shared by different products. For example, assume product ''X'' is controlled if it operates at or above 400 MHz and is not controlled if it operates below 400 MHz. If production technologies ''A'', ''B'', and ''C'' allow production at no more than 399 MHz, then technologies ''A'', ''B'', and ''C'' are not ''required'' to produce the controlled product ''X''. If technologies ''A'', ''B'', ''C'', ''D'', and ''E'' are used together, a manufacturer can produce product ''X'' that does not operate at or above 400 MHz. In this example, technologies ''D'' and ''E'' are ''required'' to make the controlled product and are themselves controlled under the General Technology Note. (See the General Technology Note.)

* * * * *

Dated: May 1, 1997.

Sue E. Eckert,

Assistant Secretary for Export Administration.

[FR Doc. 97–11727 Filed 5–8–97; 8:45 am]

BILLING CODE 3510–33–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Bunched Orders and Account Identification

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Interpretation and Approval Order.

SUMMARY: The Commodity Futures Trading Commission (''Commission'') hereby is issuing an Interpretation regarding the account identification requirement of Commission Regulation

1.35(a–1)(2)(i) as it pertains to the practice of combining orders for different accounts into a single order for placement and execution, *i.e.*, ''block'' or ''bunched'' orders. The Commission simultaneously is issuing an Order approving the National Futures Association (''NFA'') Interpretive Notice to NFA Compliance Rule 2–10 Relating to the Allocation of Block Orders for Multiple Accounts (''NFA Notice'').[1] This Interpretation provides that, with respect to bunched orders, compliance with the guidance provided in the NFA Notice, incorporated herein, and with the Commission guidance provided in this Interpretation, will be deemed by the Commission to be compliance with the account identification requirement of the above-cited regulation. The Commission also is providing an opportunity for comment prior to this Interpretation and Approval Order becoming effective.

DATES: This Interpretation and Approval Order, subject to the Commission's consideration of any comments received, shall become effective simultaneously on June 9, 1997.

ADDRESSES: Interested person should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW., Washington, DC 20581. In addition, comments may be sent by facsimile transmission to facsimile number (202) 418–5521, or by electronic mail to secretary@cftc.gov. Reference should be made to bunched orders and account identification.

FOR FURTHER INFORMATION CONTACT: Duane C. Andresen, Special Counsel, Division of Trading and Markets, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW., Washington, DC 20581. Telephone: (202) 418–5490.

SUPPLEMENTARY INFORMATION:

I. Introduction

This Interpretation sets forth certain account documentation procedures under which bunched orders may be placed, recorded, executed, ''given up'' to multiple clearing firms, where applicable, and allocated to customer accounts, which the Commission will deem as sufficient to satisfy the account identification requirement of Regulation 1.35(a–1)(2)(i). By this Approval Order, the Commission, pursuant to Section 17(j) of the Commodity Exchange Act, is approving the NFA Notice. The Commission also is setting forth additional guidance under which bunched orders may be handled, to include situations where certain of the NFA procedures may not be applicable in that they do not apply to registrants who are not members of the NFA or under the supervision of NFA members.[2]

The Commission's issuance of this Interpretation and Approval Order is based on its understanding that (1) commodity trading advisors (''CTA''), futures commission merchants (''FCM''), introducing brokers (''IB''), consistent with their responsibilities hereunder, will maintain documentation sufficient to demonstrate that the procedures authorized hereby are in fact followed, and (2) affected registrants, exchanges and the NFA will have effective systems in place that are used to monitor compliance and that appropriate procedures will be in place to address apparent noncompliance. In this connection, Commission staff recently has reviewed relevant audit and compliance procedures at the NFA and exchanges with respect to account identification for bunched orders. Commission staff also, on an ongoing basis, has encouraged the implementation of audit enhancements to address the types of allocation abuses observed in connection with exchange and Commission investigations regarding preferential allocation and other forms of allocation fraud.

In general, as specified herein with respect to bunched orders, the floor order account identification requirement of Commission Regulation 1.35(a–1)(2)(i) may be met by prefiling the appropriate order allocation procedures with a registrant clearing or executing the trades, the NFA or an exchange. That regulation's account identification requirement also may be met by the contemporaneous transmission of such allocation instructions with the order to a registrant clearing or executing the trades, either verbally or, consistent with the methodology described in the NFA Notice, electronically. These prefiled procedures or contemporaneous instructions also must include a methodology to allocate to those accounts orders that may be filled at multiple prices (''split fills'') or at less than specified quantities (''partial fills'') and, where applicable, to allocate give ups to multiple clearing firms, including a methodology to allocate split and partial fills among those clearing firms. CTAs, FCMs, IBs, their respective associated persons (''AP''), and FBs, as applicable, who do not identify the ultimate customer(s) and appropriate quantity on a floor order must satisfy the standards set forth in the NFA Notice and the Commission guidance provided herein to be in compliance with Commission Regulation 1.35(a–1)(2)(i). Compliance with the express terms of Regulation 1.35(a–1)(2)(i) will continue to be required in all cases where the procedures referenced in this Interpretation are not applicable or are not followed.

II. Background

Commission Regulation 1.35(a–1)(1) requires that each FCM and each IB receiving a customer order immediately prepare a written record of the order which includes certain account identification. Regulation 1.35(a–1)(2)(i) requires that each member of a contract market who receives a customer's order on the floor of a contract market that is not in the form of a written record also immediately prepare a written record of such order, including certain account identification. Under that rule, the floor order must include the account number for the ultimate customer for whom the order is placed or an identifying code which is directly linked to that specific customer account. This requirement has existed since Regulation 1.35(a–1)(2) became effective March 24, 1972.[3] Since this regulation was adopted, there have been changes in the manner in which orders are placed, executed and cleared on the futures markets that reflect changes in the manner of doing business and in the types of entities using these markets. With the growth of managed funds business, in which multiple accounts are advised by one adviser using one or more trading strategies, the practice of bunching multiple orders for different accounts into a single order for placement and execution has increased dramatically. In addition, the unbundling of clearing and execution services has resulted in the increasingly common use of give up arrangements, whereby orders are executed by one or more FCMs and given up for clearing to other FCMs. While the CTA selects the executing FCM, the CTA's customers may select different FCMs for clearing purposes.

[1] The NFA Notice is published herein as paragraph III to this Interpretation and Approval Order.

[2] The interpretation reflected herein pertains only to bunched orders as defined in this Interpretation or the NFA Notice. All other customer orders placed for execution must be documented in accordance with the express terms of Regulation 1.35(a–1)(2)(1) and applicable exchange rules.

[3] 37 FR 3802 (February 23, 1972). Regulation 1.35(a–1)(2) was amended effective August 30, 1993 and was redesignated as 1.35(a–1)(2)(i). 58 FR 31162 (June 1, 1993). The requirement to include customer account identification on the floor order remained unchanged.

Previously, to accommodate these changes in industry practice, Commission staff interpreted Regulation 1.35(a–1)(2)(i) to permit the placement and execution of bunched orders provided that the person placing the bunched order provided at the time of entry a single series designation that identified all accounts included in the bunched order and a predetermined allocation formula. That interpretation required that the allocation formula be provided to the FCM prior to or contemporaneously with the placement of the bunched order, specify by account number those accounts to which it would apply, specify the number of contracts to be allocated to each account, and be designed to provide fair and equitable treatment of the accounts such that no account or group of accounts received consistently favorable or unfavorable treatment. That interpretation of Regulation 1.35(a–1)(2)(i) consistently has been provided in response to specific inquiries and, in recognition that written regulatory guidance in this area may be necessary, was published in the **Federal Register** as paragraph (5) of a proposed amendment to Regulation 1.35(a–1).[4] In issuing this Interpretation, the Commission expressly is adopting procedures consistent with the staff interpretation as clarified herein and withdrawing proposed Regulation 1.35(a–1)(5).

III. The NFA Notice

The NFA Notice addresses three primary issues: (1) The manner and timing of the identification of the allocation formula; (2) principles that govern the allocation of trades; and (3) bunched orders executed on a give up basis, and reads in full as follows:

NFA Compliance Rule 2–10; Interpretive Notice Relating to the Allocation of Block Orders for Multiple Accounts

CFTC Regulation 1.35, which NFA Compliance Rule 2–10 adopts by reference, requires that each FCM receiving a customer order immediately prepare a written record of the order which includes an appropriate account identification. NFA Compliance Rule 2–4 requires CTA Members to provide FCMs with that required information. The purpose of the regulation is to prevent various forms of customer abuse, such a fraudulent allocation of trades, by providing an adequate audit trail which allows customer orders to be tracked at every step of the order processing system. Since this regulation was originally adopted, however, there have been dramatic changes in the way business is done. With the explosive growth of the managed funds business and the increasing use of ''give-up'' agreements, it is not at all uncommon for some CTAs to place block orders for hundreds of accounts on markets around the world, with orders executed by one or more FCMs and cleared by other FCMs. How the basic requirements of CFTC Regulation 1.35 apply to block orders for multiple accounts (''block or bunched order'') has been the source of considerable difficulty and confusion. While this Notice does not attempt to address all of the issues which can arise in this context, it does provide guidance on commonly recurring questions.

With respect to block orders, CFTC Regulation 1.35 has been interpreted to require that, at or before the time the order is placed, the FCM must be provided with information which identifies the accounts included in the block order and which specifies the number of contracts to be allotted to each account. In most instances, a CFTA can verbally provide all of that information contemporaneously with the placement of the order. Some of the time, however, this is not practical. Verbal transmission of numerous account numbers and allocation information could result in price slippage in filling block market orders. Most CTAs can deal with this problem by pre-filing with the FCM standing instructions which contain all of the necessary information.

For a limited number of larger and more sophisticated CTAs, however, pre-filing standing instructions may not be practicable either. For these CTAs, although their basic allocation methodology does not change, the specific allocation instructions produced by the methodology may change on a daily basis. For example, a large CTA with a dynamic trading program may regularly change its order size based upon market volatility and historical price data. Certainly, if a CTA changes its order size, then the precise number of contracts allocated to each account within the CTA's trading program will also change. Other factors could cause regular changes to a CTA's order size and/or allocation breakdowns such as the number of accounts which open and close and any additions and withdrawals made in existing accounts. In the above instances, although the specific application of a CTA's allocation methodology to the universe of its accounts may cause allocation adjustments, the allocation methodology itself remains constant. Because the methodology must meet the standards of this Notice, it must be designed to provide non-preferential treatment for all accounts. Though these CTAs could provide the allocation information to their FCMs in advance of each order, this information could disclose their trading strategies, which they are obviously reluctant to do.

In general, then, there are two alternatives to the verbal filing of all account identification data contemporaneously with order placement:

(1) pre-filing of instructions for identification of accounts included in block orders and the allocation of executed block orders to accounts; and

(2) under the stringent requirements described below, the contemporaneous filing of allocation instructions via electronic transmission.

This Interpretive Notice clarifies how either approach can be implemented consistent with the requirements of CFTC Regulation 1.35.

Pre-Filing of Allocation Instructions

Allocation instructions for trades made through block orders for multiple accounts must deal with two separate issues. The first, which arises in all such orders, involves the question of how the total number of contracts should be allocated to the various accounts included in the block order. The second involves the allocation of split or partial fills. For example, a CTA may place a block order of 100 contracts for multiple accounts. In many instances, however, a market order for 100 contracts may be filled at a number of different prices. Similarly, if an order is to be filled at a particular price, the FCM may be able to execute some but not all of the 100 lot order. In either example, the question arises of how the different prices or the contracts in the partial fill should be allocated among the accounts included in the block order.

The same set of core principles govern the procedures to be used in handling both of these issues. Any procedure for the general allocation of trades or the allocation of split and partial fills must be:

- Designed to meet the overriding regulatory objective that allocations are non-preferential, such that no account or group of accounts receive consistently favorable or unfavorable treatment;
- Sufficiently objective and specific that the appropriate allocation for any given trade can be verified in any audit by NFA, an exchange DSRO, the CFTC or the FCM's and CTA's own accountant; and
- Consistently applied by the Member firm.

In performing audits, we have noted that Members employ a wide variety of methods to allocate split and partial fills, some of which satisfy the standards stated above and some of which do not. The following examples of procedures for the allocation of split and partial fills generally satisfy the standards stated above.

Example #1—Rotation of Accounts

One basic allocation procedure involves a rotation of accounts on a regular cycle, usually daily or weekly, which receive the most favorable fills. For example, if a firm has 100 accounts trading a particular trading program, in the first phase of the cycle, Account #1 receives the best fill, Account #2 the second best, etc. In phase 2 of the cycle, Account #2 receives the best fill and Account #1 moves to the end of the line and receives the least favorable fill.

Example #2—Random Allocation

Some firms prepare on a daily basis a computer generated random order of accounts and allocate the best price to the first account on the list and the worst to the last. This method would satisfy the standards stated above.

Example #3—Highest Prices to the Highest Account Numbers

Some firms rank accounts in order of their account numbers and then allocate the highest fill prices to the accounts with the

[4] 58 FR 26270 (May 3, 1993).

highest account numbers. Any advantage the higher numbered accounts enjoy on the sell order are theoretically offset by the disadvantage on the buy orders. Although under certain market conditions this may not always be true, the method generally complies with the standards.

Example #4—Average Price and Quantity

With regard to split and partial fills, allocations made pursuant to exchange rules which provide for the allocation of average prices and quantities in block orders for multiple accounts would, of course, be acceptable. In addition, certain firms may have internal programs which calculate the average price for each block order and allocate the actual fill prices among the accounts included in the order to approximate, as closely as possible, the average fill price. These internal programs must specifically satisfy the standards stated above and be documented by the Member firm.

Though the examples cited above are the ones NFA most commonly sees in audits, others may offer comparable treatment. We would also note that the appropriateness of any particular method for allocating split and partial fills depends on the CTA's overall trading approach. For example, a daily rotation of accounts may satisfy the general standards for CTAs who trade on a daily basis but inappropriate for CTAs who trade less frequently. In addition, certain variations of these basic methods would not satisfy those requirements. For example, it would not be acceptable for the CTA to deviate from the regular rotation to accommodate an account whose performance is lagging behind others in the same program. This would inject the CTA's subjective judgment into the process, would render the allocation impossible to duplicate in the audit process and would open the potential for customer abuse.

One related issue which has generated some confusion is whether the responsibility for the allocation of split and partial fills rests with the CTA or with the FCM. The CTA certainly has the sole responsibility for ensuring that the procedures are appropriate in light of its approach to trading. With respect to the actual implementation of the procedures, since the CTA is directing the trading in the accounts, the responsibility for allocating split and partial fills among the accounts should rest with the CTA. However, there is nothing under NFA rules to preclude an FCM from agreeing to undertake this responsibility, whether it clears or executes the trades, pursuant to either its own procedures or to those supplied by the CTA. Any division of responsibilities agreed to by the FCM and CTA should be clearly documented.

There is also good deal of confusion on how the basic principles of CFTC Regulation 1.35 apply to block orders executed on a ''give-up'' basis, a process which was essentially unknown when Regulation 1.35 was originally adopted. Subject to exchange rules, in any given block order there may be multiple executing FCMs, multiple clearing FCMs or multiple FCMs serving each of these functions. The exact form of customer identification which the FCM must receive from the CTA under Regulation 1.35 may vary depending on the FCM's role in filling the order. Essentially, each FCM must receive sufficient information to allow it to perform its function. For executing FCMs, this includes, at a minimum, the number of contracts to be given up to each clearing FCM and instructions for allocation of split and partial fills among these FCMs. Information concerning the number of contracts to be allocated to each account included in the block order must be provided to the FCM which will carry out those instructions, which, in most cases, will be the FCM clearing the accounts. All of this information must be provided at or before the time the order is placed and could be provided by pre-filing a set of instructions. If the pre-filed instructions for the general allocation or the allocation of split and partial fills meet the standards set forth in this Notice, then the clerical task of implementing the instructions could be performed by either the FCM or the CTA.

If that clerical function is performed by the CTA, this does not suggest that the FCM is relieved of any further responsibility. The FCM has certain basic duties to its customers, including the duty to supervise its own activities in a way designed to ensure that it treats its customers fairly. Specifically, the FCM would violate this duty if it has actual or constructive notice that allocations for its customers may be fraudulent and fails to take appropriate action. The FCM with such notice must make a reasonable inquiry into the matter and, if appropriate, refer the matter to the proper regulatory authorities (e.g., the CFTC or the NFA or its DSRO). Obviously, whether an FCM has such notice depends upon the information that the FCM has or should have, which, in turn, is based upon the FCM's role in the executing and clearing process. For example, an FCM that both executes and clears an entire block order will possess more information than an FCM that executives or clears only a portion of an order. In order to fulfill its duties, and FCM at any level of the process should implement appropriate compliance measures. For example, an FCM may choose to spot check the allocations made to its customer accounts for conformity with the prefiled instructions it has received from the CTA and/or review the performance of accounts being traded pursuant to the same trading program.

Contemporaneous Filing of Instructions Via Electronic Transmission

Instructions for the allocation of contracts to accounts included in a block order can also be given at the time the CTA places the trade. NFA notes, however, that as a general rule allocation procedures for split and partial fills should be pre-filed with the appropriate FCM. For instructions on the number of contracts to be assigned to each account in the block order, many CTA's simply provide the necessary allocation information by phone when they call in the block order. For certain CTAs, however, providing allocation instructions verbally when the block order is placed may not be a practicable option. These CTAs may have hundreds of accounts included in the block order and providing detailed allocation information by phone may be extremely time consuming. Delaying the execution of the order while that process drags on might ultimately harm customers through market price slippage. For most of these CTAs, the prefiling of instructions provides an adequate alternative. However, for a limited number of CTAs, it may not be practicable to pre-file with the FCM a standing set of allocation instructions. The trading programs used by these CTAs are complex and dynamic. Given the fine tuning adjustments that are made on a daily basis, the exact number of contracts these CTAs allocate to any given account may vary from one day to the next, and may make the prefiling of instructions impracticable.

Under these circumstances, one way the CTA may provide the account identification information required under CFTC Regulation 1.35 would be to send the FCM, by facsimile or other form of electronic transmission, the breakdown of contracts to be assigned to each account included in the block order. The CTA would have to begin to send that information at the time the order is placed. Given the possibility of busy signals, paper jams and other limitations of electronic transmissions, there may be momentary delays in the completion of the transmission. Such delays should be neither commonplace nor lengthy, and the CTA should maintain appropriate documentation whenever such delays occur. When those delays do occur, however, CFTC Regulation 1.35 does not necessarily require the FCM to delay execution of the order until the electronic transmission of the allocation information is completed. To avoid delays in execution due to such transmission difficulties, the CTA must have provided the FCM with a written certification that:

(1) the CTA will begin the transmission to the FCM of the allocation breakdown contemporaneously with the placement of the order and will maintain appropriate documentation regarding any delays experienced in such transmission;

(2) prior to the placement of an order, the CTA has also generated a non-preferential allocation breakdown for each order which has been computer time-stamped indicating the date on which the order is to be placed and the date and time the allocation breakdown was printed;

(3) the CTA maintains with either their executing or clearing FCMs a complete list of all accounts traded by the CTA, by trading program if applicable;

(4) if a bunched order does not include all accounts within a particular trading program, then prior to the execution of the order these CTAs will identify for their FCMs the accounts which are included, by account identifier or designation;

(5) on a daily basis, these CTAs confirm that all their accounts have the correct allocation of contracts; and

(6) at least once a month, these CTAs analyze each trading program to ensure that the allocation method has been fair and equitable. If divergent performance results exist over time, then such results must be shown to be attributable to factors other than

the CTA's trade allocation or execution procedures. Additionally, a CTA must document its internal audit procedures and the results of its monthly analysis and maintain these audit procedures and results as firm records subject to review during an NFA audit.

An FCM which relies in good faith on the above certification would be deemed to be in compliance with CFTC Regulation 1.35. The CTA must also file a copy of that certification with NFA at least thirty days prior to implementing these procedures. This time period will provide NFA with an opportunity to review and verify the information contained in the certification.

For most block orders, the pre-filing of allocation instructions is the most practicable and preferred course of action. The procedure described herein relating to the contemporaneous filing of instructions via electronic transmission is an alternative available to those relatively few CTAs that can demonstrate a need for this alternative and meet the requirements of the certification. Each CTA availing itself of this alternative must not only adhere to the requirements of this Notice, but also demonstrate on a continuing basis to the appropriate regulator or self-regulator both its need to use this alternative and that the information in the certification is correct. If a CTA utilizes this alternative, it must adhere to this Notice's requirements or may face disciplinary action for its failure to do so. If any Member has questions concerning how this Interpretive Notice would apply to its operations, please contact NFA's Compliance Department.

IV. Commission Guidance

In any instance in which a CTA bunches multiple orders for different accounts into a single order for placement and execution, the antifraud provisions of Sections 4b and 4*o* of the Commodity Exchange Act may be violated if the resulting allocation is not fair, equitable and consistent in its treatment of the accounts included in the order. A CTA may bunch orders and provide, at the time of order placement with an executing registrant,[5] an allocation designator, as defined herein, that the Commission will find to constitute compliance with the account identification requirement of Regulation 1.35(a–1)(2)(i) for the accounts included in the order, by the CTA or the executing registrant, respectively, provided that, consistent with the NFA Notice and the following:

1. The CTA provides to each carrying FCM to which fills are to be allocated, either by prefiling allocation procedures or (consistent with the guidance set forth in the NFA Notice) contemporaneously providing allocation instructions with the placement of the order, a methodology to allocate contracts to customer accounts that identifies the ultimate customer account numbers and includes procedures for allocating prices and quantities for split and partial fills to those customers;

2. The order pertains to a group of specified accounts previously or contemporaneously identified to the carrying firm(s); and

3. The order is intended to provide fills for all accounts included in a single trading program.

4. The executing registrant documents the order as follows:

a. For purposes of the documentation required pursuant to this paragraph 4., an allocation designator means a symbol which represents all or any portion of the following information not reflected on the floor order as may be necessary to identify the ultimate customers, quantities and prices: that is, the trading program and the allocation procedures or methodology, including procedures for allocating prices and quantities for split and partial fills among carrying firms and/or among ultimate customers.

b. If the bunched order is to be allocated to customer accounts at one carrying FCM, prior to the time the order is executed, the floor order must reflect (1) the carrying FCM, (2) the order quantity, and (3) an allocation designator.

c. If the bunched order is to be given up for allocation to customer accounts at more than one carrying FCM, prior to the time the order is executed, the floor order must reflect (1) each carrying FCM, (2) the quantity to be given up to each such FCM, and (3) an allocation designator.[6] Consistent with the guidance provided in the NFA Notice, allocation instructions may be provided by electronic transmission to the executing registrant contemporaneously with order placement.

d. Alternatively, if the bunched order is to be given up for allocation to customer accounts at more than one FCM and the CTA has prefiled, consistent with exchange rules,[7]—with the NFA, a designated clearing member, an executing registrant, or an exchange—a set of allocation procedures which (1) Identifies each FCM to which trades will be given up, (2) identifies a methodology to determine how many contracts each FCM would receive, and (3) identifies an allocation designator, prior to the time the order is executed, the floor order must reflect the order quantity and the allocation designator identifying the prefiled procedures.

e. Prefiled procedures ordinarily would be standing procedures that would remain unchanged for a reasonable period of time.

5. Any time a CTA prefiles allocation procedures as provided herein and the CTA, rather than the executing or clearing registrant, provides specific allocations, after the execution of an order, implementing those prefiled procedures, the CTA must provide those allocations as soon as practicable.

Consistent with the NFA Notice, if an executing registrant has notice, based upon the information available to that registrant, that (1) allocation procedures are not prefiled, (2) the CTA's instructions do not conform to the prefiled procedures of (3) the give up and/or split and partial fill procedures or instructions result in allocations that are not being made in a fair, equitable and consistent manner, either by quantity or price, the executing registrant must make reasonable inquiry into the matter and, if appropriate, refer the matter to the proper regulatory authorities.

V. Conclusion

Based on the foregoing, FCMs, IBs, CTAs, their respective APs, and FBs who handle bunched orders for multiple accounts shall be deemed to be in compliance with the account identification requirement of Commission Regulation 1.35(a–1)(2)(i) if such orders are placed, recorded, executed, given up to multiple clearing firms, if applicable, and allocated to customer accounts in accordance with the provisions set forth in the NFA Notice and in compliance with the above-stated Commission guidance.

This Interpretation and Approval Order is based upon the Commission's understanding that (1) affected registrants, consistent with their responsibilities as set forth herein, will maintain documentation sufficient to demonstrate that the procedures thus authorized are in fact followed and (2) affected registrants, exchanges and the NFA will have effective systems in place to monitor compliance and to address apparent noncompliance with

[5] "Executing registrant" refers to the registrant with whom the CTA places the bunched order for execution, and may be either an FCM or a floor broker.

[6] If the allocation instructions are provided contemporaneously with order placement to a floor trading desk or floor broker's clerk, the person receiving the order may immediately transmit the order's terms (that is, contract, quantity and price) to the executing broker, either by hand signals, verbal or written communication, while continuing to record the allocation information on the floor order. Order execution need not be delayed while such information is being recorded.

[7] Any exchange which permits the prefiling of procedures with the NFA or an exchange pursuant to this interpretation of Regulation 1.35(a–1)(2)(i) must have procedures in place for their executing members to confirm that CTA allocation procedures, including designators, are in fact prefiled.

the terms hereof. The Commission intends to monitor the procedures and practices followed pursuant hereto, including through review of the results of audits of registrants handling bunched orders. Based thereon, the Commission may provide further guidance as appropriate.

Dated: May 5, 1997.

By the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 97–12161 Filed 5–8–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 95F–0163]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of high-purity furnace black as a colorant for polymers intended for use in contact with food. This action is in response to a petition filed by Cabot Corp.

DATES: The regulation is effective May 9, 1997. Submit written objections and requests for a hearing by June 9, 1997. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 178.3297(e), effective May 9, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 20, 1995 (60 FR 37452), FDA announced that a food additive petition (FAP 5B4464) had been filed by Cabot Corp., 75 State St., Boston, MA 02109–1806. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of high-purity furnace black as a colorant for polymers intended for use in contact with food.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of polynuclear aromatic hydrocarbons (PAH's), which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as polynuclear aromatic hydrocarbons in this instance, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additive anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA concludes that the additive, high-purity furnace black, is insoluble in common solvents, including aqueous and fatty foods. As a consequence, there is no potential for significant levels of migration of the furnace black to contacted food (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that because there is no potential for significant levels of migration of furnace black to contacted food, there are no concerns regarding the safety of the additive itself.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by PAH's, the carcinogenic chemicals that may be present as impurities in the additive. The risk evaluation of PAH's has two aspects: (1) Assessment exposure to the impurities from the intended use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of exposure to humans.

A. Polynuclear Aromatic Hydrocarbons

FDA has estimated the worst-case exposure to PAH's from the petitioned use of the additive as a colorant in polymers to be no greater than 0.001 parts per billion (ppb) in the daily diet (3 kilograms (kg)), or 3 nanograms per person per day (ng/person/day). Further, the dietary concentration of benzo[a]pyrene, one member of the PAH family, was estimated to be no greater than 0.01 parts per trillion in the daily diet (3 kg), or 30 picograms /person/day (Ref. 1).

PAH's occur as a mixture of compounds; the toxicity of these compounds varies, and some members of the family have been shown to be carcinogenic in animal studies. In assessing the upper-bound limit of lifetime human risk, FDA prefers to use actual toxicity data for the specific contaminants. However, in the absence of such data, the agency believes that using the toxicity of one of the most potent cogeners in a family of contaminants will ensure that the upper-bound limit of lifetime human risk will not be underestimated. For this risk estimate, FDA has made the ''worst-case'' assumption that all PAH's in the additive have the same carcinogenic potency as benzo[a]pyrene, a member of the PAH family that current data show to be one of the most potent carcinogens of this group.

The agency used data from a carcinogenesis bioassay on benzo[a]pyrene, conducted by H. Brune et al. (Ref. 3), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The

authors reported that the test material caused treatment-related benign forestomach tumors or esophageal tumors in male rats.

Based on the estimated worst-case exposure of 3 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the additive is 9×10^{-8}, or less than 1 in 10 million (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate and the carcinogenic potency of PAH's in the additive, the actual lifetime-averaged individual exposure to PAH's is likely to be substantially less than the worst-case exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to PAH's would result from the petitioned use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of PAH's present as impurities in the additive. The agency finds that specifications are necessary to ensure that the risk from PAH's resulting from the proposed use of high-purity furnace black in food-contact applications is insignificant and that use of the additive is safe. Therefore, the regulations set forth in this document prescribe that high-purity furnace black shall not contain total PAH's in excess of 0.5 parts per million and shall not contain benzo[a]pyrene in excess of 5.0 ppb.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive as a colorant in polymers is safe; (2) the additive will achieve its intended technical effect; and (3) that therefore, the regulations in § 178.3297 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 9, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch, FDA, to the Indirect Additives Branch, FDA, concerning ''FAP 5B4464 (MATS # 819 M2.0 & 2.1): Cabot Corp. petition, through their agent Keller and Heckman, dated 5–18–95. High-Purity Furnace Black as a Colorant for Polymers,'' dated April 2, 1996.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger, J. K. Marquis, and S. Karger, New York, NY, pp. 24–33, 1985.

3. Brune, H., R. P. Deutsch-Wenzel, M. Habs, S. Ivankovis, and D. Schmahl, ''Investigation of the Tumorigenic Response to Benzo[a]pyrene in Aqueous Caffeine Solution Applied Orally to Sprague-Dawley Rats,'' *Journal of Clinical Research and Clinical Oncology*, 102:153–157, 1981.

4. Memorandum from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, concerning ''Estimation of the Upper-bound Lifetime Risk from Polynuclear Aromatic Hydrocarbons (PAH's) in High-Purity Furnace Black (HPFB): subject of Food Additive Petition No. 5B4464 (Cabot Corp.),'' dated May 9, 1996.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
High-purity furnace black (CAS Reg. No. 1333–86–4) containing total polynuclear aromatic hydrocarbons not to exceed 0.5 parts per million, and benzo[a]pyrene not to exceed 5.0 parts per billion, as determined by a method entitled ''Determination of PAH Content of Carbon Black,'' dated July 8, 1994, as developed by the Cabot Corp., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.	For use at levels not to exceed 2.5 percent by weight of the polymer.
* * *	* * * *

Dated: May 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12156 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Medicated Feed Applications; Semduramicin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for revised assay limits for Type C medicated semduramicin chicken feed to 80 to 110 percent of labeled claim.

EFFECTIVE DATE: May 9, 1997.

FOR FURTHER INFORMATION CONTACT: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 140–940, which provides for revising the assay limits for Type C medicated chicken feed containing Aviax™ (semduramicin sodium) from 85 to 110 percent of labeled claim to 80 to 110 percent. The supplemental NADA is approved as of April 8, 1997, and the regulations are amended in 21 CFR 558.4(d) to reflect the approval.

Revision of the assay limits for a Type C medicated feed is based on the evaluation of the assay procedure used to analyze the feed and analysis of the assays of those feeds. The initial assay limits were established based on the results of the method trial. Evaluation of the feeds used in the market support trials, comparable to commercial manufacturing operations, support a wider assay range. This action did not require reevaluation of the safety and effectiveness data supporting the original approval. Therefore, a freedom of information summary is not required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d), in the table entitled ''Category I,'' in the entry for ''Semduramicin,'' in the last column by removing the assay limits ''85–110'' and adding in its place ''80–110.''

Dated: April 30, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–12257 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 898

[Docket No. 94N–0078]

Medical Devices; Establishment of a Performance Standard for Electrode Lead Wires and Patient Cables

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing a performance standard for electrode lead wires and patient cables. The agency is taking this action because it has determined that a performance standard is needed to prevent electrical connections between patients and electrical power sources. The final rule will substantially reduce the risk of electrocution from unprotected electrode lead wires and patient cables.

DATES: This regulation is effective August 7, 1997, except that § 898.14 (21 CFR 898.14) is stayed pending Office of Management and Budget (OMB) clearance for information collection. FDA will announce the effective date of § 898.14 in the **Federal Register**. Submit written comments on the information collection provisions of this final rule by July 8, 1997.

For information on the compliance dates, see 21 CFR 898.13(a) and (b).

ADDRESSES: Submit written comments on the information collection provisions of this final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Ave., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 19, 1994 (59 FR 26352), FDA published an advance notice of proposed rulemaking (ANPRM) and announced the need for further FDA action to address the risk of patient exposure to macro shock or electrocution due to the inappropriate connection of a patient-connected cable or electrode lead wire to an alternating current (AC) power source. In that ANPRM, FDA described various regulatory actions it had taken since the first reported incidents in 1985 of exposed male connector pins of electrode lead wires being inserted into either AC power cords or a wall outlet, rather than into the patient cable that connects to the device monitor. The ANPRM also described actions that various organizations, such as, the Emergency Care Research Institute (ECRI) and outside standard setting bodies have taken to prevent electrode lead wires from being connected to electrical power sources. A summary of these actions is provided in section VII. of this document. In the ANPRM, FDA stated that ''despite efforts to eliminate the risk, unprotected electrode lead wires and patient cabling systems are still distributed by some manufacturers as replacements for existing equipment, and may also be interchangeable among various medical devices.'' (See 59 FR 26352 at 26353.) In the ANPRM, FDA further announced that it, in conjunction with the Health Industry Manufacturers Association and the American Hospital Association (AHA), was sponsoring a public conference entitled ''Unprotected Patient Cables and Electrode Lead Wires.'' The conference was held on July 15, 1994, and provided a forum for device users, manufacturers, and other health care professionals to offer and to hear comments for FDA's consideration during the rulemaking process.

The need for FDA action to resolve the hazard of the use of unprotected electrode lead wires and patient cables with medical devices was further emphasized in a letter dated August 2, 1994, to FDA Commissioner David A. Kessler, from the Honorable Ron Wyden, then Chairman, U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology (Ref. 1). In that letter, Mr. Wyden stated that ''shocks, burns, and electrocutions occur despite warnings issued by the FDA to hospitals, manufacturers, and others.''

Specifically, Mr. Wyden wrote that:

> Hospitals have been told to purchase and use only protected wires and cables. They have also been told to remove unprotected equipment and to alert staff members of possible hazards to patients.
>
> Manufacturers have been encouraged to modify their designs to prevent lead wires from being inserted into electrical outlets.
>
> Despite warnings and other communications, some manufacturers still distribute to hospitals unprotected [patient cables and] lead wires as replacements for deteriorated equipment.
>
> It is clear that regulatory action, as well as additional education and training, is needed to stop the slow but steady flow of children (and adults) who are burned or electrocuted.

FDA's records of incidents with unprotected electrode lead wires and patient cables reveal the following:

Between 1985 and 1994, 24 infants or children received ''macro-shock'' (large externally applied currents) from electrode lead wires or cables, including five children who died by electrocution (Ref. 2). The most recent death (1993), of a 12-day old infant, occurred in a hospital. The apnea monitor involved in the incident had been sold to the hospital with a protected electrode lead wire and patient cable. However, when the infant was electrocuted, an unprotected patient cable from a second manufacturer and unprotected prewired electrodes from a third manufacturer were being used instead of the protected configuration.

There are reports of injuries associated with unsafe electrode lead wires and patient cables involving medical devices other than apnea monitors (Ref. 3). In 1986, for example, a death occurred when the electrocardiogram (ECG) lead wires were inserted into a pulse oximeter power cord. FDA has received additional reports of similar events that resulted in electrical shocks, burns, and possible brain damage to patients.

In response to the death and electrical burns that occurred in 1985, FDA issued an alert to home-use apnea monitor manufacturers, home user support organizations, and apnea monitor users, announcing, among other things, the agency's intent to embark on a cooperative effort with industry and the medical profession to resolve the problem of users making a hazardous electrical connection between the patient and an electrical power source. FDA also requested each home-use apnea monitor manufacturer to assess its device for potential electrode lead wire and patient cable connection hazards and, when necessary, to consider design changes to preclude insertion of electrode lead wire connectors into AC power cords and outlets. In addition to issuing the alert, FDA's Center for Devices and Radiological Health's (CDRH's) July 1985 ''Medical Devices Bulletin'' was devoted primarily to publicizing the unprotected electrode lead wire and patient cable connection hazard.

Since 1985, FDA has not cleared for marketing any home-use apnea monitor that features an unprotected electrode lead wire and patient cable configuration. For all apnea monitors cleared for marketing since 1989, FDA has required a protected electrode lead wire and patient cable design, whether or not the device was intended for home use. Despite these efforts, some hospitals continue to use older units, or electrode lead wires and patient cables from other devices, which do not have the protected cable and electrode lead wire design. Even with the new protected models, as evidenced by the 1993 incident, it may be possible to switch to use of an unprotected electrode lead wire and patient cable configuration, thereby recreating the hazard.

On September 3, 1993, FDA issued a safety alert to hospital administrators, risk managers, and pediatric department directors, warning them that the use of unprotected electrode lead wires and patient cables with an apnea monitor may be dangerous to the patient, and may be in violation of section 518(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h(a)) (Ref. 4). FDA included in the alert a number of recommendations to help prevent these accidents. FDA also sent all apnea monitor manufacturers a notification letter under section 518(a) of the act (Ref. 5).

Section 518(a) of the act authorizes the agency to issue an order to ensure that adequate notification is provided in an appropriate form, by the means best suited under the circumstances involved, to all health care professionals who prescribe or use a particular device and to any other person who should properly receive such notification, in

order to eliminate an unreasonable and substantial harm to the public health when no other practicable means is available under the act to eliminate such risk. FDA stated that, for these devices, notification should include replacement of unprotected apnea monitor electrode lead wires and patient cables, and that a warning label should be permanently affixed to all apnea monitors stating that unprotected electrode lead wires and patient cables should not be used with the device because inappropriate electrical connections may pose an unreasonable risk of adverse health consequences or death. FDA also requested manufacturers of all apnea monitors to cease further distribution of unprotected electrode lead wires and patient cables. On September 20, 1993, FDA issued a similar letter to all known third-party manufacturers of electrode lead wires and patient cables (Ref. 6).

On December 28, 1993, FDA issued a Public Health Advisory to hospital nursing directors, risk managers, and biomedical/clinical engineering departments for distribution to all units in their hospitals and outpatient clinics, as well as to home health care providers and suppliers affiliated with those facilities, advising them of the hazards associated with use of electrode lead wires with unprotected male connector pins (Ref. 7). In the Public Health Advisory, FDA expanded the scope of its September 3, 1993, apnea monitor safety alert to include all devices using unprotected electrode lead wires and patient cables. FDA noted that, even though many manufacturers have changed the design of their devices to minimize the potential hazard, some facilities are still using older models that make it possible for staff to switch to unprotected patient cables and lead wires, thus recreating the hazard. FDA recommended various precautions be taken to prevent the use of unprotected electrode lead wires and patient cables.

Manufacturers of devices other than apnea monitors that utilize patient-connected electrode lead wires, e.g., ECG monitors, have been encouraged by various organizations to modify their electrode lead wires and patient cables so that they cannot be inserted into AC power cords or outlets. For example, in February 1987 and May 1993, ECRI issued hazard reports concerning electrical shock hazards from unprotected electrode lead wires and patient cables. Further, standards-setting bodies have developed various standards, both in draft and final form, that have the same goal in mind—safety requirements for electrode lead wires and patient cables.

In March 1995, the International Electrotechnical Commission (IEC) published a second amendment to IEC 601–1 (1988), the safety standard for electromedical equipment, which includes a requirement that electrode lead wires be unable to make contact with hazardous voltages.

The Underwriters Laboratories (UL) adopted a modified version of IEC 601–1 by issuing its standard 2601–1, which became effective on August 31, 1994. This standard superseded UL 544 (referenced in the ANPRM). In adopting the IEC standard, UL included a deviation requiring that patient-connected electrodes be designed to avoid connection to electrical power sources. (See UL 2601–1, Medical Electrical Equipment Part 1: General Requirements for Safety.) The UL standard states in the rationale section that ''this is a basic safety concern prompted by recent accidents involving patient injury, including infant deaths. Patients were being accidently connected to hazardous circuits while being connected to applied parts of medical equipment, such as an apnea monitor.'' FDA has been advised that it is possible that UL will modify its requirement to be equivalent to the one included in the second amendment to IEC 601–1 (1988).

There is also a German DIN standard for touch proof connectors for electromedical applications. This design standard was also referenced in the ANPRM and states that it was developed because of the accidents that occurred with infants in 1985 and 1986.

The National Fire Protection Agency (NFPA) is also proposing a standard for patient electrode lead wire connectors. FDA has received information that, even though it is voluntary, this NFPA standard will be adopted by many States and municipalities as a mandatory standard for health care facilities. Further, this standard is referenced by the hospital accrediting body, the Joint Commission on Accreditation of Health Care Organizations.

Finally, the Association for the Advancement of Medical Instrumentation (AAMI) has developed a standard that covers electrode lead wires and patient cables for surface electrocardiographic monitoring in cardiac monitor applications (ECG cables and lead wires, ANSI/AAMI EC53–1995). This design standard addresses safety and performance of electrode lead wires and patient cables with the added purpose of discouraging the availability of unprotected patient cable and lead wire configurations for ECG monitoring applications. The standard defines a safe (no exposed metal pins) common interface at the cable yoke and electrode lead wire connector. The standard was approved by ANSI on December 7, 1995.

FDA believes that industry also recognizes the importance of addressing this hazard. In response to FDA's alert letter in June 1985, manufacturers voluntarily began to redesign their electrode lead wires and patient cables for home apnea monitors. More recently, many firms have taken voluntary action to recall electrode lead wires and patient cables with unprotected exposed metal pins. Apnea monitor firms are replacing their male pin lead wires and associated cables with safety cable systems, usually free of charge, while other device manufacturers are making adapters and warning labels available. Some device manufacturers have ceased supplying unprotected electrode lead wires and patient cables altogether.

II. The Proposed Rule

Despite repeated efforts to reduce the risk associated with the use of unprotected electrode lead wires and patient cables, these products are still available and in use in homes and in various health care settings.

In the **Federal Register** of June 21, 1995 (60 FR 32406), FDA issued a proposed rule designed to allow the orderly removal of unprotected electrode lead wires and patient cables from the marketplace. The proposal set forth a phased-in approach for removing unprotected lead wires and patient cables while seeking to minimize the economic impact to manufacturers and user facilities during the transition to a protected cabling configuration.

Under FDA's proposed phased-in approach, unprotected lead wires and patient cables would be subject to a proposed performance standard, developed by FDA. The effective date for any final regulation based on the proposal was to be phased-in over 1 or 3 years, depending on the device type. Under the proposed rule, any devices that did not meet the standard on its effective date would be banned.

Devices that were to be subject to the 1-year effective date were those devices believed to present the greatest potential risk of harm as demonstrated by use in environments where accidental inappropriate connections could reasonably be anticipated, and by frequent use of the devices and frequent connections of electrode lead wires. Devices subject to the 1-year effective date included all devices that had been the subject of reported adverse events, as well as other devices believed to present the greatest potential risk of

harm. Devices that were proposed to be subject to the 3-year effective date were those devices that did not satisfy the criteria for the 1-year effective date but also utilized unprotected electrode lead wires. As stated earlier, the agency proposed to ban those devices that did not meet the standard on its effective date.

FDA received comments on various aspects of the proposed rule, including: (1) The cost of conversion for manufacturers and user facilities; (2) the placement of a given device on the 1-year or the 3-year list; (3) the appropriate list for devices that were not specifically mentioned on either list, as well as for future devices; and (4) whether the agency might adopt one of the consensus performance standards mentioned in the proposed rule instead of issuing a new one. This final rule addresses these concerns and others in providing a cost effective remedy to eliminate an inappropriate, but preventable occurrence of macro shock or electrocution due to the accidental connection of an electrode lead wire or patient cable to an AC power source.

III. Highlights of the Final Rule

In response to comments, the agency has revised and clarified certain provisions of the final regulation. The final rule establishes a performance standard that FDA believes will eliminate the risk, to the extent possible, of unprotected electrode lead wires and patient cables being inadvertently inserted or manipulated so as to make contact with live parts of an AC power cord or electrical outlet. This standard applies to all electrode lead wires and patient cables. The revisions in the final rule are based on focusing the regulation on the most cost-effective mechanism of accomplishing its important public health goal. The most significant changes from the proposed rule follow:

1. The performance standard being established applies directly to electrode lead wires and patient cables, rather than to the medical equipment to which they are attached. This revision focuses the standard on the actual products that could create a patient hazard.

2. In issuing this standard, the agency is adopting the relevant portion of a recently updated international standard (IEC 601–1). This standard contains all the necessary provisions for patient protection. Moreover, by adopting an existing and widely followed international standard, the cost to industry in complying with this standard is minimized.

3. The agency is revising the effective date so that only the electrode lead wires and patient cables used with those devices presenting the greatest potential risk will be required to conform to the standard within 1 year. Specifically, the 1-year category has been limited to 10 devices that, if unprotected, present the greatest potential risk of harm as demonstrated by past incidents, their use in environments where accidental inappropriate connections could most likely be anticipated, or by the frequency with which the devices are used and the frequency of connections of the patient-connected electrode lead wires. Electrode lead wires and patient cables that are intended for use with those 10 devices will be required to conform to the standard within 1 year. FDA has placed all remaining devices in the 3-year category. Electrode lead wires and patient cables that are subject to the 3-year effective date are those used with, or intended for use with devices that are not subject to the 1-year effective date.

4. The agency has deleted the provision banning devices that do not meet the standard because such a provision is unnecessary. Under section 501(e) of the act (21 U.S.C. 351(e)) electrode lead wires and patient cables not meeting the performance standard on or following the effective date are adulterated.

5. This rule constitutes the first mandatory performance standard established by FDA under section 514 of the act (21 U.S.C. 360d).

IV. The Framework

In order to eliminate the risk of macro shock and electrocution in the future, the agency is establishing a performance standard for all electrode lead wires and patient cables. In reaching this decision, the agency reviewed several standards that are in various stages of development before deciding to adopt a provision of the international performance standard of IEC 601–1 on lead wires for medical devices.

Firms whose electrode lead wire and patient cable systems are subject to this performance standard should begin to adapt existing products to meet the standard, if they have not already done so, before the effective date of the standard. These efforts are consistent with Congress' admonition that ''stockpiling of nonconforming devices is discouraged, since standards will apply to all devices in commercial channels on their effective date.'' (See H. Rept. 853, 94th Cong., 2d sess. 30; see also 45 FR 7474, February 1, 1980, final standards regulation.)

Later in this document, FDA is publishing a list of the 10 devices at highest risk of a user inadvertently connecting the device's electrode lead wire(s) or patient cable to an AC power source. One year from the publication date of this rule, unprotected electrode lead wires and patient cables intended for use with, or used with, any of these 10 devices will be subject to FDA's performance standard. Three years after the publication date of this rule, unprotected patient cable and lead wire systems intended for use with any other medical device, absent an FDA waiver or exemption, will be subject to FDA's performance standard. FDA reserves the right, upon proper notification to interested parties, to amend the list of devices in the future. FDA believes the effective dates are reasonable and consistent with the congressional intent in enacting section 514 of the act, as well as with comments received at the public conference and written comments on the proposed rule.

The agency anticipates a smooth, but rapid, transition for the vast majority of existing devices to a protected electrode lead wire and patient cable configuration following publication of the final rule.

V. Performance Standard

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) prescribes changes to the act (21 U.S.C. 321–394), as amended, that improve the regulation of medical devices and strengthen the Medical Device Amendments of 1976, which established a comprehensive framework for the regulation of medical devices.

The SMDA amended section 513 of the act (21 U.S.C. 360c) to redefine class II as the class of devices that is or will be subject to special controls, and amended section 514 of the act to simplify the requirements for establishing performance standards. Section 513 of the act states that the ''special controls * * * shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device.'' The legislative history of the SMDA states that:

> by simplifying the process for establishing performance standards, and by allowing the Secretary discretion to employ such standards as one of a variety of additional controls to assure the safety and effectiveness of Class II devices, performance standards will become valuable tools to regulate those devices for which they are most needed.

(S. Rept. 513, 101st Cong., 2d sess. 19 (1990))

Under this rule, the mandatory performance standard applies to all electrode lead wires and patient cables intended for use with medical devices and is phased-in over a period of 1 or

3 years. New § 898.12(a) and (b) identifies the devices that are subject to the performance standard, with the applicable effective dates of the standard.

A. The Standard

FDA is issuing the following standard for electrode lead wires or patient cables:

Electrode lead wires and patient cables shall comply with the International Electrotechnical Commission (IEC) standard 601–1 subclause 56.3, paragraph c (1995).

Compliance with this standard shall be determined by inspection and by applying the test requirements also found in IEC 601–1, subclause 56.3(c). This standard is available from the American National Standards Institute (ANSI), 11 West 42nd Street, New York, NY 10036.

B. The Effective Date for Compliance

21 CFR 861.36 states that:

A regulation establishing * * * a performance standard will set forth the date upon which it will take effect. To the extent practical, consistent with the public health and safety, such effective date will be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade.

(See also section 514(b)(3)(B) of the act)

FDA has determined that the cost of converting or adapting unsafe electrode lead wire configurations in order to comply with the performance standard being established minimizes economic loss to, and disruption or dislocation of, domestic and international trade because the standard is to be phased in over a 1- or 3-year period, depending on the device(s) with which the electrode lead wire or patient cable is intended to be used, and the vast majority of devices fall under the 3-year rule. Furthermore, FDA believes that this cost is justifiable given the severity of the adverse events that have occurred and the fact that such adverse events are entirely preventable.

VI. The Banning Action

FDA proposed to ban devices under section 516 of the act (21 U.S.C. 360f) that did not meet the standard on the applicable effective date. Upon reconsideration, FDA has determined that a ban is unnecessary. Under section 501(e) of the act, devices not meeting the performance standard on its effective date are adulterated. Furthermore, original equipment manufacturers (OEM's) and third-party suppliers will not be permitted to supply replacement cables and lead systems that fail to meet the standard, absent an FDA waiver or exemption.

VII. Summary and Analysis of Comments and FDA's Response

The agency received 27 written comments from manufacturers, distributors, user facilities, and trade associations in response to the proposed rule. A summary of the written comments is provided below.

1. In general, several comments supported FDA's efforts to resolve the problem of macro shock or electrocution due to an improper connection of a patient-connected electrode lead wire to an AC power source. However, a few comments expressed concern that the proposed banning action would apply to the devices that utilize unprotected electrode lead wires and patient cables instead of the lead wire systems themselves.

FDA has shifted the applicability of the performance standard from the device utilizing the electrode lead wires and patient cables onto the electrode lead wires and patient cables themselves. Moreover, FDA has withdrawn the banning action from the final rule, because it was determined not to be necessary.

2. FDA received several comments questioning which devices should be subject to the 1-year effective date and which should be subject to the 3-year effective date. One comment suggested that the two lists of devices in the proposed rule be eliminated from the final rule and that the ban simply be made effective for all devices 1 year from the publication date of the final rule. Other comments questioned whether particular devices should be placed on the 1-year list and, thus, subjected to the ban and performance standard after 1 year or whether the devices should properly be included in the 3-year list and thus be given additional time to meet the standard.

In response to the comments, FDA has limited the devices on the 1-year list to the 10-device types that the agency believes to be most likely to expose persons to macro shock or electrocution based on the reported adverse events and the environments in which the devices are used. Electrode lead wires or patient cables intended for use with any other device will be subject to the performance standard 3 years from the date of publication.

3. One comment suggested replacing the word ''protected'' in the proposed performance standard (§ 898.11) with the word ''designed'' to allow greater flexibility for electrode lead wire designers.

FDA advises that, although the standard that the agency is issuing in this final rule has been modified from the proposed standard, the word ''protected'' in the proposed rule was intended to encompass creative design changes to devices as well as the development of adapters for use with existing devices in order to achieve a safe electrode lead wire and patient cable configuration. The agency believes that the mandatory performance standard being established in this final rule accomplishes the goal of providing manufacturers flexibility in achieving the desired protected configuration. It is anticipated that the marketplace will determine one or more suitable design standards for the manufacture of new equipment and adapters which will provide safe and effective protected electrode lead wire and patient cable configurations.

4. One comment suggested that, instead of instituting a ban on unprotected electrode lead wires and patient cables and establishing a mandatory performance standard, it would be easier to simply fire the hospital employee who plugs a patient into a receptacle.

FDA disagrees with this comment. The agency believes that proactive measures are appropriate to address the risk of harm presented by unprotected electrode lead wires and patient cables, particularly when it is reasonably foreseeable that risk of misuse of a device will result in serious adverse health consequences or death. Imposing sanctions after adverse incidents would not necessarily reduce the risk presented by those devices, nor would it address the risks presented by them when used in a home environment. The agency has determined that a change in the design of electrode lead wires and patient cables to a protected configuration is both technologically and economically feasible, if given a reasonable time for implementation.

5. One comment questioned whether devices that utilize unprotected patient cables and/or electrode lead wires which simply contact the patient during operation, as opposed to being directly attached to him or her, are included in this rule.

FDA has determined that, because the electrical contact between a patient and an unprotected cable or electrode lead wire that is plugged into an AC power source need only be momentary to produce disastrous results, devices that simply contact the patient during operation are also hazardous and, consequently, are included within the scope of the performance standard.

6. One comment suggested that a company should be allowed to label its conforming product as registered and approved by FDA so that physicians

could buy from an FDA approved manufacturer.

The act specifically prohibits a manufacturer from representing its medical device as having been approved. (See section 301(l) of the act (21 U.S.C. 331(l)); and see also 21 CFR 807.97, regarding premarket notifications.) In addition, compliance with a mandatory performance standard is different from FDA approval of a device.

7. Several comments expressed concern over the ability of their health care facilities to absorb the cost of either adapting old equipment to the protected configuration or purchasing new equipment to meet the performance standard in a 1-year timeframe. These comments requested that a particular device be moved from the proposed 1-year list to the 3-year list in order to have an adequate opportunity for compliance.

It is not the intent of the agency to create undue economic hardship on facilities in its efforts to minimize the risk of injury or death from an improper connection of a patient cable or electrode lead wire to an AC power source. The agency is interested in balancing the cost of implementing this rule with the demonstrated risk. The agency has addressed the issue of cost to facilities in the following two ways. First, in the final rule, FDA has significantly reduced the number of devices subject to the performance standard in the 1-year timeframe. Due to the higher level of risk they present, unprotected electrode lead wires and patient cables cannot be used with the 10-device types that remain in this category 1 year after the publication date of this rule. However, 3 years from the date of publication of this rule, unprotected electrode lead wires and patient cables cannot be manufactured, distributed, sold, resold, or used on patients unless they meet the performance standard. On the effective date of the performance standard, electrode lead wire and patient cable manufacturers can no longer produce or supply unprotected electrode lead wires and patient cables as replacements for use with these existing devices.

FDA encourages the entrepreneurial development of suitable adapters that can be used with existing equipment to speed the creation of a safer environment for patients.

8. Several comments have cited the professionalism of their health care staff as evidence of the improbability that an adverse event such as a macro shock or electrocution would occur in their facility. These comments believe that their devices should not be subject to the ban or performance standard.

FDA disagrees with these statements. Since 1985, when the first incident occurred, various groups have made the argument that such events do not, have not, and would not happen at their facility. After the first death in 1985 in a patient's home, it was argued that these events could only happen outside of a health care facility, away from the watchful eye of a professional. However, since that time, at least 23 additional cases of macro shock or electrocution have occurred, including 3 electrocutions by nurses. FDA believes that, while some areas of a health care setting are more stressful than others, human error can and does occur. A patient should not needlessly be exposed to a known and preventable risk simply because it has not happened yet in a particular area of a facility. However, in an effort to address the cost considerations for health care facilities, the agency has moved most devices to the 3-year effective date.

9. One comment suggested that FDA simply encourage manufacturers to comply with one of the existing voluntary standards (e.g., IEC 601–1), rather than issuing its own mandatory standard. Other comments suggested that enforcement of a voluntary standard could be achieved through manufacturer ''self-certification'' of compliance with IEC 601–1. It was further suggested that compliance with a voluntary standard could be monitored through the 510(k) review process.

FDA disagrees with a voluntary approach. The agency has determined that a mandatory performance standard is necessary to address the significant risk of harm presented by unprotected electrode lead wires and patient cables. However, FDA has taken the suggestion that the agency adopt an existing consensus standard rather than develop its own and possibly conflicting standard.

10. Two comments questioned the need for a protected electrode lead wire performance standard to apply to battery-powered devices, such as a transcutaneous electrical nerve stimulator (TENS) device. The comments indicated that TENS devices use a lead wire with a 2.5 millimeters (mm) coaxial pin connection that is not universally interchangeable with apnea monitors and ECG lead systems.

FDA disagrees with these comments. Two electrocutions occurred when one child plugged his own attached lead wire into a wall socket and when a second child plugged a sibling's attached lead wire into a power cord. These incidents happened with a 2.0 mm exposed pin, but could easily have happened with a 2.5 mm plug. The point that these devices are battery-powered is not relevant because it is the dangling patient-connected cable or electrode lead wire that is dangerous, not the battery-powered device.

11. Several comments suggested that each electrode lead wire or cable simply be labeled with specific warnings about exposed pins and the potential hazard of electrocution when connected to an AC power source.

FDA is aware that, in response to the section 518(a) of the act letters that the agency issued in 1993 (Ref. 7), many firms conducted voluntary recalls of unprotected electrode lead wires to correct the labeling on these devices. However, FDA has determined that the continued marketing of unprotected electrode lead wires and patient cables, no matter how they are labeled, presents an unreasonable and substantial risk of illness or injury to individuals, and provides no benefit to the public health that is not provided by protected electrode lead wires and patient cables. Use of unprotected electrode lead wire and patient cable configurations have resulted in, and can be expected to continue to result in, serious adverse health consequences or death because these devices are inherently dangerous when used in a reasonably foreseeable, albeit inappropriate, manner. There are no labeling requirements that can reliably prevent inappropriate connections of unprotected electrode lead wires and patient cables and, thus, unprotected electrode lead wire configurations cannot be safely marketed for their intended purpose.

Accordingly, FDA determined that a change in labeling will not suffice. Indeed, labeling warnings are meaningless when unprotected electrode lead wires and patient cables are available to preschool children or individuals with limitations such as vision problems or cognitive impairments. Further, labeling is often an inadequate solution in certain hospital settings when health care professionals find themselves in busy, stressful situations in which they may not be provided with, or could inadvertently overlook, instructions.

12. Two comments questioned whether 2.5 mm coaxial pin electrode lead wires should be subject to the performance standard because these lead wires may not produce the same potentially damaging result. These comments cited a 1994 class II recall and labeling action by CDRH's Office of Compliance in which the agency did not call for user notification and labeling of

2.5 mm coaxial plugs. In addition, one comment stated that there is no reasonable possibility of substitution of a 2.5 mm coaxial plug for use with an apnea monitor patient cable designed to accept individually exposed 2.0 mm pins.

FDA disagrees. The August 1993 incident in which a protected 2.0 mm electrode lead wire and patient cable system for an apnea monitor had been replaced by an unprotected 2.0 mm cable and lead wire configuration had disastrous results. In this incident, an infant was electrocuted when the replacement unprotected electrode lead wire was directly connected to an AC power cord. CDRH's Office of Compliance required contraindication labeling of exposed 2.0 mm pin lead wires which, in short, warned users not to use unprotected 2.0 mm pin lead wires with apnea monitors. Older apnea monitor designs use electrode lead wires with individual 2.0 mm pins and a patient cable with 2.0 mm sockets. Unprotected electrode lead wires having a 2.5 mm pin (such as those used with TENS devices) were exempted from the labeling requirement because it was believed to be physically impossible to fit a 2.5 mm plug into a 2.0 mm patient cable socket. FDA accepted the firm's argument against labeling an unprotected lead wire with a 2.5 mm pin to warn against its use with an apnea monitor.

In view of the information available to the agency at the time, on March 8, 1994, the agency informed a contract leads manufacturer that, ''It is our understanding from discussions with other manufacturers that a 2.5 mm pin plug is too large to fit into an electrical power cord or wall outlet, and therefore would not need to be labeled.'' However, that assessment was subsequently changed following test results submitted by two TENS/national medical equipment supplies manufacturers, both of whom confirmed that the 2.5 mm coaxial pin could be inserted into power cords and wall outlets. One manufacturer also showed the same results for flexible 2.75 mm ''banana'' plugs. One test showed no electrical current flow for the 2.5 mm pins, while a second test showed that an electrical connection was made.

Because it is physically possible to insert a 2.5 mm pin into an AC power source, these devices are subject to the performance standard established in this rule.

13. One comment sought clarification of FDA's assertion in the proposal that, ''if an adapter is used, it should prevent removal by the user.'' The comment suggested that ''like the patient cable, an adapter can trap blood and other contaminants during use. A reusable adapter must be easily and thoroughly cleaned and sterilized. The adapter should be submersible, capable of being abrasively scrubbed, and autoclavable.''

FDA agrees that, in some applications, it may be necessary to have an adapter that is capable of being removed from the device for cleaning purposes. However, because reported adverse events have shown a propensity for individuals to simply remove a protected configuration from a device and replace it with an unprotected configuration for the sake of convenience, the agency recommends use of adapters that are not easily removed by the user (e.g., only detachable with the use of a tool). The agency believes that, for those applications where device contamination is of concern, the adapter should be disposable, if possible, and that the device should not be suited to accept and function with an unprotected electrode lead wire and patient cable configuration.

14. One comment sought to clarify whether only electrodes with preattached lead wires were unprotected or whether the ''snap-on'' electrodes without the lead wires are also considered unprotected. Another comment questioned whether patient-connected electrodes with exposed wires were covered under the standard or only those having a pin attached at the end distal to the patient.

FDA considers any patient cable or electrode lead wire having a distal end that is capable of making conductive contact with an AC power source (e.g., a power cord, or wall outlet) to be unprotected and, therefore, subject to the performance standard. The standard applies to the lead wires themselves, and not to detachable ''snap-on'' electrodes with which they may be used.

15. One comment questioned who would be responsible for product inventory once the banning action becomes effective. Another comment expressed opposition to manufacturers having to recover product from the field. Yet another comment sought clarification of the responsibility of the manufacturer for a device that was introduced into the marketplace prior to the effective date of the standard but the user returns the device for repair or maintenance under a maintenance agreement and the device has not yet been modified in accordance with the standard.

As mentioned in section VI. of this document, FDA has eliminated the proposed banning action in this final rule. FDA believes that the manufacturer, distributor, seller, and user should share in the responsibility for removing adulterated goods under their control from the marketplace. Because many of the devices that are affected by the performance standard may be retrofitted in the field, or perhaps equipped with a suitable adapter, the agency has not determined that a device recall is warranted at this time. The agency believes that each participant in the chain of commerce has a role to play in ensuring that the devices under their control meet the performance standard by the effective date. The responsibility for equipping a device that is returned to the manufacturer under a maintenance agreement such that it conforms to the standard would likely depend upon the specific terms of the agreement. As both users and manufacturers are equally concerned for the safety and welfare of the patients that they serve, FDA anticipates that they will work cooperatively to ensure that these devices are in compliance with the performance standard. FDA reiterates that the performance standard in the final rule applies to the lead wire and patient cable, not to the medical equipment to which they are attached.

16. One comment suggested that the agency adopt the comparable IEC 601–1 standard (i.e., IEC 601–1, subclause 56.3(c)) as the performance standard because it addresses test methods that were not included in FDA's proposed performance standard. The comment believed that adoption of this international standard would also promote global harmonization of standards.

FDA agrees with this comment. Prior to drafting the proposed standard, FDA evaluated the voluntary standards that were then in existence to determine whether any of these standards might be adopted to address the concerns of the agency with unprotected electrode lead wires. At the time of publication of the proposed rule, IEC 601–1 was being amended and it could not be determined whether the amended standard would be adopted by the membership and, if so, when it would be published. However, in March 1995, IEC published the second amendment to IEC 601–1, including subclause 56.3(c), which prohibits electrode lead wires and patient cables from having the capacity to make conductive contact with hazardous voltages. After examination of this ratified amendment, the agency has determined that adherence to the IEC 601–1 as amended would provide acceptable protection of patients from connections to hazardous

voltages. In addition, FDA's adoption of this requirement of the IEC standard demonstrates the agency's continued interest in promoting the adoption of international voluntary standards, where feasible, to satisfy safety and effectiveness requirements for medical devices.

17. One comment asked whether, for a preamendment device, FDA would accept a letter of notification of a change to a protected configuration. The comment believed that it would be unreasonable to subject a preamendment device, that has been modified to incorporate a protected configuration, to additional regulatory requirements while those devices under a 510(k) require only an addendum.

FDA is establishing the following procedures for notifying the agency of device modifications in compliance with the following performance standard:

For a device reviewed through the premarket notification (510(k)) process or for a preamendment device, information regarding modification of the device from an unprotected electrode lead wire and patient cable configuration to a protected configuration, and information demonstrating compliance with the performance standard, should be documented in the manufacturer's device master records in accordance with the current good manufacturing practice regulation. FDA recognizes that a change from the unprotected to the protected configuration is a change that under 21 CFR 807.81(a)(3) could affect safety and effectiveness. However, in the interest of public health, and due to the straightforward nature of the device modification and demonstration of compliance with the performance standard, the agency is not requiring prior clearance for this specific device modification. FDA recognizes that this procedure differs from the agency's previous recommendation that manufacturers who were voluntarily making changes from the unprotected to the protected configuration submit documentation of the changes as an addendum to their existing premarket notification (510(k)) files. Because compliance with the performance standard will no longer be voluntary, but will be mandatory, placement of documentation of the device modification from an unprotected configuration to a protected configuration and of documentation demonstrating compliance with the performance standard into the device master records will be sufficient.

For devices reviewed through the premarket approval process, modifications from an unprotected electrode lead wire and patient cable configuration to a protected configuration also may be implemented without prior approval by FDA. FDA has determined under 21 CFR 814.39(e) that an alternate submission, a periodic report, is appropriate. Thus, in the interest of public health, and due to the straightforward nature of the device modification, information regarding modifications to the protected configuration and information demonstrating compliance with the performance standard should be provided in the next annual report to the applicable premarket approval application (PMA). The modification can be made prior to submission of the annual report.

The information provided in the manufacturer's device master record or the PMA annual report should include engineering drawings and a description of the change(s), an explanation of how the change(s) prevents connection to a power source, and documentation demonstrating compliance with the performance standard. If an adapter design is implemented, an explanation of how the signal acquisition and processing is not compromised by the addition of the adapter, and how the design of the adapter prevents removal by the user, should also be provided.

18. One comment sought clarification of the manner in which the agency would identify those devices that would be subject to this rule, but have not yet been classified (e.g., electrode lead wires and patient cables intended for use with dental TENS units).

All devices that meet the applicability section of the standard (§ 898.11) are subject to the requirements under the rule, whether or not they have been formally classified.

19. One comment wrote that implementation of the ban and performance standard in 1 year might not provide the time needed for design changes, validation, and manufacturing, and for production of a device inventory sufficient to meet global demand. The comment believed that difficulties in meeting the 1-year timeline may cause some manufacturers to abandon businesses associated with the affected devices, which potentially could affect supply.

The agency believes that changes made to the final rule adequately balance public health concerns with the economic impact of making this transition. Under the final rule, the devices for which the performance standard will become effective in 1 year are only those electrode lead wires and patient cables associated with the 10 devices presenting the highest risk of a user inappropriately connecting the electrode lead wire or patient cable to an AC power source. Of these 10 devices, electrode lead wires and patient cables intended for use with apnea monitors are largely in compliance with the standard. Because of their early involvement with electrocution and macro shock incidents, new apnea monitor devices without a protected electrode lead wire configuration have not received agency clearance for marketing since 1989. ECG manufacturers have also been encouraged by the agency to provide protected electrode lead wire and patient cable systems with their devices. In addition, the agency published the ANPRM in the **Federal Register** of May 19, 1994, held a public conference on the issue in July 1994, and advised the manufacturing and medical user community of efforts to address this problem through wide dissemination of public health advisories, direct mailings to the users and the manufacturing communities, and published its proposal to establish a performance standard and a ban in the June 21, 1995, proposed rule. The agency believes that both manufacturers and the medical user community have had ample time to begin modifying these 10-device types, and electrode lead wires and patient cables intended for use with them, to avoid this potential problem. The agency is establishing the effective date of the performance standard for electrode lead wire and patient cables for use with these 10 devices at 1 year from the date of publication of the final rule to provide further time for a steady transition to a safe electrode lead wire and patient cable configuration. Finally, for exceptional circumstances that are not adequately addressed in the 1-year timeframe, the agency has established a variance procedure in which affected parties may request an exemption or additional time in which to meet the standard.

20. One comment stated that the marginal replacement costs mentioned in section IX. of the proposed rule (60 FR 32406 at 32414) assume an appropriate replacement accessory is available through the manufacturer at costs comparable to the original lead system. According to the comment, because lead wire manufacturers do not have to produce replacement leads, but rather must cease producing unprotected patient cables and leads, the costs of unplanned replacement of even a small fraction of expensive diagnostic devices as a result of the unavailability of the protected style

accessories is exponentially greater than the lead-for-lead replacement costs alluded to section IX. of the proposed rule.

FDA disagrees with this statement. Several lead wire manufacturers have already informed the agency that they are now, or soon will be, producing protected electrode lead wire and patient cable configurations. The agency does not have any evidence to show that manufacturers will simply cease manufacturing unprotected electrode lead wires and patient cables and fail to produce a protected electrode lead wire configuration as a replacement.

21. One comment suggested that in cases where the electrode lead wires are permanently attached to incontinence electrodes, the leads could not migrate to other uses or environments and, therefore, the lead wire cannot be detached from the uniquely shaped electrodes.

Sections 898.11 and 898.13 specify the applicability of the performance standard. If a device meets the applicability requirements under § 898.11 and an interested party believes, due to the unique circumstances of the device, its intended use, or its reasonably foreseeable misuse, that no electrical hazard is presented to a patient, the party may petition the agency under the variance procedure for review of these unique circumstances.

22. One comment expressed concern about not having a sufficient manufacturing staff to retrofit its devices. Concern was also expressed that hospital staffs lack qualifications to perform and validate changes to installed medical devices. The comment contended that making these changes increases the risk of device failure due to unapproved or improperly tested device adaptations, and increases legal liability for the institution.

FDA disagrees with this comment. It is imperative that the manufacturer of a device that utilizes electrode lead wires and patient cables provide a connection arrangement from the patient to the monitoring or treatment device which cannot be conductively connected to a hazardous voltage. The manufacturer has a choice of modifying the design of the equipment to accept only a protected cable and electrode lead wire, of providing an adapter for the equipment interface to receive only a protected electrode lead wire configuration, or of directing the user of its medical device to a third-party manufacturer of protected electrode lead wires and patient cables or suitable adapters. Hospital staff with ability to make an unprotected patient cable and lead wire connection from the patient to the device are equally capable of making a protected connection. It is up to the manufacturer to ensure that the device change is in conformity with its specifications and labeling.

23. One comment noted that lead wires are not always class II devices and, therefore, it is not clear that FDA has the authority to regulate all electrode lead wires with a mandatory standard.

FDA agrees that a few unprotected cable and electrode lead wire systems are class I devices, and, as such, are not subject to a mandatory performance standard. Specifically, these devices include:

TABLE 1.

Phase	Product code	21 CFR section	Class	Device name
2	89 IKD	890.1175	I	Cable, Electrode (for Use With Diagnostic Physical Medicine Devices).
2	74 KARI	870.4200	I	Accessory Equipment, Cardiopulmonary Bypass.
2	87 KQX	888.1500	I	Goniometer, AC-Powered.

Because of the degree of the health risk, the agency plans to initiate procedures to reclassify these devices into class II so that all electrode lead wires and patient cables will be subject to the mandatory performance standard.

24. Another comment questioned whether a manufacturer would be in violation of the banning action for repairing a user's banned device.

As stated above, FDA is not banning these devices. Therefore, this comment is now moot.

25. One comment suggested that there may be cases where the OEM is out of business and protected replacement cables and electrode lead wires cannot be obtained.

FDA has no evidence to suggest that the absence of the OEM would pose a significant obstacle to obtaining suitable lead wire replacements. Replacement cables and electrode lead wires may often be obtained from third-party manufacturers, or an adapter set may be used to convert the unprotected pin configuration to a protected one. In rare cases, where a user finds that the OEM is unwilling or unable to supply a protected electrode lead wire and patient cable system, and that there exists no thirdparty equivalent, the user has the option of petitioning the agency under the variance procedure by documenting the special circumstances that warrant an exception to the standard.

VIII. Enforcement

FDA's statutory authority to issue performance standards is derived from section 514 of the act. Section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to issue binding regulations for the efficient enforcement of the act. (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973); see also *Weinberger* v. *Bentex Pharmaceuticals Inc.,* 412 U.S. 645, 653 (1973); *National Assn. of Pharmaceutical Manufacturer* v. *FDA,* 637 F.2d 877 (2d Cir.), *cert. denied,* 423 U.S. 827 (1975).) Section 519(a) of the act (21 U.S.C. 360i(a)) also authorizes the agency to issue regulations requiring manufacturers of devices to maintain and provide records to ensure that devices are not adulterated, misbranded, unsafe, or ineffective. FDA's performance standards for medical devices are substantive regulations with the force and effect of law. (See *United States* v. *Undetermined Quantities of Various Articles of Device* * * * *Proplast II,* 800 F. Supp. 499, 502 (S.D. Tex. 1992); *United States* v. *789 Cases* * * * *Latex Surgeons' Gloves,* 799 F. Supp. 1275, 1287 (D.P.R. 1982).)

Section 501(e) of the act deems a device to be adulterated, and thus prohibited from commerce, if it is a device subject to a performance standard established under section 514 of the act, unless such device is in all respects in conformity with such standard. Introduction into interstate commerce of a device that fails to comply with the requirements established by section 514 of the act is a prohibited act under section 301(a) of the act (21 U.S.C. 331(a)), and the agency will use its enforcement powers to deter noncompliance. Persons who violate section 301 of the act may be subject to injunction under section 302(a) of the act (21 U.S.C. 332(a)). In addition, any person responsible for

violating section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)) and criminal prosecution under section 303(a).

IX. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Unfunded Mandates Reform Act of 1995

Under the Unfunded Mandates Reform Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives and determined that the final rule is the least burdensome and the most cost effective alternative that would meet the objectives of this rule. Because FDA anticipates no significant additional costs to State, local, or tribal governments, this regulatory action does not require an assessment under the Unfunded Mandates Reform Act.

XI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact on small entities. As a result of its analysis, FDA has determined that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, the Commissioner of Food and Drugs certifies that the rule will not have a significant economic impact on a substantial number of small entities.

XII. Introduction to Economic Analysis

FDA believes that the presence of unprotected lead wires in a home, hospital, or other user facility creates an unreasonable risk to patients of hazardous electrical connections from electrical power sources. In the proposed rule of June 21, 1995, FDA proposed to create a performance standard for electrode lead wires, and to ban the use of unprotected leads. Many comments supported the intent of the proposal, and agreed with the phased approach toward eliminating the problem. Other comments, however, expressed the view that the benefits would be outweighed by the costs associated with converting the large number of device types listed in the proposed rule. For example, AHA wrote that ''[when] all costs from all devices are considered, the total cost impact to a facility would be at least $45 per licensed bed * * *. For the over one million hospital beds in the United States, the impact would be greater than $45 million.'' AHA called this a conservative estimate, and requested that a comprehensive impact analysis be performed by FDA, which would include logistical costs, stocking costs, cost for ongoing surveillance, and the capital cost to replace equipment for which protected style lead systems are not available. In this economic analysis, FDA considers those costs and benefits that would be incurred as a direct result of this final regulation.

Due to liability concerns, many of today's manufacturers are already moving toward protected lead and cable pin configurations for select devices. In order to prevent future adverse incidents, however, FDA is issuing a new regulation that will ensure the movement toward protected electrode lead wires and patient cables. Phase I of the regulation applies to unprotected lead wires used with the 10 devices for which there is the highest risk of accidental connection to hazardous voltages. In 1 year from the publication date of this rule, electrode lead wires and patient cables used with or intended for use with the following devices will be subject to a performance standard: Patient cable, apnea/breathing frequency monitor, ECG monitor, cardiac monitor, multi-parameter/vital signs monitor, ECG electrode with attached lead wire, arrhythmia monitor, transmitters and receivers/physiological signal/radiofrequency, recorder/magnetic tape/medical, and transmitters and receivers, electrocardiograph/telephone. Phase II applies to electrode lead wires and patient cables used with or intended for use with all other medical devices. Three years from the effective date of this rule, lead wires and patient cables that do not meet the performance standard may no longer be used or sold. The rule also states that exemptions may be requested for devices that justifiably cannot meet the standard on the date it goes into effect.

A. Regulatory Benefits

Since 1985, there have been at least 24 reported incidents involving the use of unprotected electrode lead wires and patient cables. These incidents occurred with both infants and children who received ''macro-shock'' due to the improper use of these leads and cables. Such occurrences have caused burns to the skin under the electrodes, cardiorespiratory arrest, comas, neurological damage, or other serious injuries. In five of these incidents, children died by electrocution. Less significant incidents are probably underreported as FDA typically receives reports on only a fraction of all events.[1]

FDA believes that this regulation will eliminate, to the extent possible, the hazard associated with unprotected lead wires and patient cables. While most comments acknowledged the unacceptable risk attributable to the unprotected Phase I devices, many denied the need to extend the scope of the rule to the Phase II devices. FDA, however, finds that the interchangeability of electrode lead wires and patient cables among medical equipment establishes the need to encompass such a large number of devices. Regardless of where or what device they are used with, unprotected electrode lead wires themselves can be plugged into a receptacle and become hazardous. Through the implementation of this regulation, FDA expects to prevent another incident of ''macro-shock'' or death.

B. Regulatory Costs

In order to comply with this final rule, unprotected devices will either be replaced or modified to accept only protected leads, and all new devices under development will need to be designed to accept only protected leads. The agency received no comments indicating that incremental cost to manufacturers for the redesign of new devices would be substantial, if adequate time was allowed. Moreover, few existing devices will need to be prematurely replaced because virtually all devices can be made safe through the use of protected lead wires and either adaptors or other modifications of the connecting equipment. Where adaptors or modifications are not feasible, FDA

[1] ''Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting,'' United States General Accounting Office Report to the Chairman, Committee on Governmental Affairs, U.S. Senate, p. 61, December 1986.

will consider individual variance requests. A number of manufacturers have indicated that adaptors are inexpensive and easy to install, and provide no loss of signal integrity. Adaptors are not presently available for all existing devices, because there is inadequate current demand. The regulation, however, will create strong incentives for device manufacturers or other suppliers to develop adequate adaptors, and the extended phase-in periods will provide sufficient time for such conversions to be made. Thus, FDA expects that there will be minimal costs for redesigning the new devices currently under development, and most existing devices will comply by obtaining appropriate adaptors. As derived below, FDA estimates the total cost of bringing all of these devices into compliance to be about $21 million.

1. Phase I

a. *Devices.* For the purpose of this analysis, the lead wires and patient cables used with or intended for use with the 10 previously mentioned Phase I devices have been grouped into two categories. The first category consists solely of the lead wires and patient cables used with the apnea/breathing frequency monitor. In the early 1990's, a Federal performance standard was proposed to phase out the use of unprotected lead wires with apnea monitors. Encouraged by the intense liability concerns among industry, almost all of the lead wires for these monitors are now protected. Therefore, FDA assumes no costs associated with bringing this first category of lead wires into compliance.

The second category consists of the lead wires used with the remaining nine devices (hereinafter referred to as ECG-type devices). The useful life for these devices reportedly ranges from 7 to 10 years. Using an average useful life of 8 years 6 months, the 1-year phase-in period implies that about 88 percent of these devices will have to be converted. According to a survey by AHA conducted in early 1994,[2] approximately 78 percent of their responding members indicated that steps have already been taken to replace the unprotected lead wires on their ECG devices. In this cost analysis, therefore, FDA only counts the costs associated with bringing into compliance the lead wires on the remaining 22 percent of those devices that would still have some remaining useful life by the conclusion of the 1-year timeframe following publication of this rule.

b. *Lead wires.* All of the ECG-type devices have three lead wires except for the arrhythmia monitors and the Holter monitors (classified under transmitters and receivers/physiological signal/radiofrequency, recorder/magnetic tape/medical, and transmitters and receivers, electrocardiograph/telephone). The number of lead wires on an arrhythmia monitor could range from 5 to 12. For analysis, FDA estimates the mean number of lead wires on an arrhythmia monitor to be 8.5. The number of lead wires on a Holter monitor generally ranges from three to five. Thus, FDA estimates the mean number of lead wires on a Holter monitor to be four.

Lead wires are generally sold in pairs, sets, or bulk quantities. For this analysis, FDA uses an average price of $7 for a set of three lead wires, or $2.33 per unit. This estimate may be too high as some user facilities may purchase lead wires in bulk at less expensive per unit prices.

There is only an incidental price difference between the protected lead wires and those that are not protected. Therefore, no incremental costs have been added for the purchase of the protected leads as compared to the unprotected leads. As costs are counted only for leads that need to be replaced while they still have some useful life, FDA charges only half the cost of the purchase of these lead wires to the regulation. Because the lead wires for ECG-type devices have a useful life of approximately 2 years, 50 percent of these lead wires will be replaced on average within the 1-year timeframe after the publication date of this final rule.

c. *Adaptors.* For all ECG-type devices, FDA assumes that adaptors will be available to connect the cables and lead wires. Only one cable is used per ECG-type device, with the exception of the Holter monitor. These cables cost between $50 to $100 to be replaced. Because it is less costly to purchase adaptors than to purchase new cables to fit the protected lead wires, FDA assumes that user facilities would purchase adaptors to use for the remaining useful life of the cables. For Holter monitors, FDA assumes that adaptors will be used between the lead wires and the device itself. The costs of purchasing adaptors is approximately $5 each. One adaptor is needed for each lead wire used with or intended for use with the device. Therefore, most ECG-type devices would require three adaptors, the arrhythmia monitor would use 8.5 adaptors, and the Holter monitor would use four adaptors on average. A block of adaptors may be purchased, however, FDA assumes the unit price will remain unchanged. After discussions with various manufacturers, FDA finds that the distal ends of most cables are either already protected or too large to be forced into contact with a hazardous voltage. Thus, no costs were assigned for attaching adaptors to the distal end of the cables.

Because the useful life of cables for ECG-type devices is approximately from 2 to 3 years, FDA estimates that 40 percent of these original cables will need to be replaced with cables that accept the protected lead wires within 1 year after the publication date of this final rule. As redesigned cables are sold at about the same price as the older cables, no added cost is attributable to these cables. Therefore, only about 60 percent of these devices will require an adaptor due to the regulation. Some facilities whose cables have little remaining useful life may opt to replace their cables earlier, even though the price of new cables are significantly higher than that of adaptors. Nevertheless, this analysis assumes that users would purchase new cables only if they were a less costly option.

d. *Adaptor installation.* FDA uses the 1995 median weekly earnings of $598[3] for engineering and related technologists and technicians as the base for the costs associated with affixing the adaptors onto the unprotected cables. Adding 40 percent for benefits, total hourly earnings are estimated at $20.93. The following tables show a per minute salary rate of $0.35. Based on discussions with industry representatives, FDA estimates that it will take a total of about 5 minutes to thoroughly clean the connector area on the cable or device itself, and then to affix the adaptor to the cable or device. For those instances where the adaptor is to be affixed onto a cable, FDA allots 5 minutes per device, regardless of the number of lead wires utilized by the device. This time should be adequate because one block of adaptors could be used to convert the entire device. For those instances where the adaptors are to be affixed onto the device itself, FDA allots 5 minutes per lead wire. FDA also added a one-time cost for each facility to capture the amount of time they would need to familiarize themselves with the conversion process and to locate the affected devices.

e. *User facilities.* The user facilities examined are hospitals, nursing homes,

[2] "Electrode Leadwire Survey," distributed by the American Society for Hospital Engineering of AHA, early 1994.

[3] *Employment and Earnings,* U.S. Department of Labor Bureau of Labor Statistics, Table 39, p. 206, January 1996.

ambulances, and doctor's offices, and clinics. It is in these facilities that the majority of ECG-type devices are found. ECG-type devices found in Free-Standing Ambulatory Care Centers and in Cardiac Labs of Hospital Outpatient Centers are accounted for under costs to doctor's offices and clinics.

(i). *Cost to hospitals.* In 1993, 6,467 hospitals were accepted for registration by AHA, with an average number of 179 beds in each of these hospitals.[4] According to several clinical engineers and bioengineering directors at various hospitals, one ECG-type device is found at approximately 30 percent of these beds. Therefore, FDA calculates that approximately 347,278 ECG-type devices are used in hospitals across the United States. Because the arrhythmia monitors were estimated to make up about 10 to 20 percent of the ECG-type devices used in the average hospital, FDA assumes that 15 percent of ECG-type devices in all hospitals are arrhythmia monitors. Holter monitors were estimated to make up another 15 percent of the ECG-type devices used in the average hospital. In addition, assuming that it might take roughly 1 minute to scan the devices in each room, FDA adds 3 hours per facility to account for the time it will take an average hospital to locate the appropriate devices. As shown in the table below, the total cost of this rule to hospitals comes to about $1.6 million.

TABLE 2.—COST OF PROTECTED LEAD WIRES TO HOSPITALS

Hospitals	Number of ECG's per hospital	Percent (%) of ECG's not protected	Percent (%) of leads to be replaced	Percent (%) of ECG's with useful life	Cost per lead	Number of leads	Percent (%) of useful lead life remaining	Total cost
ECG-Type Devices Except the Arrhythmia Monitor and the Holter Monitor								
6,467	38	22%	50%	88%	$2.33	3	50%	$82,581
The Arrhythmia Monitor								
6,467	8	22%	50%	88%	$2.33	8.5	50%	$50,138
The Holter Monitor								
6,467	8	22%	50%	88%	$2.33	4	50%	$23,594

TABLE 3.—COST OF ADAPTORS TO HOSPITALS

Hospitals	Number of ECG's per hospital	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Cost per adaptor	Number of adaptors	Total cost
ECG-Type Devices Except the Arrhythmia Monitor and the Holter Monitor							
6,467	38	22%	60%	88%	$5.00	3	$424,700
The Arrhythmia Monitor							
6,467	8	22%	60%	88%	$5.00	8.5	$257,854
The Holter Monitor							
6,467	8	22%	N/A	88%	$5.00	4	$202,238

[4] *The Statistical Abstract of the United States,* U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183, p. 125, 1995.

TABLE 4.—COST TO INSTALL ADAPTORS TO HOSPITALS

Hospitals	Number of ECG's per hospital	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Salary per minute	Installation time (in minutes)	Learning cost per hospital	Total cost
ECG-Type Devices Except the Holter Monitor								
6,467	46	22%	60%	88%	$0.35	5	N/A	$59,965
The Holter Monitor								
6,467	8	22%	N/A	88%	$0.35	20	N/A	$70,547
Learning Time								
6,467	N/A	N/A	N/A	N/A	N/A	N/A	$62.79	$406,063
Total Cost to Hospitals (Tables 1 through 3) =								**$1,577,680**

(ii). *Cost to nursing homes.* In 1993, there were approximately 11,309 skilled nursing facilities[5] in the United States. FDA estimates that there are approximately one to two ECG-type devices per nursing home (assuming no arrhythmia monitors or Holter monitors). FDA adds one-half hour to account for the time it would take each individual facility to learn how to convert their devices. As shown below, the total cost of this rule to the nursing homes amounts to about $157,000.

TABLE 5.—COST OF PROTECTED LEAD WIRES TO NURSING HOMES

Skilled nursing facilities	Number of ECG's per nursing home	Percent (%) of ECG's not protected	Percent (%) of leads to be replaced	Percent (%) of ECG's with useful life	Cost per lead	Number of leads per device	Percent (%) of useful lead life remaining	Total cost
11,309	1.5	22%	50%	88%	$2.33	3	50%	$5,763

TABLE 6.—COST OF ADAPTORS TO NURSING HOMES

Skilled nursing facilities	Number of ECG's per nursing home	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Cost per adaptor	Number of adaptors	Total cost
11,309	1.5	22%	60%	88%	$5.00	3	$29,636

TABLE 7.—COST TO INSTALL ADAPTORS TO NURSING HOMES

Skilled nursing facilities	Number of ECG's per nursing home	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Salary per minute	Installation time (in minutes)	Learning cost per facility	Total cost
11,309	1.5	22%	60%	88%	$0.35	5	N/A	$3,446
				Learning Time				
11,309	N/A	N/A	N/A	N/A	N/A	N/A	$10.47	$118,349
Total Cost to Nursing Homes (Tables 4 through 6) =								**$157,194**

(iii). *Cost to ambulances and other ground transport vehicles.* In 1995, the United States was reported to have 59,640 active and reserve ground transport vehicles for emergency purposes.[6] This figure does not include emergency vehicles designed to extinguish fires. Of this total number of vehicles, some are classified with advanced life support (ALS) services. These vehicles carry a manual defibrillator with an ECG monitor. These ECG-type devices have three lead wires and a screen with the ability to print a tape. The other vehicles have basic life support (BLS) services. Of these BLS transport vehicles, some have an automated external defibrillator (AED) which fires shocks automatically. These ECG-type devices have two lead wires, but do not have a screen or the capability to print a tape.

According to a survey completed by the National Association of State Emergency Medical Services (EMS) Directors in 1992, 59 percent of all emergency transport vehicles have ALS transport services.[7] Therefore, FDA estimates that 35,188 vehicles are ALS transport systems. Of the reporting organizations in 1995, 48 percent are classified as BLS with AED.[8] To determine the number of BLS vehicles with AED, FDA assumes that all 30,000 organizations with emergency transport vehicles identified in the 1995 survey[9] have two vehicles per organization. If all organizations reporting BLS with AED services have at least one vehicle offering this service, 14,314 BLS transport vehicles have AED. FDA adds one-half hour to account for the time it would take each individual organization to learn to convert its devices. Because FDA assumed two vehicles per organization, the costs associated with one-quarter hour per vehicle are shown in the table below. The total cost of this regulation amounts to approximately $362,000 for ambulances and other ground transport vehicles.

[5] *The Statistical Abstract of the United States,* U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 200, p. 134, 1995.

[6] ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications, p. 40.

[7] ''Transportation Systems, 1994,'' produced by the National Association of State EMS Directors, p. 2, 1994.

[8] ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications, p. 17.

[9] ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications.

TABLE 8.—COST OF PROTECTED LEAD WIRES TO AMBULANCES

Ground transport vehicles	Number of ECG's per vehicle	Percent (%) of ECG's not protected	Percent (%) of leads to be replaced	Percent (%) of ECG's with useful life	Cost per lead	Number of leads per device	Percent (%) of useful lead life remaining	Total cost
ECG-Type Devices on ALS Transport Vehicles								
35,188	1	22%	50%	88%	$2.33	3	50%	$11,954
ECG-Type Devices on BLS Transport Vehicles								
14,314	1	22%	50%	88%	$2.33	2	50%	$3,242

TABLE 9.—COST OF ADAPTORS TO AMBULANCES

Ground transport vehicles	Number of ECG's per vehicle	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Cost per adaptor	Number of adaptors	Total cost
ECG-Type Devices on ALS Transport Vehicles							
35,188	1	22%	60%	88%	$5.00	3	$61,476
ECG-Type Devices on BLS Transport Vehicles							
14,314	1	22%	60%	88%	$5.00	2	$16,671

TABLE 10.—COST TO INSTALL ADAPTORS TO AMBULANCES

Ground transport vehicles	Number of ECG's per vehicle	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Salary per minute	Installation time (in minutes)	Learning cost per organization	Total cost
49,502	1	22%	60%	88%	$0.35	5	N/A	$10,056
Learning Time								
49,502	N/A	N/A	N/A	N/A	N/A	N/A	$5.23	$259,019
Total Cost to Ambulances and Other Ground Transport Vehicles (Tables 7 through 9) =								**$362,418**

(iv). *Cost to doctor's offices and clinics.* In 1992, there were approximately 199,500 offices and clinics of medical doctors[10] in the United States. FDA estimates that, on average, there is at most one Holter monitor and/or ECG-type device per office, and one to two ECG-type devices per clinic. For analysis, FDA assumes 1.25 ECG-type devices per doctor's office and clinic. FDA further assumes an equal proportion of Holter monitors and other ECG-type devices would be found in both doctor's offices and clinics. FDA adds one-half hour to account for the time it would take each individual facility to learn how to convert their devices. The total cost of this rule to the doctor's offices and clinics comes to about $3 million.

[10] *The Statistical Abstract of the United States,* U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 1316, p. 795, 1995.

TABLE 11.—COST OF PROTECTED LEAD WIRES TO OFFICES AND CLINICS

Doctor's offices and clinics	Number of ECG's per office and clinic	Percent (%) of ECG's not protected	Percent (%) of leads to be replaced	Percent (%) of ECG's with useful life	Cost per lead	Number of leads	Percent (%) of useful lead life remaining	Total cost
ECG-Type Devices Except the Arrhythmia Monitor and the Holter Monitor								
199,500	0.6	22%	50%	88%	$2.33	3	50%	$40,605
The Holter Monitor								
199,500	0.6	22%	50%	88%	$2.33	4	50%	$54,140

TABLE 12.—COST OF ADAPTORS TO OFFICES AND CLINICS

Doctor's offices and clinics	Number of ECG's per office and clinic	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Cost per adaptor	Number of adaptors	Total cost
ECG-Type Devices Except the Arrhythmia Monitor and the Holter Monitor:							
199,500	0.6	22%	60%	88%	$5.00	3	$209,123
The Holter Monitor							
199,500	0.6	22%	N/A	88%	$5.00	4	$464,718

TABLE 13.—COST TO INSTALL ADAPTORS TO OFFICES AND CLINICS

Doctor's offices and clinics	Number of ECG's per office and clinic	Percent (%) of ECG's not protected	Percent (%) of cables to be replaced	Percent (%) of ECG's with useful life	Salary per minute	Installation time (in minutes)	Learning cost per facility	Total cost
ECG-Type Devices Except the Holter Monitor								
199,500	0.6	22%	60%	88%	$0.35	5	N/A	$24,316
The Holter Monitor								
199,500	0.6	22%	N/A	88%	$0.35	20	N/A	$162,109
Learning Time								
199,500	N/A	N/A	N/A	N/A	N/A	N/A	$10.47	2,087,768
Total Cost to Doctor's Offices and Clinics (Tables 10 through 12) =								**$3,042,779**

2. Phase II

This section examines the cost to user facilities for Phase II of this regulation. Although FDA believes that the use of adaptors will be an effective and available conversion method for most affected devices, facilities are permitted to request a variance for those devices that cannot be modified to accept protected leads. Therefore, the agency has not counted the cost of conversion methods other than adaptors.

For analysis, FDA has grouped most of the devices into the following general categories: Electrosurgery appliances, telemetry transmitters, external pacemakers, supervised diagnostic equipment, stimulators, and patient monitoring devices. While FDA recognizes that a small number of devices may not be represented in these categories, these device categories are based on the categories used in a survey distributed by AHA in 1995.[11] FDA assumes that at the end of 3 years, adaptors will be available for all devices. Therefore, the only costs identified as a direct result of the regulation are the cost of the adaptors, and the costs associated with their installation. FDA continues to assume that the distal ends of these cables have either previously been protected or are too large to be forced into a connection with a hazardous voltage, and therefore, no adaptor will be needed to attach the distal ends of these cables to the face plates of the devices. FDA has not included the costs of purchasing new cables or new lead wires because the 3-year phase-in period allows adequate time for protected models to be purchased through general attrition. The percentage of devices that utilize patient cables are estimated for each category. For example, all machines in the category of patient monitoring devices, typically have cables. As these devices move toward protected lead wire and patient cable designs, they will incur no extra costs as a direct result of this regulation.

[11] ''Electrode Leadwire Survey II,'' distributed by the American Society for Hospital Engineering of AHA, fall 1995.

Because specific data on the number of all affected devices are unavailable, FDA examines the cost to hospitals for Phase II of the rule by again estimating the device quantities as a percentage of hospital beds. As in Phase I, FDA's estimates are based upon the 6,467 hospitals in the United States and the reported average number of 179 beds in each hospital.[12] To determine the total number of devices in each category, FDA relied on estimates from clinical and biomedical engineering directors for the percentage of beds that would have these devices. The estimates are: Six percent for electrosurgery appliances, 15 percent for telemetry transmitters, 5 percent for external pacemakers, 13 percent for supervised diagnostic equipment, and 6 percent for stimulators. FDA assumed that between 90 percent to 100 percent of the devices have not already been converted to protected styles, and that a general useful life ranges from 7 to 10 years. Also, only devices without cables would need modification. These percentages were estimated to be approximately 75 percent for electrosurgery appliances, 100 percent for telemetry transmitters, 60 percent for external pacemakers, 50 percent for supervised diagnostic equipment, and 100 percent for stimulators. As previously noted, FDA uses a $20.93 hourly compensation figure to estimate incremental labor costs, or a per minute salary rate of $0.35.

The agency once more estimates it will take a total of 5 minutes per lead wire to both thoroughly clean the connector area on the device itself and to affix the adaptor to the device. The number of adaptors needed for each of the device categories is based on estimates of the average number of lead wires found on all devices in each category. FDA estimates that the adaptors cost $5 apiece and that it will take each hospital twice as long as for the Phase I devices, or 6 additional hours, to locate all of the Phase II devices. This adds $812,126 to the total cost of Phase II of this regulation. Using an average useful life of 8 years 6 months, the 3-year phase-in period implies that about 65 percent of these devices would have to be converted. The total costs to hospitals are illustrated in the following tables.

TABLE 14.—COST OF ADAPTORS TO HOSPITALS ONLY

	Electrosurgery appliances	Telemetry transmitters	External pacemakers	Supervised diagnostic equipment	Stimulators
Number of hospitals	6,467	6,467	6,467	6,467	6,467
Number of beds	179	179	179	179	179
Percent (%) of beds	6%	15%	5%	13%	6%
Percent (%) not protected	90% to 100%	90% to 100%	90% to 100%	90% to 100%	90% to 100%
Percent (%) without cables	70% to 80%	100%	55% to 65%	50%	100%
Percent (%) to be converted	65%	65%	65%	65%	65%
Cost per adaptor	$5	$5	$5	$5	$5
Number of adaptors (average)	1.5	10.5	3.5	10	3
TOTAL COST	$213,315–$270,877	$5,332,886–$5,925,429	$325,899–$427,948	$2,200,874–$2,445,415	$609,473–$677,192
Total Cost of Adaptors =	$8,682,447–$9,746,861				

[12] *The Statistical Abstract of the United States,* U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183, p. 125, 1995.

TABLE 15.—COST OF INSTALL ADAPTORS TO HOSPITALS ONLY

	Electrosurgery appliances	Telemetry transmitters	External pacemakers	Supervised diagnostic equipment	Stimulators
Number of hospitals	6,467	6,467	6,467	6,467	6,467
Number of beds	179	179	179	179	179
Percent (%) of beds	6%	15%	5%	13%	6%
Percent (%) not protected	90% to 100%	90% to 100%	90% to 100%	90% to 100%	90% to 100%
Percent (%) without cables	70% to 80%	100%	55% to 65%	50%	100%
Percent (%) with useful life	65%	65%	65%	65%	65%
Salary per minute	$0.35	$0.35	$0.35	$0.35	$0.35
Installation time per adaptor	5 minutes	5 minutes	5 minutes	5 minutes	5 minutes
Number of adaptors	1.5	10.5	3.5	10	3
TOTAL COST	$14,882–$18,898	$372,058–$413,397	$22,737–$29,856	$153,548–$170,608	$42,520–$47,245
Total Cost to Install Adaptors =	$605,745–$680,008				

Because these numbers account for the cost to hospitals only, FDA uses quantity of shipment data from the 1994 Current Industrial Report for Electromedical and Irradiation Equipment[13] to establish a proportion between the number of the devices found in a hospital setting versus all other user facilities. To make the Current Industrial Report data more applicable, FDA derived some quantity estimates from the value of shipment data, made categorical adjustments, corrected for exports, and consulted additional sources to customize the categorical adjustments, corrected for exports, and consulted additional sources to customize the estimates. In instances where no quantity data was given, FDA used the average price of equipment in the particular device category and the value of shipments data to derive a quantity of shipments. The average prices used are as follows: Electrosurgery appliances, $10,000; telemetry transmitters, $4,000; external pacemakers, $5,000; supervised diagnostic equipment, $35,000; and stimulators, $3,500. To account for the telemetry transmitters, which were not specifically mentioned in the Current Industrial Reports, FDA used worldwide sales data for total cardiac diagnostic equipment and the telemetry monitoring markets.[14] This figure includes sales data on electrocardiographs, long-term electrocardiographs, and cardiac telemetry systems. The agency multiplied this figure by 55 percent to account for U.S. sales in this market.[15] To break out the sales data for the telemetry products, FDA subtracted the U.S. sales data for electrocardiographs in 1994 as given by the Current Industrial Report. To break out data for the external pacemakers covered by this rule, FDA used the sales data for all pacemakers in the Current Industrial Report, and subtracted out the sales for implantable cardiac pacemakers.[16] Since this 1990 sales data for cardiac pacemakers is worldwide, FDA multiplied this data by 43 percent, which represents the percentage of the world medical device market held by the United States in 1990.[17] The following categories were counted under the Supervised Diagnostic Equipment category: Magnetic resonance imaging equipment, electroencephalograph, electromyograph, and respiratory analysis equipment. The value of shipment data for all other medical therapy equipment was used to derive FDA's stimulator estimate. Total quantity data estimates by FDA for 1994 are as follows: Electrosurgery appliances, 24,447; telemetry transmitters, 6,432; external pacemakers, 5,813; supervised diagnostic equipment, 9,325; and stimulators, 132,340. To adjust for exports, FDA multiplied these numbers by 57 percent in accordance with the U.S. Industrial Outlook forecast that 43 percent of U.S. electromedical equipment production would be exported in 1994.[18] The estimated total number of devices sold in the United States per year were then multiplied by the average useful life to make the data comparable to the number of devices found in a hospital setting. An analysis of both data sources indicates that 60 percent of all of the above devices are located in hospitals. Therefore, the hospital cost estimates are assumed to be 60 percent of the total costs of Phase II of this rule, and the total costs are increased to account for the 40 percent of devices found in other user facilities.

The analysis assumes that Phase II costs will be incurred in equal increments for the first 3 years after the regulation is issued. Therefore, annual costs of $6 million will be incurred for 3 years. Using a 7 percent discount rate, the present value of the total costs for Phase II is approximately $16 million.

[13] ''Current Industrial Reports—Electromedical Equipment and Irradiation Equipment (including x-ray)—MA38R,'' U.S. Department of Commerce News, Bureau of the Census, issued September 1995.

[14] ''Forecasts of the Total World Cardiac Diagnostic Equipment and Telemetry Monitoring Market,'' Frost and Sullivan, 1992, April 1995.

[15] Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th ed., p. 92, 1992.

[16] Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th ed., p. 75, 1992.

[17] Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th ed., p. 69, 1992.

[18] U.S. Industrial Outlook, U.S. Department of Commerce, International Trade Administration, pp. 44–113, 1994.

C. Small Business Impact

FDA certifies that the rule will not have a significant economic impact on a substantial number of small entities. To illustrate this result, the agency examined the potential impact of the rule on small entities by using the highest cost scenario for analysis. Hospitals will absorb an approximate total of $11 million over both phases of this regulation. The cost for an average-sized 179 bed hospital would be about $1,723, or less than $10 per bed. According to the Small Business Administration, profit-making hospitals with revenue at $5 million or less per year are considered a small business. Using this criteria and 1993 data from AHA[19], FDA finds that most hospitals with 6 to 24 beds are small businesses. Because the individual cost to hospitals with 6, 24, 50, or 100 beds would be approximately $230, $394, $629, and $1,084 respectively, it would be less than 1 percent of the total net revenue for any of these bed size categories, and far less than 1 percent of gross revenue. Nursing homes would absorb approximately $157,000 of the total costs, or about $14 per nursing home. Ambulances and other ground transport vehicles would incur approximately $362,000 or about $7 per vehicle, and approximately $15 per organization. If doctor's offices and clinics incur the remainder of the costs, they absorb approximately $3 million under Phase I of the rule and approximately $6 million under Phase II. These estimates amount to about $47 per office and clinic. While some user facilities will incur a greater share of these costs than others, all of the above cost figures represent far less than 1 percent of total gross revenue per facility. As a result, FDA finds that the magnitude of the individual costs determined above would not represent a significant impact for a substantial number of small user facilities.

D. Conclusion

FDA estimates the total costs for Phase I of the regulation to be $5 million. The Phase II costs are approximately $6 million per year for 3 years, or a total present value cost of $16 million. All cost estimates are based upon the use of adaptors as a viable conversion method. Adding costs for Phase I and Phase II, total costs for this rule are $21 million.

As shown in section XIII. of this document, the reporting and recordkeeping burden is minimal for user facilities. Using the previously mentioned $20.93 hourly compensation figure, FDA calculates the recordkeeping burden to user facilities and manufacturers for filing an exemption or variance. FDA estimates these reporting costs under § 10.30 to be $10,465 per year. Such a minimal amount does not significantly add to the final costs of this regulation.

XIII. Paperwork Reduction Act 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Exemptions and Variances from the Performance Standard for Electrode Lead Wires and Patient Cables

Description: Section 898.14 provides that any person subject to the standard may submit a petition under § 10.30 (21 CFR 10.30) requesting an exemption or variance from the standard. The petition must demonstrate why compliance with the standard is unnecessary or unfeasible and what alternate means will be used to protect the public health. FDA will use this information to determine whether granting an exemption is in the best interests of the public health. Allowing for exemptions and variances will provide for flexibility while assuring public health protection.

Description of Respondents: Manufacturers, distributors, health care facilities.

TABLE 16—ESTIMATED ADDITIONAL ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	50	1	50	10	500

There are no capital costs or operating and maintenance costs expected as a result of this rule.

The proposed rule did not include a Paperwork Reduction Act burden estimate because it contained no information collection provisions. In the final rule, a new regulation, providing that requests for exemptions and variances from the performance standard may be submitted under § 10.30, has been added. Because of the resulting anticipated additional reporting burden under § 10.30, FDA is providing a burden estimate and an opportunity for public comment, as required by the Paperwork Reduction Act of 1995. Therefore, FDA now invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Individuals and organizations may submit comments on the information collection provisions of this final rule by July 8, 1997. Comments should be directed to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provision as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public

[19] ''Hospital Statistics,'' The American Hospital Association Profile of U.S. Hospitals, Table 11, p. 206, 1994.

comment to OMB will be provided at that time. After receiving OMB's decision, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. The effective date of § 898.14 will be announced in the **Federal Register** after OMB approval has been received. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XIV. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter to FDA Commissioner David A. Kessler from Ron Wyden, then Chairman, U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, dated August 2, 1994.
2. Information from FDA's medical device reporting (MDR) data base, Rockville, MD.
3. Information from FDA's MDR data base, Rockville, MD.
4. ''FDA Safety Alert: Unsafe Patient Lead Wires and Cables,'' FDA's September 3, 1993, Safety Alert.
5. Section 518(a) notification letter to apnea monitor manufacturers, September 3, 1993.
6. Section 518(a) notification letter to patient cable and lead wire manufacturers, September 20, 1993.
7. FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used With Medical Devices, December 28, 1993.
8. Proceedings, Unprotected Patient Cables and Electrode Lead Wires Conference, July 15, 1994.
9. ''Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting,'' United States General Accounting Office Report to the Chairman, Committee on Governmental Affairs, U.S. Senate, p. 61, December 1986.
10. Fran Hos ''Electrode Leadwire Survey,'' distributed by the American Society for Hospital Engineering of AHA, early 1994.
11. Employment and Earnings, U.S. Department of Labor Bureau of Labor Statistics, Table 39, p. 206, January 1996.
12. The Statistical Abstract of the United States, U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183, p. 125, 1995.
13. The Statistical Abstract of the United States, U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 200, p. 134, 1995.
14. ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications, p. 40.
15. ''Transportation Systems, 1994,'' produced by the National Association of State EMS Directors, p. 2, 1994.
16. ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications, p. 17.
17. ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications.
18. ''The Statistical Abstract of the United States,'' U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 1316. p. 795, 1995.
19. *The Statistical Abstract of the United States*, U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183. p. 125, 1995.
20. ''Electrode Leadwire Survey II,'' distributed by the American Society for Hospital Engineering of AHA, fall 1995.
21. *The Statistical Abstract of the United States*, U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183, p. 125, 1995.
22. ''Current Industrial Reports—Electromedical Equipment and Irradiation Equipment (including x-ray)—MA38R,'' U.S. Department of Commerce News, Bureau of the Census, issued September 1995.
23. ''Forecasts of the Total World Cardiac Diagnostic Equipment and Telemetry Monitoring Market,'' Frost and Sullivan, April 1995.
24. Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th edition, p. 92, 1992.
25. Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th edition, p. 75, 1992.
26. Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th edition, p. 69, 1992.
27. U.S. Industrial Outlook, U.S. Department of Commerce, International Trade Administration, pp. 44–113, 1994.

List of Subjects in 21 CFR Part 898

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. Part 898 is added to read as follows:

PART 898–PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

Sec.
898.11 Applicability.
898.12 Performance standard.
898.13 Compliance dates.
898.14 Exemptions and variances.

Authority: Secs. 501, 502, 513, 514, 530–542, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374); secs. 351, 361 of the Public Health Service Act (42 U.S.C. 262, 264).

§ 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in § 898.12.

§ 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

601–1: Medical Electrical Equipment

601–1 (1988) Part 1: General requirements for safety

Amendment No. 1 (1991)

Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

§ 898.13 Compliance dates.

The dates for compliance with the standard set forth in § 898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998:

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE

May 11, 1998

Phase	Product code	21 CFR section	Class	Device name
1	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE—Continued

May 11, 1998

Phase	Product code	21 CFR section	Class	Device name
1	74 DPS	870.2340	II	Electrocardiograph.
1	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radio Frequency.
1	74 DRT	870.2300	II	Monitor, Cardiac (including Cardiotachometer and Rate Alarm).
1	74 DRX	870.2360	II	Electrode, Electrocardiograph.
1	74 DSA	870.2900	II	Cable, Transducer and Electrode, Patient (including Connector).
1	74 DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1	74 DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1	74 DXH	870.2920	II	Transmitters and Receivers, Electrocardiograph, Telephone.

(b) For electrode lead wires and patient cables used with, or intended for use with, any other device, the date for which compliance is required is May 9, 2000.

§ 898.14 Exemptions and variances.

(a) A request for an exemption or variance shall be submitted in the form of a petition under §10.30 of this chapter and shall comply with the requirements set out therein. The petition shall also contain the following:

(1) The name of the device, the class in which the device has been classified, and representative labeling showing the intended uses(s) of the device;

(2) The reasons why compliance with the performance standard is unnecessary or unfeasible;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that a patient will not be inadvertently connected to hazardous voltages via an unprotected patient cable or electrode lead wire for intended use with the device; and

(4) Other information justifying the exemption or variance.

(b) An exemption or variance is not effective until the agency approves the request under § 10.30(e)(2)(i) of this chapter.

Dated: April 28, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–11967 Filed 5–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 8717]

RIN 1545–AU14

Termination of a Partnership Under Section 708(b)(1)(B)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the termination of a partnership upon the sale or exchange of 50 percent or more of the total interest in partnership capital and profits within a 12-month period. The final regulations affect all partnerships that terminate under section 708(b)(1)(B).

DATES: These regulations are effective May 9, 1997.

For applicability dates, see Effective Dates under Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Steven R. Schneider, (202) 622–3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On May 13, 1996, a notice of proposed rulemaking (PS–5–96) was published in the **Federal Register** (61 FR 21985) containing proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 708 of the Internal Revenue Code (Code). The notice of proposed rulemaking also contained proposed amendments to other sections of the Income Tax Regulations to reflect the amendments to the regulations under section 708. Written comments responding to this notice were received. A public hearing was held on September 5, 1996, pursuant to the notice published in the **Federal Register** on May 13, 1996. After consideration of all comments received, the proposed amendments are adopted as revised by this Treasury decision.

Explanation of Provisions

Section 708(b)(1)(B) provides that, for purposes of section 708(a), a partnership shall be considered terminated if within a 12-month period there is a sale or exchange of 50 percent or more of the total interest in partnership capital and profits. The existing regulations under § 1.708–1(b)(1)(iv) provide that, if a partnership is terminated by a sale or exchange of an interest, the following is deemed to occur: The partnership distributes its properties to the purchaser and the other remaining partners in proportion to their respective interests in the partnership properties; and, immediately thereafter, the purchaser and the other remaining partners contribute the properties to a new partnership, either for the continuation of the business or for its dissolution and winding up. The final regulations adopt the proposed regulations and change the mechanics of a termination under section 708(b)(1)(B) so that the following is deemed to occur on a termination: The partnership contributes all of its assets and liabilities to a new partnership in exchange for an interest in the new partnership; and, immediately thereafter, the partnership liquidates by distributing interests in the new partnership to the purchaser and the other remaining partners, followed by the continuation of the business by the new partnership or its dissolution and winding up. The final regulations also clarify certain aspects of the proposed regulations in response to comments received.

One commentator requested clarification of the section 704(c) consequences of a termination. The proposed regulations provide for a section 704(b) capital account ''book up'' upon the deemed contribution of assets by the terminated partnership to

the new partnership and also upon the deemed distribution in liquidation of the terminated partnership. This would have resulted in a new layer of section 704(c) property. The final regulations amend the regulations under section 704(b) to provide that the deemed contribution of assets to a new partnership and the distribution of the new partnership interests to the partners of the terminated partnership are disregarded for purposes of maintaining capital accounts. As a result, the termination of a partnership does not change the capital accounts of the partners or the books of the partnership and the deemed contribution of assets to a new partnership does not create additional section 704(c) property. The final regulations also provide that the new partnership is not bound by the section 704(c) method used by the terminated partnership.

A commentator requested clarification of whether a termination under the new section 708(b)(1)(B) construct will trigger recapture of investment tax credit under section 47.

Although not specifically addressed in the regulations, a section 708(b)(1)(B) termination no longer triggers recapture of the investment tax credit under the ''mere change in form'' exception in § 1.47–3(f) of the regulations.

Commentators also requested guidance on whether a section 1491 excise tax may be triggered upon a section 708(b)(1)(B) termination of a foreign partnership with U.S. partners. This issue is currently under study and the IRS and Treasury welcome comments from interested taxpayers and practitioners.

One commentator requested clarification of whether the distribution of the interests in the new partnership will be subject to section 731(c). The section 731(c) final regulations, December 26, 1996 (61 FR 67936), provide that the deemed distribution of partnership interests under § 1.708–1(b)(1)(iv) does not trigger the application of section 731(c).

Several commentators suggested that partnerships should be allowed to apply the final regulations to terminations under section 708(b)(1)(B) occurring on or after the date the proposed regulations were filed with the **Federal Register**. In response, the final regulations provide that the regulations may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply the regulations to the termination in a consistent manner.

The final regulations also provide an example illustrating the mechanics of a termination under section 708(b)(1)(B). In addition, the final regulations provide that the new partnership retains the TIN of the terminated partnership. However, if the new partnership has already applied for a new TIN, the partnership should continue to use the new TIN.

Finally, the regulations make several revenue rulings obsolete. The holdings of revenue rulings 87–50 and 87–51 (dealing with the effect of terminations under section 708(b)(1)(B) on lower-tier partnerships) and revenue rulings 86–73 and 88–42 (dealing with the effect of a § 754 election made by the terminating partnership) are now incorporated, without substantive change, into the regulations under § 1.708–1. Additionally, the final regulations make revenue ruling 93–90 (dealing with minimum gain chargeback in a section 708(b)(1)(B) termination) obsolete because the § 704(b) capital account ''book up'' that is the subject of the revenue ruling is eliminated.

Effective Date

These regulations apply to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, these regulations may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply these regulations to the termination in a consistent manner.

Effect on Other Documents

The following publications are obsolete as of May 9, 1997:

Rev. Rul. 86–73, 1986–1 C.B. 282

Rev. Rul. 87–50, 1987–1 C.B. 157

Rev. Rul. 87–51, 1987–1 C.B. 158

Rev. Rul. 88–42, 1988–1 C.B. 265

Rev. Rul. 93–90, 1993–2 C.B. 238

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Steven R. Schneider of the Office of Assistant Chief Counsel (Passthroughs and Special Industries), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.704–1 is amended as follows:

1. Paragraph (b)(2)(iv)(*d*)(*1*) is amended by revising the second sentence.

2. Paragraph (b)(2)(iv)(*l*) is amended by removing the last three sentences and adding four sentences in their place.

3. Paragraph (b)(5) *Example 13*(v) is amended by removing all the text following the third sentence and adding four sentences in its place.

The revisions and additions read as follows:

§ 1.704–1 Partner's distributive share.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(*d*) * * *

(*1*) * * * See *Example 13*(i) of paragraph (b)(5) of this section. * * *

* * * * *

(*l*) * * * If the transfer of an interest in a partnership causes a termination of the partnership under section 708(b)(1)(B), the capital account of the transferee partner and the capital accounts of the other partners of the terminated partnership carry over to the new partnership that is formed as a result of the termination of the partnership under § 1.708–1(b)(1)(iv). Moreover, the deemed contribution of assets and liabilities by the terminated partnership to a new partnership and

the deemed liquidation of the terminated partnership that occur under § 1.708–1(b)(1)(iv) are disregarded for purposes of this paragraph (b)(2)(iv). See Example 13 of paragraph (b)(5) of this section and the example in § 1.708–1(b)(1)(iv). The previous three sentences apply to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, the sentences may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply the sentences to the termination in a consistent manner.

* * * * *

(5) * * *

Example 13. * * *

(v) * * * Immediately preceding the constructive liquidation, the capital accounts of Z and LK equal $11,000 each (LK having inherited Y's $11,000 capital account) and the book value of the G Corp. securities is $22,000 (original purchase price of securities). Under paragraph (b)(2)(iv)(*l*) of this section, the deemed contribution of assets and liabilities by the terminated partnership to the new partnership and the deemed liquidation of the terminated partnership that occur under § 1.708–1(b)(1)(iv) in connection with the constructive liquidation of the terminated partnership are disregarded in the maintenance and computation of the partners' capital accounts. As a result, the capital accounts of Z and LK in the new partnership equal $11,000 each (their capital accounts in the terminated partnership immediately prior to the termination), and the book value of the G Corp. securities remains $22,000 (its book value immediately prior to the termination). This *Example 13*(v) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this *Example 13*(v) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this *Example 13*(v) to the termination in a consistent manner.

* * * * *

Par. 3. Section 1.704–3 is amended as follows:

1. Paragraph (a)(2) is amended by adding two sentences at the end of the paragraph.

2. Paragraph (a)(3)(i) is amended by adding three sentences at the end of the paragraph.

The additions read as follows:

§ 1.704–3 Contributed property.

(a) * * *

(2) * * * A new partnership formed as the result of the termination of a partnership under section 708(b)(1)(B) is not required to use the same method as the terminated partnership with respect to section 704(c) property deemed contributed to the new partnership by the terminated partnership under § 1.708–1(b)(1)(iv). The previous sentence applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, the sentence may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply the sentence to the termination in a consistent manner.

(3) * * *

(i) * * * Property deemed contributed to a new partnership as the result of the termination of a partnership under section 708(b)(1)(B) is treated as section 704(c) property in the hands of the new partnership only to the extent that the property was section 704(c) property in the hands of the terminated partnership immediately prior to the termination. See § 1.708–1(b)(1)(iv) for an example of the application of this rule. The previous two sentences apply to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, the sentences may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply the sentences to the termination in a consistent manner.

* * * * *

Par. 4. Section 1.704–4 is amended by revising paragraphs (a)(4)(ii) and (c)(3) to read as follows:

§ 1.704–4 Distribution of contributed property.

(a) * * *

(4) * * *

(ii) *Section 708(b)(1)(B) terminations.* A termination of the partnership under section 708(b)(1)(B) does not begin a new five-year period for each partner with respect to the built-in gain and built-in loss property that the terminated partnership is deemed to contribute to the new partnership under § 1.708–1(b)(1)(iv). See § 1.704–3(a)(3)(ii) for the definitions of built-in gain and built-in loss on section 704(c) property. This paragraph (a)(4)(ii) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this paragraph (a)(4)(ii) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this paragraph (a)(4)(ii) to the termination in a consistent manner.

* * * * *

(c) * * *

(3) *Section 708(b)(1)(B) terminations.* Section 704(c)(1)(B) and this section do not apply to the deemed distribution of interests in a new partnership caused by the termination of a partnership under section 708(b)(1)(B). A subsequent distribution of section 704(c) property by the new partnership to a partner of the new partnership is subject to section 704(c)(1)(B) to the same extent that a distribution by the terminated partnership would have been subject to section 704(c)(1)(B). See also § 1.737–2(a) for a similar rule in the context of section 737. This paragraph (c)(3) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this paragraph (c)(3) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this paragraph (c)(3) to the termination in a consistent manner.

* * * * *

Par. 5. Section 1.708–1 is amended as follows:

1. Paragraph (b)(1)(ii) is amended by adding three sentences after the third sentence.

2. Paragraph (b)(1)(iv) is revised.

3. Paragraph (b)(1)(v) is added.

The additions and revisions read as follows:

1.708–1 Continuation of partnership.

* * * * *

(b) * * *

(1) * * *

(ii) * * * Moreover, if the sale or exchange of an interest in a partnership (upper-tier partnership) that holds an interest in another partnership (lower-tier partnership) results in a termination of the upper-tier partnership, the upper-tier partnership is treated as exchanging its entire interest in the capital and profits of the lower-tier partnership. If the sale or exchange of an interest in an upper-tier partnership does not terminate the upper-tier partnership, the sale or exchange of an interest in the upper-tier partnership is not treated as a sale or exchange of a proportionate share of the upper-tier partnership's interest in the capital and profits of the lower-tier partnership. The previous two sentences apply to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, the sentences may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply the sentences to the termination in a consistent manner. * * *

* * * * *

(iv) If a partnership is terminated by a sale or exchange of an interest, the following is deemed to occur: The partnership contributes all of its assets and liabilities to a new partnership in exchange for an interest in the new partnership; and, immediately

thereafter, the terminated partnership distributes interests in the new partnership to the purchasing partner and the other remaining partners in proportion to their respective interests in the terminated partnership in liquidation of the terminated partnership, either for the continuation of the business by the new partnership or for its dissolution and winding up. In the latter case, the new partnership terminates in accordance with (b)(1)(i) of this section. This paragraph (b)(1)(iv) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this paragraph (b)(1)(iv) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this paragraph (b)(1)(iv) to the termination in a consistent manner. The provisions of this paragraph (b)(1)(iv) are illustrated by the following example:

Example. (i) A and B each contribute $10,000 cash to form AB, a general partnership, as equal partners. AB purchases depreciable Property X for $20,000. Property X increases in value to $30,000, at which time A sells its entire 50 percent interest to C for $15,000 in a transfer that terminates the partnership under section 708(b)(1)(B). At the time of the sale, Property X had an adjusted tax basis of $16,000 and a book value of $16,000 (original $20,000 tax basis and book value reduced by $4,000 of depreciation). In addition, A and B each had a capital account balance of $8,000 (original $10,000 capital account reduced by $2,000 of depreciation allocations with respect to Property X).

(ii) Following the deemed contribution of assets and liabilities by the terminated AB partnership to a new partnership (new AB) and the liquidation of the terminated AB partnership, the adjusted tax basis of Property X in the hands of new AB is $16,000. See Section 723. The book value of Property X in the hands of new partnership AB is also $16,000 (the book value of Property X immediately before the termination) and B and C each have a capital account of $8,000 in new AB (the balance of their capital accounts in AB prior to the termination). See § 1.704–1(b)(2)(iv)(*l*) (providing that the deemed contribution and liquidation with regard to the terminated partnership are disregarded in determining the capital accounts of the partners and the books of the new partnership). Additionally, under § 301.6109–1(d)(2)(iii) of this chapter, new AB retains the taxpayer identification number of the terminated AB partnership.

(iii) Property X was not section 704(c) property in the hands of terminated AB and is therefore not treated as section 704(c) property in the hands of new AB, even though Property X is deemed contributed to new AB at a time when the fair market value of Property X ($30,000) was different from its adjusted tax basis ($16,000). See § 1.704–3(a)(3)(i) (providing that property contributed to a new partnership under § 1.708–1(b)(1)(iv) is treated as section 704(c) property only to the extent that the property was section 704(c) property in the hands of the terminated partnership immediately prior to the termination).

(v) If a partnership is terminated by a sale or exchange of an interest in the partnership, a section 754 election (including a section 754 election made by the terminated partnership on its final return) that is in effect for the taxable year of the terminated partnership in which the sale occurs, applies with respect to the incoming partner. Therefore, the bases of partnership assets are adjusted pursuant to sections 743 and 755 prior to their deemed contribution to the new partnership. This paragraph (b)(1)(v) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this paragraph (b)(1)(v) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this paragraph (b)(1)(v) to the termination in a consistent manner.

* * * * *

Par. 6. Section 1.737–2 is amended as follows:

1. Paragraph (a) is revised.

2. In paragraph (d)(1), the first sentence is revised and one sentence is added after the first sentence.

The additions and revisions read as follows:

§ 1.737–2 Exceptions and special rules.

(a) *Section 708(b)(1)(B) terminations.* Section 737 and this section do not apply to the deemed distribution of interests in a new partnership caused by the termination of a partnership under section 708(b)(1)(B). A subsequent distribution of property by the new partnership to a partner of the new partnership that was formerly a partner of the terminated partnership is subject to section 737 to the same extent that a distribution from the terminated partnership would have been subject to section 737.

See also § 1.704–4(c)(3) for a similar rule in the context of section 704(c)(1)(B). This paragraph (a) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this paragraph (a) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this paragraph (a) to the termination in a consistent manner.

* * * * *

(d) * * * (1) * * * Any portion of the distributed property that consists of property previously contributed by the distributee partner (previously contributed property) is not taken into account in determining the amount of the excess distribution or the partner's net precontribution gain. The previous sentence applies on or after May 9, 1997. * * *

* * * * *

Par. 7. In section 1.743–1, paragraph (d) is added to read as follows:

§ 1.743–1 Optional adjustment to basis of partnership property.

* * * * *

(d) *Section 708(b)(1)(B) terminations.* A partner with a special basis adjustment in property held by a partnership that terminates under section 708(b)(1)(B) will continue to have the same special basis adjustment with respect to property deemed contributed by the terminated partnership to the new partnership under § 1.708–1(b)(1)(iv), regardless of whether the new partnership makes a section 754 election. This paragraph (d) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this paragraph (d) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this paragraph (d) to the termination in a consistent manner.

Par. 8. In § 1.761–1, paragraph (e) is added to read as follows:

§ 1.761–1 Terms defined.

* * * * *

(e) *Distribution of partnership interest.* For purposes of section 708(b)(1)(B) and § 1.708–1(b)(1)(iv), the deemed distribution of an interest in a new partnership by a partnership that terminates under section 708(b)(1)(B) is not a sale or exchange of an interest in the new partnership. However, the deemed distribution of an interest in a new partnership by a partnership that terminates under section 708(b)(1)(B) is treated as an exchange of the interest in the new partnership for purposes of section 743. This paragraph (e) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this paragraph (e) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this paragraph (e) to the termination in a consistent manner.

PART 301—PROCEDURE AND ADMINISTRATION

Par. 9. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 10. Section 301.6109–1 is amended by adding paragraph (d)(2)(iii) as follows:

§ 301.6109–1 Identifying numbers.

* * * * *

(d) * * *

(2) * * *

(iii) *Special rule for Section 708(b)(1)(B) terminations.* A new partnership that is formed as a result of the termination of a partnership under section 708(b)(1)(B) will retain the employer identification number of the terminated partnership. This paragraph (d)(2)(iii) applies to terminations of partnerships under section 708(b)(1)(B) occurring on or after May 9, 1997; however, this paragraph (d)(2)(iii) may be applied to terminations occurring on or after May 9, 1996, provided that the partnership and its partners apply this paragraph (d)(2)(iii) to the termination in a consistent manner.

* * * * *

Margaret Milner Richardson,

Commissioner of Internal Revenue.

Approved: May 1, 1997.

Donald C. Lubick,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 97–12061 Filed 5–8–97; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8718]

RIN 1545–AS49

Arbitrage Restrictions on Tax-Exempt Bonds

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations on the arbitrage and related restrictions applicable to tax-exempt bonds issued by State and local governments. Changes to the applicable law were made by the Tax Reform Act of 1986, the Technical and Miscellaneous Revenue Act of 1988, the Revenue Reconciliation Act of 1989, and the Revenue Reconciliation Act of 1990. These regulations affect issuers of tax-exempt bonds and provide guidance for complying with the arbitrage and related restrictions.

DATES: These regulations are effective May 9, 1997.

For dates of applicability of these regulations, see §§ 1.103–8(a)(5), 1.142–4(d), 1.148–11, 1.148–11A, 1.149(d)–1(g)(3), and 1.150–1(a)(2).

FOR FURTHER INFORMATION CONTACT: Brigitte Finley, (202) 622–3980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in these final regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1347. Responses to these collections of information are required to obtain a benefit from treating a contract as a qualified hedge or treating certain general obligation bonds as a single issue.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The estimated average annual burden hours per recordkeeper: 2 hours.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20024, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to collections of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Section 148 of the Internal Revenue Code restricts the use of proceeds of tax-exempt State and local bonds to acquire higher yielding investments. On June 18, 1993, final regulations (TD 8476) relating to the arbitrage restrictions and related rules under sections 103, 148, 149, and 150 (the June 1993 regulations) were published in the **Federal Register** (59 FR 33510). Corrections to the June 1993 regulations were published in the **Federal Register** on August 23, 1993 (58 FR 44451), and May 11, 1994 (59 FR 24350).

On May 10, 1994, temporary and final regulations (TD 8538) to clarify and revise certain provisions of the June 1993 regulations were published in the **Federal Register** (59 FR 24039). A notice of proposed rulemaking (FI–7–94) cross-referencing the temporary regulations and proposing additional changes to the June 1993 regulations was published in the **Federal Register** on the same day (59 FR 24094). Written comments were received, and a public hearing was held on September 25, 1995.

After consideration of all the comments, the proposed regulations have been modified and are adopted in final form, and the corresponding temporary regulations are redesignated as final regulations. The principal changes to the regulations, as well as the major comments and suggestions, are discussed below. Comments relating to regulations under section 148 other than those in the proposed regulations also were received. The changes requested by those comments are not addressed in these final regulations, but are under consideration.

Explanation of Provisions

A. Section 1.142–4—Interest on Bonds To Finance Certain Exempt Facilities

The proposed regulations provide generally that costs incurred before the issue date of an exempt facility bond may not be financed with the proceeds of that bond unless an official action was taken within 60 days of the date those costs were incurred. For tax-exempt bonds subject to § 1.150–2, however, a reimbursement allocation may be made if the official action was taken within 60 days of the date that the costs were paid. One commentator requested that the official action and reimbursement allocation rules for exempt facility bonds be the same as the rules in § 1.150–2. The final regulations generally adopt this suggestion. The final regulations also clarify that a refinancing of a taxable debt other than a State or local bond is not treated as a refunding for purposes of this rule. In addition, the final regulations redesignate this provision, which was previously contained in § 1.103–8(a)(5), as new § 1.142–4.

B. Section 1.148–1—Definitions and Elections

1. Bonds Financing a Working Capital Reserve

The June 1993 regulations provide that replacement proceeds may arise if a working capital reserve is directly or indirectly financed with bond proceeds, but not to the extent the issuer has maintained a working capital reserve. The proposed regulations provide a method for determining whether an issuer has maintained a working capital reserve. This method is based on the average amount of working capital

maintained by the issuer before the issue date of the bonds.

One commentator stated that start-up operations are unable to demonstrate any average reserves for past periods and, therefore, cannot show that they have not indirectly financed a working capital reserve with bond proceeds.

The determination of whether an issuer has financed a working capital reserve with bond proceeds is based on facts and circumstances. The method in the proposed regulations provides one way of making that determination. An issuer may use alternative methods to establish that a working capital reserve is not indirectly financed with bond proceeds. Therefore, the final regulations adopt the provision in the proposed regulations.

2. Definition of Investment-Type Property

The proposed regulations clarify that the definition of investment-type property includes a contract that would be a hedge under § 1.148–4(h) except that it contains a significant investment element. The proposed regulations also provide that an interest rate cap contains a significant investment element if the payments for the cap are made more quickly than in level annual installments over the term of the cap, the cap hedges a bond that is not a variable rate debt instrument (VRDI) under § 1.1275–5, or the cap rate is less than the on-market swap rate on the date the cap is entered into.

Commentators requested that the provisions relating to whether an interest rate cap contains a significant investment element be deleted because they asserted that those conditions do not give rise to an expected return from the cap. One commentator stated that these rules were misplaced and should be included in the provision in § 1.148–4(h) dealing with significant investment element.

The final regulations modify the proposed regulations in several ways. First, the provision that a cap contains a significant investment element if the cap rate is less than the on-market swap rate has been deleted. The deletion of this rule is balanced by another rule addressing the timing of payments for a cap. (See discussion below.) Second, the requirement relating to the pattern of payments for a cap and the prohibition on hedging an instrument other than a VRDI have been moved to § 1.148–4(h). (See discussion below.) Third, the final regulations clarify that investment-type property includes only the investment element of a hedge that contains a significant investment element. This element does not necessarily include all payments on or receipts from a hedge.

C. Section 1.148–4—Yield on an Issue of Bonds

1. Yield on Certain Mortgage Revenue and Student Loan Bonds

The proposed regulations provide that, for purposes of applying sections 148 and 143(g) to a variable yield issue of qualified mortgage bonds, qualified veterans' mortgage bonds, or qualified student loan bonds, the yield on the issue is computed over the term of the issue, and § 1.148–4(d) (relating to conversion from a variable yield issue to a fixed yield issue) does not apply. The proposed regulations also address how to compute yield over the term of the issue.

One commentator requested that this rule be amended so it applies only for yield restriction purposes or only to variable yield issues that are expected to convert to fixed yield issues. The commentator explained that applying the rule for rebate purposes may be inappropriate. The final regulations generally adopt this comment by providing that the rule applies only to issues that are expected to convert to a fixed yield and only for purposes of applying sections 148 and 143(g) to purpose investments.

2. Qualified Hedging Transactions

a. Definition of hedge. The final regulations expand the definition of hedge to include certain hedges of bonds of an issue that would otherwise be a fixed yield issue (a fixed-to-variable hedge). Generally, a fixed-to-variable hedge must be entered into no later than 15 days after the issue date of the issue (or the deemed issue date under § 1.148–4(d)) or no later than the expiration of another qualified hedge with respect to the bonds. The permitted fixed-to-variable hedges are limited in this manner to minimize the complex computations and potential for abuse that may arise if an issue switches between fixed yield treatment and variable yield treatment during the term of the issue. Comments are requested on the extent to which other fixed-to-variable hedges should be treated as a hedge.

b. Significant investment element. The definition of investment-type property in the proposed regulations provides that an interest rate cap contains a significant investment element if the payments for the cap are made more quickly than in level annual installments. Commentators requested that this provision be deleted because they asserted that early payment of a cap premium never gives rise to an expected return from the cap.

Amounts paid for an interest rate cap generally relate increasingly to the later years of the term of the cap. Thus, this rule reflects the concern that the issuer receives an arbitrage benefit by making a prepayment. This prepayment concern also arises in connection with other types of hedges when an issuer makes payments before the period to which those payments relate. Therefore, the final regulations provide that a hedge contains a significant investment element if the issuer's payments for the hedge are significantly front-loaded. In addition, a hedge contains a significant investment element if the issuer's payments are significantly back-loaded. The final regulations also include a special rule for caps that permits cap fees to be paid in level installments over the term of the cap.

c. Interest based. The definition of investment-type property in the proposed regulations provides that an interest rate cap contains a significant investment element if the cap hedges a bond that is not a VRDI within the meaning of § 1.1275–5. Commentators requested that this provision be deleted because they asserted that hedging a bond that is not a VRDI does not give rise to an expected return from the cap.

The final regulations clarify that a contract meets the requirement that it be interest based only if, (i) before the contract is taken into account, each hedged bond is a type of obligation that is respected as solely tax-exempt debt under the original issue discount regulations (i.e., a fixed rate bond, a VRDI within the meaning of § 1.1275–5 that is not based on an objective rate other than a qualified inverse floating rate or a qualified inflation rate, a tax-exempt obligation described in § 1.1275–4(d)(2), or an inflation-indexed debt instrument within the meaning of § 1.1275–7T), and (ii) after the contract is taken into account, each hedged bond is substantially the same as one of these types of debt instruments.

d. Timing and allocation of payments. The proposed regulations provide that the period to which a payment made by the issuer relates is based on general Federal income tax principles, and that generally a payment received by the issuer is taken into account in the period that the interest payment that the payment hedges is required to be made. The final regulations amend these rules to provide that payments made or received by the issuer under a qualified hedge are taken into account in the period that those amounts would be treated as income or deductions under § 1.446–4 (without regard to the

exclusion from § 1.446–4 for tax-exempt obligations).

e. Certain variable yield bonds treated as fixed yield bonds—certain terminations disregarded. Under the June 1993 regulations, a variable yield issue is treated as a fixed yield issue if the issuer enters into a qualified hedge that meets certain requirements. The proposed regulations in general provide that upon a termination of this type of qualified hedge, the issue of which the hedged bonds are a part is treated for purposes of § 1.148–3 (relating to rebate) as if it were reissued as of the termination date. The proposed regulations also provide that the termination will be disregarded (i.e., the issue will continue to be treated as a fixed yield issue) if (i) the issuer immediately replaces the terminated hedge and there is no change in the yield or (ii) the termination is caused by the bankruptcy or insolvency of the hedge provider and the Commissioner determines that the termination occurred without any action by the issuer. The final regulations modify the proposed regulations by deleting the provision relating to terminations of a qualified hedge caused by the bankruptcy or insolvency of the hedge provider because, unless the issuer enters into a replacement hedge, any termination of the hedge may cause a change in the yield on the bonds.

f. Certain acquisition payments. The proposed regulations provide that if an issuer receives a single, up-front payment relating to the off-market portion of an otherwise qualified hedge, the hedge does not fail to be a qualified hedge as long as the off-market rates are separately identified and are not taken into account in determining yield on the bonds. The proposed regulations also provide that the on-market rates are determined as of the date the parties enter into the contract. The final regulations adopt this rule. In the case of hedges entered into before the issue date (e.g., a forward swap), the on-market rate is the forward on-market rate on the date the parties enter into the hedge.

g. Treatment of hedges entered into before issue date of hedged bonds. The proposed regulations provide that a hedge entered into before the issue date may be a qualified hedge, even if the payments received by the issuer do not correspond to interest payments on the hedged bonds. Commentators requested clarification about what other special rules apply to these types of hedges. In particular, commentators suggested that payments made or received by an issuer before the issue date should not prevent these types of hedges from treatment as a qualified hedge.

The final regulations clarify the treatment of two different types of hedges entered into before the issue date. First, if an issuer expects that a hedge will be closed in connection with the issuance of bonds, payments on the hedge made or received, or deemed made or received, adjust the issue price of the hedged bonds. For this purpose, issue price is adjusted by taking into account the future value as of the issue date of the payments made or received before the issue date. Second, if an issuer does not expect that a hedge will be closed in connection with the issuance of the bonds and does not close the hedge in connection with the issuance of the bonds, the payments and receipts on the hedge adjust payments and receipts on the hedged bonds in the same manner as other qualified hedges. Payments on the hedge made by the issuer before the issue date, however, are not taken into account for purposes of determining yield on the hedged bond.

h. Authority of Commissioner. The proposed regulations permit the Commissioner to determine that a contract is not a qualified hedge if treating the contract as a qualified hedge provides a material potential for arbitrage. In addition, the proposed regulations permit the Commissioner to recompute the yield on an issue by taking into account a hedge if the issuer fails to meet the qualified hedge rules and the failure distorts the yield or otherwise fails to clearly reflect the economic substance of the transaction.

Some commentators asserted that this grant of authority is too broad and adds uncertainty about the proper treatment of certain transactions that are not specifically addressed by the regulations, such as asset hedges.

In general, an issuer may choose whether a hedge is treated as a qualified hedge, as long as that choice is prospective. Section 1.148–10(e) gives the Commissioner the authority to depart from the rules of §§ 1.148–1 through 1.148–11 to reflect the economic substance of a transaction if a principal purpose of the transaction is to obtain an arbitrage benefit that is inconsistent with the purposes of section 148. Therefore, in general a separate anti-abuse rule is unnecessary. The final regulations amend § 1.148–10(e) to clarify that the actions the Commissioner may take to clearly reflect the economic substance of a transaction include treating a hedge as a qualified hedge or treating a hedge as other than a qualified hedge. Because special considerations apply to identification of hedges entered into before the issue date of the hedged bonds, the final regulations also provide that this type of hedge will be treated as a hedge of bonds that are similar to the bonds that the issuer expected to issue when it entered into the hedge.

i. Asset hedging. The proposed regulations do not provide specific rules for the treatment of hedges of assets allocable to the proceeds of tax-exempt bonds. One commentator suggested that the regulations extend the integration principles currently applicable to qualified hedges to include comparable principles for hedges of assets allocable to the proceeds of tax-exempt bonds. The final regulations do not adopt this comment or provide specific rules for asset hedging. However, comments are requested relating to the proper treatment of asset hedges for purposes of section 148.

D. Section 1.148–5—Yield and Valuation of Investments

1. Permissive Application of Single Investment Rules to Certain Yield Restricted Investments for all Purposes of Section 148

The proposed regulations provide that for all purposes of section 148, an issuer may blend the yield of all yield restricted, nonpurpose investments in a refunding escrow and a sinking fund that is reasonably expected as of the issue date to be maintained to reduce the yield on the investments in the refunding escrow. Commentators requested that this rule be amended to permit blending of the yield on all yield restricted nonpurpose investments. The final regulations do not adopt this comment because a more flexible yield blending rule could permit avoidance of the requirement that rebatable arbitrage must be paid for periods of no greater than 5 years. In addition, the final regulations clarify that the rule applies only to sinking funds that are reasonably expected as of the issue date to be established and maintained solely to reduce the yield on the investments in the refunding escrow. For example, the rule does not apply to investments in a reasonably required reserve fund that the issuer intends to use to reduce the yield on the investments in a refunding escrow.

2. Manner of Payment of Yield Reduction Payments

The proposed regulations provide that yield reduction payments must be made at the same time and in the same manner as rebate amounts are required to be paid under § 1.148–3(f), and that the date a payment is required to be

paid is determined without regard to § 1.148–3(h), which allows the issuer to pay a penalty in lieu of loss of tax-exemption in certain situations. The proposed regulations also provide that a yield reduction payment that is paid untimely is not taken into account unless the Commissioner determines that the failure to pay timely is not due to willful neglect.

One commentator noted that this rule imposes a procedural standard that is different from the rules regarding late rebate payments and requested that this rule be amended to eliminate the requirement of action by the Commissioner and to otherwise conform to the rules for late payment of rebate. The final regulations adopt this comment.

3. External Commingled Funds

The June 1993 regulations provide that an issuer that invests in a commingled fund may take indirect administrative costs of the commingled fund into account for purposes of determining payments and receipts on nonpurpose investments if certain requirements are met. In general, the issuer and any related parties must not own more than 10 percent of the beneficial interest in the fund. The proposed regulations provide a test for determining whether the 10 percent limit is met.

One commentator stated that under the method for determining whether the 10 percent requirement is met the investor is uncertain whether its deposit will cause it to exceed the 10 percent limit, whether actions of another investor will cause it to exceed the 10 percent limit at any time for the duration of this investment, whether the whole fund is tainted if one investor exceeds the 10 percent limit, whether the impact is limited to those days that the 10 percent limit is exceeded, how the 10 percent limit is measured, and whether the semiannual period is a fixed or a floating period. The commentator suggested that the test should be applied only at the time that a deposit is made and the result should not be affected by simultaneous or subsequent activity in the pool.

The final regulations generally adopt this suggestion. The final regulations clarify that this rule applies only to widely held commingled funds and that the determination of whether a fund is widely held is based on the average number of investors during the immediately preceding, fixed, semiannual period chosen by the fund (e.g., semiannual periods ending June 30 and December 31). Thus, the determination of whether any issuer that has invested in a commingled fund may take indirect administrative costs into account may change from one 6-month period to another. The final regulations also provide that the determination of whether an investor exceeds the 10 percent limit is made on the date of deposit into the commingled fund and whether that investor exceeds the 10 percent limit is not affected by subsequent actions of investors in the fund. In addition, if any investor exceeds the 10 percent limit, no investor in the fund may take indirect administrative costs into account until that investor makes sufficient withdrawals from the fund to meet the 10 percent limit. Thus, if a fund continues to be widely held and does not accept any deposits from an investor that exceeds the 10 percent limit, all issuers that have invested tax-exempt bond proceeds in the fund may take the indirect administrative costs of the fund into account.

4. Qualified Administrative Costs of Guaranteed Investment Contracts

The June 1993 regulations generally provide that administrative costs must be reasonable in order to be qualified administrative costs. The proposed regulations provide that a broker's commission for a guaranteed investment contract is treated as an administrative cost and is not a qualified administrative cost to the extent that the present value of the fee exceeds the present value of annual payments equal to .05 percent of the weighted average amount reasonably expected to be invested each year during the term of the contract. The final regulations clarify that a broker's commission is a qualified administrative cost to the extent it does not exceed the lesser of a reasonable amount or the .05 percent limit. No inference should be drawn that there are necessarily any situations in which a commission equal to .05 percent is reasonable.

E. Section 1.150–1—Definitions

The proposed regulations define ''issue'' for all purposes of sections 103 and 141 through 150. The final regulations adopt the definition as proposed with one modification. The final regulations delete the rule that a variable yield bond is treated as sold on its issue date and clarify that the definition of ''sale date'' applies to all bonds.

The proposed regulations also provide a special rule relating to the treatment of general obligation bonds sold and issued on the same dates pursuant to a single offering document as part of the same issue. Commentators expressed concern that this special rule is mandatory and conflicts with other rules relating to the determination of whether bonds are part of a single issue. The commentators requested that the relationship of the rules be clarified and that the general obligation rule not be mandatory.

The final regulations generally adopt these comments by permitting an issuer to elect to treat tax-exempt general obligation bonds sold and issued on the same dates pursuant to a single offering document as part of the same issue. However, taxable bonds still must be treated as a separate issue. A proposed amendment to the exception for taxable bonds in § 1.150–1(c)(2), proposed in regulations published in the **Federal Register** on December 30, 1994, is not addressed by these final regulations.

F. Effective Dates

The final regulations generally are effective for bonds issued on or after July 8, 1997. An issuer generally may apply the final regulations to bonds that are outstanding on July 8, 1997 and to which certain prior regulations apply. In addition, the rules in the temporary regulations have been redesignated as §§ 1.148–1A through 1.148–6A, 1.148–9A, 1.148–10A, 1.148–11A, 1.149(d)–1A, and 1.150–1A and, together with the applicable provisions of the June 1993 regulations, continue to apply to bonds issued before July 8, 1997.

Special Analysis

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the notice of proposed rulemaking preceding the regulations was issued prior to March 29, 1996, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Brigitte Finley and William P. Cejudo, Office of Assistant Chief Counsel (Financial Institutions and Products). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by removing the entry for § 1.148–11T to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. In § 1.103–8, paragraph (a)(5) is revised to read as follows:

§ 1.103–8 Interest on bonds to finance certain exempt facilities.

(a) * * *

(5) *Limitation.* (i) A facility qualifies under this section only to the extent that there is a valid reimbursement allocation under § 1.150–2 with respect to expenditures that are incurred before the issue date of the bonds to provide the facility and that are to be paid with the proceeds of the issue. In addition, if the original use of the facility begins before the issue date of the bonds, the facility does not qualify under this section if any person that was a substantial user of the facility at any time during the 5-year period before the issue date or any related person to that user receives (directly or indirectly) 5 percent or more of the proceeds of the issue for the user's interest in the facility and is a substantial user of the facility at any time during the 5-year period after the issue date, unless—

(A) An official intent for the facility is adopted under § 1.150–2 within 60 days after the date on which acquisition, construction, or reconstruction of that facility commenced; and

(B) For an acquisition, no person that is a substantial user or related person after the acquisition date was also a substantial user more than 60 days before the date on which the official intent was adopted.

(ii) A facility, the original use of which commences (or the acquisition of which occurs) on or after the issue date of bonds to provide that facility, qualifies under this section only to the extent that an official intent for the facility is adopted under § 1.150–2 by the issuer of the bonds within 60 days after the commencement of the construction, reconstruction, or acquisition of that facility. Temporary construction or other financing of a facility prior to the issuance of the bonds to provide that facility will not cause that facility to be one that does not qualify under this paragraph (a)(5)(ii).

(iii) For purposes of paragraph (a)(5)(i) of this section, *substantial user* has the meaning used in section 147(a)(1), *related person* has the meaning used in section 144(a)(3), and a user that is a governmental unit within the meaning of § 1.103–1 is disregarded.

(iv) Except to the extent provided in §§ 1.142–4(d), 1.148–11A(i), and 1.150–2(j), this paragraph (a)(5) applies to bonds issued after June 30, 1993, and sold before July 8, 1997. See § 1.142–4(d) for rules relating to bonds sold on or after July 8, 1997.

* * * * *

§ 1.103–8T [Removed]

Par. 3. Section 1.103–8T is removed.

Par. 4. Section 1.142–4 is added to read as follows:

§ 1.142–4 Use of proceeds to provide a facility.

(a) *In general.* [Reserved].

(b) *Reimbursement allocations.* If an expenditure for a facility is paid before the issue date of the bonds to provide that facility, the facility is described in section 142(a) only if the expenditure meets the requirements of § 1.150–2 (relating to reimbursement allocations). For purposes of this paragraph (b), if the proceeds of an issue are used to pay principal of or interest on an obligation other than a State or local bond (for example, temporary construction financing of the conduit borrower), that issue is not a refunding issue, and, thus, § 1.150–2(g) does not apply.

(c) *Limitation on use of facilities by substantial users*—(1) *In general.* If the original use of a facility begins before the issue date of the bonds to provide the facility, the facility is not described in section 142(a) if any person that was a substantial user of the facility at any time during the 5-year period before the issue date or any related person to that user receives (directly or indirectly) 5 percent or more of the proceeds of the issue for the user's interest in the facility and is a substantial user of the facility at any time during the 5-year period after the issue date, unless—

(i) An official intent for the facility is adopted under § 1.150–2 within 60 days after the date on which acquisition, construction, or reconstruction of that facility commenced; and

(ii) For an acquisition, no person that is a substantial user or related person after the acquisition date was also a substantial user more than 60 days before the date on which the official intent was adopted.

(2) *Definitions.* For purposes of paragraph (c)(1) of this section, *substantial user* has the meaning used in section 147(a)(1), *related person* has the meaning used in section 144(a)(3), and a user that is a governmental unit within the meaning of § 1.103–1 is disregarded.

(d) *Effective date*—(1) *In general.* This section applies to bonds sold on or after July 8, 1997. See § 1.103–8(a)(5) for rules applicable to bonds sold before that date.

(2) *Elective retroactive application.* An issuer may apply this section to any bond sold before July 8, 1997.

Par. 5. In § 1.148–0, paragraph (c) is amended as follows:

1. An entry for § 1.148–1, paragraph (e) is added.

2. The entries for § 1.148–4, paragraph (h)(4) and (h)(5) are revised.

3. An entry for § 1.148–4, paragraph (h)(6) is added.

4. An entry for § 1.148–11, paragraph (b)(3) is added.

5. Entries for § 1.148–11, paragraphs (c)(1) and (g) are revised.

6. Entries for § 1.148–11, paragraphs (h) and (i) are removed.

The revised and added provisions read as follows:

§ 1.148–0 Scope and table of contents.

* * * * *

(c) * * *

§ 1.148–1 Definitions and elections.

* * * * *

(e) Investment-type property.

* * * * *

§ 1.148–4 Yield on an issue of bonds.

* * * * *

(h) * * *

(4) Certain variable yield bonds treated as fixed yield bonds.

(5) Contracts entered into before issue date of hedged bond.

(6) Authority of the Commissioner.

* * * * *

§ 1.148–11 Effective dates.

* * * * *

(b) * * *

(3) No elective retroactive application for hedges of fixed rate issues.

(c) * * *

(1) Retroactive application of overpayment recovery provisions.

* * * * *

(g) Provisions applicable to certain bonds sold before effective date.

§§ 1.148–1T, 1.148–2T, 1.148–3T, 1.148–4T, 1.148–5T, 1.148–6T, 1.148–9T, 1.148–10T, and 1.148–11T [Redesignated as §§ 1.148–1A, 1.148–2A, 1.148–3A, 1.148–4A, 1.148–5A, 1.148–6A, 1.148–9A, 1.148–10A, and 1.148–11A]

Par. 6. Sections 1.148–1T, 1.148–2T, 1.148–3T, 1.148–4T, 1.148–5T, 1.148–6T, 1.148–9T, 1.148–10T, and 1.148–11T are redesignated as §§ 1.148–1A, 1.148–2A, 1.148–3A, 1.148–4A, 1.148–5A, 1.148–6A, 1.148–9A, 1.148–10A, and 1.148–11A, respectively, and added under an undesignated centerheading immediately preceding the undesignated centerheading ''Deductions for Personal Exemptions'' to read as follows:

Regulations Applicable to Certain Bonds Sold Prior to July 8, 1997.

Par. 6a. The section headings of newly designated §§ 1.148–1A, 1.148–2A, 1.148–3A, 1.148–4A, 1.148–5A, 1.148–6A, 1.148–9A, 1.148–10A, and 1.148–11A are amended by removing the language ''(temporary)''.

Par. 7. Section 1.148–1 is amended as follows:

1. Paragraph (b) is amended by revising the definition of Investment-type property, by adding the definition of Replacement proceeds in alphabetical order, and by adding a new sentence at the end of the definition of *Sale proceeds.*

2. Paragraph (c)(4)(ii)(A) is revised.

3. Paragraph (e) is added.

The revised and added provisions read as follows:

§ 1.148–1 Definitions and elections.

* * * * *

(b) * * *

* * * * *

Investment-type property is defined in paragraph (e) of this section.

* * * * *

Replacement proceeds is defined in paragraph (c) of this section.

* * * * *

Sale proceeds * * * See also § 1.148–4(h)(5) treating amounts received upon the termination of certain hedges as sale proceeds.

* * * * *

(c) * * *

(4) * * *

(ii) *Bonds financing a working capital reserve*—(A) *In general.* Except as otherwise provided in paragraph (c)(4)(ii)(B) of this section, replacement proceeds arise to the extent a working capital reserve is, directly or indirectly, financed with the proceeds of the issue (regardless of the expenditure of proceeds of the issue). Thus, for example, if an issuer that does not maintain a working capital reserve borrows to fund a working capital reserve, the issuer will have replacement proceeds. To determine the amount of a working capital reserve maintained, an issuer may use the average amount maintained as a working capital reserve during annual periods of at least 1 year, the last of which ends within 1 year before the issue date. For example, the amount of a working capital reserve may be computed using the average of the beginning or ending monthly balances of the amount maintained as a reserve (net of unexpended gross proceeds) during the 1 year period preceding the issue date.

* * * * *

(e) *Investment-type property*—(1) *In general.* Investment-type property includes any property, other than property described in section 148(b)(2)(A), (B), (C), or (E), that is held principally as a passive vehicle for the production of income. For this purpose, production of income includes any benefit based on the time value of money, including the benefit from making a prepayment.

(2) *Non-customary prepayments.* Except as otherwise provided in this paragraph (e), a prepayment for property or services gives rise to investment-type property if a principal purpose for prepaying is to receive an investment return from the time the prepayment is made until the time payment otherwise would be made. A prepayment does not give rise to investment-type property if—

(i) The prepayment is made for a substantial business purpose other than investment return and the issuer has no commercially reasonable alternative to the prepayment; or

(ii) Prepayments on substantially the same terms are made by a substantial percentage of persons who are similarly situated to the issuer but who are not beneficiaries of tax-exempt financing.

(3) *Certain hedges.* Investment-type property also includes the investment element of a contract that is a hedge (within the meaning of § 1.148–4(h)(2)(i)(A)) and that contains a significant investment element because a payment by the issuer relates to a conditional or unconditional obligation by the hedge provider to make a payment on a later date. See § 1.148–4(h)(2)(ii) relating to hedges with a significant investment element.

Par. 8. In § 1.148–2, paragraph (b)(2)(ii) is revised to read as follows:

§ 1.148–2 General arbitrage yield restriction rules.

* * * * *

(b) * * *

(2) * * *

(ii) *Exceptions to certification requirement.* An issuer is not required to make a certification for an issue under paragraph (b)(2)(i) of this section if—

(A) The issuer reasonably expects as of the issue date that there will be no unspent gross proceeds after the issue date, other than gross proceeds in a bona fide debt service fund (e.g., equipment lease financings in which the issuer purchases equipment in exchange for an installment payment note); or

(B) The issue price of the issue does not exceed $1,000,000.

* * * * *

Par. 9. In § 1.148–3, the last sentence of paragraph (h)(3) is revised to read as follows:

§ 1.148–3 General arbitrage rebate rules.

* * * * *

(h) * * *

(3) * * * For purposes of this paragraph (h)(3), willful neglect does not include a failure that is attributable solely to the permissible retroactive selection of a short first bond year if the rebate amount that the issuer failed to pay is paid within 60 days of the selection of that bond year.

* * * * *

Par. 10. Section 1.148–4 is amended as follows:

1. Paragraphs (b)(5), (g), (h)(1), (h)(2) introductory text, and (h)(2)(i) are revised.

2. Paragraph (h)(2)(vi) and (h)(2)(vii) are removed.

3. Paragraphs (h)(2)(ii) through (h)(2)(v) are redesignated as paragraphs (h)(2)(iii) through (h)(2)(vi) and paragraphs (h)(2)(viii) and (h)(2)(ix) are redesignated as paragraphs (h)(2)(vii) and (h)(2)(viii).

4. New paragraph (h)(2)(ii) is added.

5. Newly designated paragraphs (h)(2)(iv), (h)(2)(v), (h)(2)(vi), and (h)(2)(viii) and paragraphs (h)(3), (h)(4), and (h)(5) are revised.

6. Paragraph (h)(6) is added.

The revised and added provisions read as follows:

§ 1.148–4 Yield on an issue of bonds.

* * * * *

(b) * * *

(5) *Special aggregation rule treating certain bonds as a single fixed yield bond.* Two variable yield bonds of an issue are treated in the aggregate as a single fixed yield bond if—

(i) Aggregate treatment would result in the single bond being a fixed yield bond; and

(ii) The terms of the bonds do not contain any features that could distort the aggregate fixed yield from what the

yield would be if a single fixed yield bond were issued. For example, if an issue contains a bond bearing interest at a floating rate and a related bond bearing interest at a rate equal to a fixed rate minus that floating rate, those two bonds are treated as a single fixed yield bond only if neither bond may be redeemed unless the other bond is also redeemed at the same time.

* * * * *

(g) *Yield on certain mortgage revenue and student loan bonds.* For purposes of section 148 and this section, section 143(g)(2)(C)(ii) applies to the computation of yield on an issue of qualified mortgage bonds or qualified veterans' mortgage bonds. For purposes of applying section 148 and section 143(g) with respect to purpose investments allocable to a variable yield issue of qualified mortgage bonds, qualified veterans' mortgage bonds, or qualified student loan bonds that is reasonably expected as of the issue date to convert to a fixed yield issue, the yield may be computed over the term of the issue, and, if the yield is so computed, paragraph (d) of this section does not apply to the issue. As of any date, the yield over the term of the issue is based on—

(1) With respect to any bond of the issue that has not converted to a fixed and determinable yield on or before that date, the actual amounts paid or received to that date and the amounts that are reasonably expected (as of that date) to be paid or received with respect to that bond over the remaining term of the issue (taking into account prepayment assumptions under section 143(g)(2)(B)(iv), if applicable); and

(2) With respect to any bond of the issue that has converted to a fixed and determinable yield on or before that date, the actual amounts paid or received before that bond converted, if any, and the amount that was reasonably expected (on the date that bond converted) to be paid or received with respect to that bond over the remaining term of the issue (taking into account prepayment assumptions under section 143(g)(2)(B)(iv), if applicable).

(h) *Qualified hedging transactions*—(1) *In general.* Payments made or received by an issuer under a qualified hedge (as defined in paragraph (h)(2) of this section) relating to bonds of an issue are taken into account (as provided in paragraph (h)(3) of this section) to determine the yield on the issue. Except as provided in paragraphs (h)(4) and (h)(5)(ii)(E) of this section, the bonds to which a qualified hedge relates are treated as variable yield bonds from the issue date of the bonds. This paragraph (h) applies solely for purposes of sections 143(g), 148, and 149(d).

(2) *Qualified hedge defined.* Except as provided in paragraph (h)(5) of this section, the term *qualified hedge* means a contract that satisfies each of the following requirements:

(i) *Hedge*—(A) *In general.* The contract is entered into primarily to modify the issuer's risk of interest rate changes with respect to a bond (a hedge). For example, the contract may be an interest rate swap, an interest rate cap, a futures contract, a forward contract, or an option.

(B) *Special rule for fixed rate issues.* If the contract modifies the issuer's risk of interest rate changes with respect to a bond that is part of an issue that, absent the contract, would be a fixed rate issue, the contract must be entered into—

(*1*) No later than 15 days after the issue date (or the deemed issue date under paragraph (d) of this section) of the issue; or

(*2*) No later than the expiration of a qualified hedge with respect to bonds of that issue that satisfies paragraph (h)(2)(i)(B)(*1*) of this section; or

(*3*) No later than the expiration of a qualified hedge with respect to bonds of that issue that satisfies either paragraph (h)(2)(i)(B)(*2*) of this section or this paragraph (h)(2)(i)(B)(*3*).

(C) *Contracts with certain acquisition payments.* If a hedge provider makes a single payment to the issuer (e.g., a payment for an off-market swap) in connection with the acquisition of a contract, the issuer may treat a portion of that contract as a hedge provided—

(*1*) The hedge provider's payment to the issuer and the issuer's payments under the contract in excess of those that it would make if the contract bore rates equal to the on-market rates for the contract (determined as of the date the parties enter into the contract) are separately identified in a certification of the hedge provider; and

(*2*) The payments described in paragraph (h)(2)(i)(C)(*1*) of this section are not treated as payments on the hedge.

(ii) *No significant investment element*—(A) *In general.* The contract does not contain a significant investment element. Except as provided in paragraph (h)(2)(ii)(B) of this section, a contract contains a significant investment element if a significant portion of any payment by one party relates to a conditional or unconditional obligation by the other party to make a payment on a different date. Examples of contracts that contain a significant investment element are a debt instrument held by the issuer; an interest rate swap requiring any payments other than periodic payments, within the meaning of § 1.446–3 (periodic payments) (e.g., a payment for an off-market swap or prepayment of part or all of one leg of a swap); and an interest rate cap requiring the issuer's premium for the cap to be paid in a single, up-front payment.

(B) *Special level payment rule for interest rate caps.* An interest rate cap does not contain a significant investment element if—

(*1*) All payments to the issuer by the hedge provider are periodic payments;

(*2*) The issuer makes payments for the cap at the same time as periodic payments by the hedge provider must be made if the specified index (within the meaning of § 1.446–3) of the cap is above the strike price of the cap; and

(*3*) Each payment by the issuer bears the same ratio to the notional principal amount (within the meaning of § 1.446–3) that is used to compute the hedge provider's payment, if any, on that date.

* * * * *

(iv) *Hedged bonds.* The contract covers, in whole or in part, all of one or more groups of substantially identical bonds in the issue (i.e., all of the bonds having the same interest rate, maturity, and terms). Thus, for example, a qualified hedge may include a hedge of all or a pro rata portion of each interest payment on the variable rate bonds in an issue for the first 5 years following their issuance. For purposes of this paragraph (h), unless the context clearly requires otherwise, *hedged bonds* means the specific bonds or portions thereof covered by a hedge.

(v) *Interest based contract.* The contract is primarily interest based. A contract is not primarily interest based unless—

(A) The hedged bond, without regard to the contract, is either a fixed rate bond, a variable rate debt instrument within the meaning of § 1.1275–5 provided the rate is not based on an objective rate other than a qualified inverse floating rate or a qualified inflation rate, a tax-exempt obligation described in § 1.1275–4(d)(2), or an inflation-indexed debt instrument within the meaning of § 1.1275–7T; and

(B) As a result of treating all payments on (and receipts from) the contract as additional payments on (and receipts from) the hedged bond, the resulting bond would be substantially similar to either a fixed rate bond, a variable rate debt instrument within the meaning of § 1.1275–5 provided the rate is not based on an objective rate other than a qualified inverse floating rate or a

qualified inflation rate, a tax-exempt obligation described in § 1.1275–4(d)(2), or an inflation-indexed debt instrument within the meaning of § 1.1275–7T. For this purpose, differences that would not prevent the resulting bond from being substantially similar to another type of bond include a difference between the index used to compute payments on the hedged bond and the index used to compute payments on the hedge where one index is substantially the same, but not identical to, the other; the difference resulting from the payment of a fixed premium for a cap (e.g., payments for a cap that are made in other than level installments); and the difference resulting from the allocation of a termination payment where the termination was not expected as of the date the contract was entered into.

(vi) *Payments closely correspond*. The payments received by the issuer from the hedge provider under the contract correspond closely in time to either the specific payments being hedged on the hedged bonds or specific payments required to be made pursuant to the bond documents, regardless of the hedge, to a sinking fund, debt service fund, or similar fund maintained for the issue of which the hedged bond is a part.

* * * * *

(viii) *Identification*. The contract must be identified by the actual issuer on its books and records maintained for the hedged bonds not later than 3 days after the date on which the issuer and the hedge provider enter into the contract. The identification must specify the hedge provider, the terms of the contract, and the hedged bonds. The identification must contain sufficient detail to establish that the requirements of this paragraph (h)(2) and, if applicable, paragraph (h)(4) of this section are satisfied. In addition, the existence of the hedge must be noted on the first form relating to the issue of which the hedged bonds are a part that is filed with the Internal Revenue Service on or after the date on which the contract is identified pursuant to this paragraph (h)(2)(viii).

(3) *Accounting for qualified hedges*—(i) *In general*. Except as otherwise provided in paragraph (h)(4) of this section, payments made or received by the issuer under a qualified hedge are treated as payments made or received, as appropriate, on the hedged bonds that are taken into account in determining the yield on those bonds. These payments are reasonably allocated to the hedged bonds in the period to which the payments relate, as determined under paragraph (h)(3)(iii) of this section. Payments made or received by the issuer include payments deemed made or received when a contract is terminated or deemed terminated under this paragraph (h)(3). Payments reasonably allocable to the modification of risk of interest rate changes and to the hedge provider's overhead under this paragraph (h) are included as payments made or received under a qualified hedge.

(ii) *Exclusions from hedge*. If any payment for services or other items under the contract is not expressly treated by paragraph (h)(3)(i) of this section as a payment under the qualified hedge, the payment is not a payment with respect to a qualified hedge.

(iii) *Timing and allocation of payments*. Except as provided in paragraphs (h)(3)(iv) and (h)(5) of this section, payments made or received by the issuer under a qualified hedge are taken into account in the same period in which those amounts would be treated as income or deductions under § 1.446–4 (without regard to § 1.446–4(a)(2)(iv)) and are adjusted as necessary to reflect the end of a computation period and the start of a new computation period.

(iv) *Termination payments*—(A) *Termination defined*. A termination of a qualified hedge includes any sale or other disposition of the hedge by the issuer or the acquisition by the issuer of an offsetting hedge. A deemed termination occurs when the hedged bonds are redeemed or when a hedge ceases to be a qualified hedge of the hedged bonds. In the case of an assignment by a hedge provider of its remaining rights and obligations under the hedge to a third party or a modification of the hedging contract, the assignment or modification is treated as a termination with respect to the issuer only if it results in a deemed exchange of the hedge and a realization event under section 1001 to the issuer.

(B) *General rule*. A payment made or received by an issuer to terminate a qualified hedge, including loss or gain realized or deemed realized, is treated as a payment made or received on the hedged bonds, as appropriate. The payment is reasonably allocated to the remaining periods originally covered by the terminated hedge in a manner that reflects the economic substance of the hedge.

(C) *Special rule for terminations when bonds are redeemed*. Except as otherwise provided in this paragraph (h)(3)(iv)(C) and in paragraph (h)(3)(iv)(D) of this section, when a qualified hedge is deemed terminated because the hedged bonds are redeemed, the fair market value of the qualified hedge on the redemption date is treated as a termination payment made or received on that date. When hedged bonds are redeemed, any payment received by the issuer on termination of a hedge, including a termination payment or a deemed termination payment, reduces, but not below zero, the interest payments made by the issuer on the hedged bonds in the computation period ending on the termination date. The remainder of the payment, if any, is reasonably allocated over the bond years in the immediately preceding computation period or periods to the extent necessary to eliminate the excess.

(D) *Special rules for refundings*. To the extent that the hedged bonds are redeemed using the proceeds of a refunding issue, the termination payment is accounted for under paragraph (h)(3)(iv)(B) of this section by treating it as a payment on the refunding issue, rather than the hedged bonds. In addition, to the extent that the refunding issue is redeemed during the period to which the termination payment has been allocated to that issue, paragraph (h)(3)(iv)(C) of this section applies to the termination payment by treating it as a payment on the redeemed refunding issue.

(E) *Safe harbor for allocation of certain termination payments*. A payment to terminate a qualified hedge does not result in that hedge failing to satisfy the applicable provisions of paragraph (h)(3)(iv)(B) of this section if the payment is allocated in accordance with this paragraph (h)(3)(iv)(E). For an issue that is a variable yield issue after termination of a qualified hedge, an amount must be allocated to each date on which the hedge provider's payment, if any, would have been made had the hedge not been terminated. The amounts allocated to each date must bear the same ratio to the notional principal amount (within the meaning of § 1.446–3) that would have been used to compute the hedge provider's payment, if any, on that date, and the sum of the present values of those amounts must equal the present value of the termination payment. Present value is computed as of the day the qualified hedge is terminated, using the yield on the hedged bonds, determined without regard to the termination payment. The yield used for this purpose is computed for the period beginning on the first date the qualified hedge is in effect and ending on the date the qualified hedge is terminated. On the other hand, for an issue that is a fixed yield issue after termination of a qualified hedge, the termination payment is taken into account as a single payment on the date it is paid.

(4) *Certain variable yield bonds treated as fixed yield bonds*—(i) *In general.* Except as otherwise provided in this paragraph (h)(4), if the issuer of variable yield bonds enters into a qualified hedge, the hedged bonds are treated as fixed yield bonds paying a fixed interest rate if:

(A) *Maturity.* The term of the hedge is equal to the entire period during which the hedged bonds bear interest at variable interest rates, and the issuer does not reasonably expect that the hedge will be terminated before the end of that period.

(B) *Payments closely correspond.* Payments to be received under the hedge correspond closely in time to the hedged portion of payments on the hedged bonds. Hedge payments received within 15 days of the related payments on the hedged bonds generally so correspond.

(C) *Aggregate payments fixed.* Taking into account all payments made and received under the hedge and all payments on the hedged bonds (i.e., after netting all payments), the issuer's aggregate payments are fixed and determinable as of a date not later than 15 days after the issue date of the hedged bonds. Payments on bonds are treated as fixed for purposes of this paragraph (h)(4)(i)(C) if payments on the bonds are based, in whole or in part, on one interest rate, payments on the hedge are based, in whole or in part, on a second interest rate that is substantially the same as, but not identical to, the first interest rate and payments on the bonds would be fixed if the two rates were identical. Rates are treated as substantially the same if they are reasonably expected to be substantially the same throughout the term of the hedge. For example, an objective 30-day tax-exempt variable rate index or other objective index may be substantially the same as an issuer's individual 30-day interest rate.

(ii) *Accounting.* Except as otherwise provided in this paragraph (h)(4)(ii), in determining yield on the hedged bonds, all the issuer's payments on the hedged bonds and all payments made and received on a hedge described in paragraph (h)(4)(i) of this section are taken into account. If payments on the bonds and payments on the hedge are based, in whole or in part, on variable interest rates that are substantially the same within the meaning of paragraph (h)(4)(i)(C) of this section (but not identical), yield on the issue is determined by treating the variable interest rates as identical. For example, if variable rate bonds bearing interest at a weekly rate equal to the rate necessary to remarket the bonds at par are hedged with an interest rate swap under which the issuer receives payments based on a short-term floating rate index that is substantially the same as, but not identical to, the weekly rate on the bonds, the interest payments on the bonds are treated as equal to the payments received by the issuer under the swap for purposes of computing the yield on the bonds.

(iii) *Effect of termination*—(A) *In general.* Except as otherwise provided in this paragraph (h)(4)(iii) and paragraph (h)(5) of this section, the issue of which the hedged bonds are a part is treated as if it were reissued as of the termination date of the qualified hedge covered by paragraph (h)(4)(i) of this section in determining yield on the hedged bonds for purposes of § 1.148–3. The redemption price of the retired issue and the issue price of the new issue equal the aggregate values of all the bonds of the issue on the termination date. In computing the yield on the new issue for this purpose, any termination payment is accounted for under paragraph (h)(3)(iv) of this section, applied by treating the termination payment as made or received on the new issue under this paragraph (h)(4)(iii).

(B) *Effect of early termination.* Except as otherwise provided in this paragraph (h)(4)(iii), the general rules of paragraph (h)(4)(i) of this section do not apply in determining the yield on the hedged bonds for purposes of § 1.148–3 if the hedge is terminated or deemed terminated within 5 years after the issue date of the issue of which the hedged bonds are a part. Thus, the hedged bonds are treated as variable yield bonds for purposes of § 1.148–3 from the issue date.

(C) *Certain terminations disregarded.* This paragraph (h)(4)(iii) does not apply to a termination if, based on the facts and circumstances (e.g., taking into account both the termination and any qualified hedge that immediately replaces the terminated hedge), there is no change in the yield.

(5) *Contracts entered into before issue date of hedged bond*—(i) *In general.* A contract does not fail to be a hedge under paragraph (h)(2)(i) of this section solely because it is entered into before the issue date of the hedged bond. However, that contract must be one to which either paragraph (h)(5)(ii) or (h)(5)(iii) of this section applies.

(ii) *Contracts expected to be closed substantially contemporaneously with the issue date of hedged bond*—(A) *Application.* This paragraph (h)(5)(ii) applies to a contract if, on the date the contract is identified, the issuer reasonably expects to terminate or otherwise close (terminate) the contract substantially contemporaneously with the issue date of the hedged bond.

(B) *Contract terminated.* If a contract to which this paragraph (h)(5)(ii) applies is terminated substantially contemporaneously with the issue date of the hedged bond, the amount paid or received, or deemed to be paid or received, by the issuer in connection with the issuance of the hedged bond to terminate the contract is treated as an adjustment to the issue price of the hedged bond and as an adjustment to the sale proceeds of the hedged bond for purposes of section 148. Amounts paid or received, or deemed to be paid or received, before the issue date of the hedged bond are treated as paid or received on the issue date in an amount equal to the future value of the payment or receipt on that date. For this purpose, future value is computed using yield on the hedged bond without taking into account amounts paid or received (or deemed paid or received) on the contract.

(C) *Contract not terminated.* If a contract to which this paragraph (h)(5)(ii) applies is not terminated substantially contemporaneously with the issue date of the hedged bond, the contract is deemed terminated for its fair market value as of the issue date of the hedged bond. Once a contract has been deemed terminated pursuant to this paragraph (h)(5)(ii)(C), payments on and receipts from the contract are no longer taken into account under this paragraph (h) for purposes of determining yield on the hedged bond.

(D) *Relation to other requirements of a qualified hedge.* Payments made in connection with the issuance of a bond to terminate a contract to which this paragraph (h)(5)(ii) applies do not prevent the contract from satisfying the requirements of paragraph (h)(2)(vi) of this section.

(E) *Fixed yield treatment.* A bond that is hedged with a contract to which this paragraph (h)(5)(ii) applies does not fail to be a fixed yield bond if, taking into account payments on the contract and the payments to be made on the bond, the bond satisfies the definition of fixed yield bond. See also paragraph (h)(4) of this section.

(iii) *Contracts expected not to be closed substantially contemporaneously with the issue date of hedged bond*—(A) *Application.* This paragraph (h)(5)(iii) applies to a contract if, on the date the contract is identified, the issuer does not reasonably expect to terminate the contract substantially contemporaneously with the issue date of the hedge bond.

(B) *Contract terminated.* If a contract to which this paragraph (h)(5)(iii) applies is terminated in connection with the issuance of the hedged bond, the amount paid or received, or deemed to be paid or received, by the issuer to terminate the contract is treated as an adjustment to the issue price of the hedged bond and as an adjustment to the sale proceeds of the hedged bond for purposes of section 148.

(C) *Contract not terminated.* If a contract to which this paragraph (h)(5)(iii) applies is not terminated substantially contemporaneously with the issue date of the hedged bond, no payments with respect to the hedge made by the issuer before the issue date of the hedged bond are taken into account under this section.

(iv) *Identification.* The identification required under paragraph (h)(2)(viii) of this section must specify the reasonably expected governmental purpose, issue price, maturity, and issue date of the hedged bond, the manner in which interest is reasonably expected to be computed, and whether paragraph (h)(5)(ii) or (h)(5)(iii) of this section applies to the contract. If an issuer identifies a contract under this paragraph (h)(5)(iv) that would be a qualified hedge with respect to the anticipated bond, but does not issue the anticipated bond on the identified issue date, the contract is taken into account as a qualified hedge of any bond of the issuer that is issued for the identified governmental purpose within a reasonable interval around the identified issue date of the anticipated bond.

(6) *Authority of the Commissioner.* The Commissioner, by publication of a revenue ruling or revenue procedure (see § 601.601(d)(2) of this chapter), may specify contracts that, although they do not meet the requirements of paragraph (h)(2) of this section, are qualified hedges or, although they do not meet the requirements of paragraph (h)(4) of this section, cause the hedged bonds to be treated as fixed yield bonds.

Par. 11. In § 1.148–5, paragraphs (b)(2)(iii), (c)(2)(i), (c)(3)(ii), (d)(3)(ii), (e)(2)(ii)(B) and (e)(2)(iii) are revised to read as follows:

§ 1.148–5 Yield and valuation of investments.

* * * * *

(b) * * *

(2) * * *

(iii) *Permissive application of single investment rules to certain yield restricted investments for all purposes of section 148.* For all purposes of section 148, if an issuer reasonably expects as of the issue date to establish and maintain a sinking fund solely to reduce the yield on the investments in a refunding escrow, then the issuer may treat all of the yield restricted nonpurpose investments in the refunding escrow and that sinking fund as a single investment having a single yield, determined under this paragraph (b)(2). Thus, an issuer may not treat the nonpurpose investments in a reasonably required reserve fund and a refunding escrow as a single investment having a single yield under this paragraph (b)(2)(iii).

* * * * *

(c) * * *

(2) *Manner of payment*—(i) *In general.* Except as otherwise provided in paragraph (c)(2)(ii) of this section, an amount is paid under this paragraph (c) if it is paid to the United States at the same time and in the same manner as rebate amounts are required to be paid or at such other time or in such manner as the Commissioner may prescribe. For example, yield reduction payments must be made on or before the date of required rebate installment payments as described in §§ 1.148–3(f), (g), and (h). The provisions of § 1.148–3(i) apply to payments made under this paragraph (c).

* * * * *

(3) * * *

(ii) *Exception to yield reduction payments rule for advance refunding issues.* Paragraph (c)(1) of this section does not apply to investments allocable to gross proceeds of an advance refunding issue, other than—

(A) Transferred proceeds to which paragraph (c)(3)(i)(C) of this section applies;

(B) Replacement proceeds to which paragraph (c)(3)(i)(F) of this section applies; and

(C) Transferred proceeds to which paragraph (c)(3)(i)(E) of this section applies, but only to the extent necessary to satisfy yield restriction under section 148(a) on those proceeds treating all investments allocable to those proceeds as a separate class.

(d) * * *

(3) * * *

(ii) *Exception to fair market value requirement for transferred proceeds allocations, universal cap allocations, and commingled funds.* Paragraph (d)(3)(i) of this section does not apply if the investment is allocated from one issue to another issue as a result of the transferred proceeds allocation rule under § 1.148–9(b) or the universal cap rule under § 1.148–6(b)(2), provided that both issues consist exclusively of tax-exempt bonds. In addition, paragraph (d)(3)(i) of this section does not apply to investments in a commingled fund (other than a bona fide debt service fund) unless it is an investment being initially deposited in or withdrawn from a commingled fund described in § 1.148–6(e)(5)(iii).

* * * * *

(e) * * *

(2) * * *

(ii) * * *

(B) *External commingled funds.* A widely held commingled fund in which no investor in the fund owns more than 10 percent of the beneficial interest in the fund. For purposes of this paragraph (e)(2)(ii)(B), a fund is treated as widely held only if, during the immediately preceding fixed, semiannual period chosen by the fund (e.g., semiannual periods ending June 30 and December 31), the fund had a daily average of more than 15 investors that were not related parties, and the daily average amount each investor had invested in the fund was not less than the lesser of $500,000 and 1 percent of the daily average of the total amount invested in the fund. For purposes of this paragraph (e)(2)(ii)(B), an investor will be treated as owning not more than 10 percent of the beneficial interest in the fund if, on the date of each deposit by the investor into the fund, the total amount the investor and any related parties have on deposit in the fund is not more than 10 percent of the total amount that all investors have on deposit in the fund. For purposes of the preceding sentence, the total amount that all investors have on deposit in the fund is equal to the sum of all deposits made by the investor and any related parties on the date of those deposits and the closing balance in the fund on the day before those deposits. If any investor in the fund owns more than 10 percent of the beneficial interest in the fund, the fund does not qualify under this paragraph (e)(2)(ii)(B) until that investor makes sufficient withdrawals from the fund to reduce its beneficial interest in the fund to 10 percent or less.

(iii) *Special rule for guaranteed investment contracts.* For a guaranteed investment contract, a broker's commission or similar fee paid on behalf of either an issuer or the provider is treated as an administrative cost and, except in the case of an issue that satisfies section 148(f)(4)(D)(i), is a qualified administrative cost to the extent that the present value of the commission, as of the date the contract is allocated to the issue, does not exceed the lesser of a reasonable amount within the meaning of paragraph (e)(2)(i) of this section or the present value of annual payments equal to .05 percent of the

weighted average amount reasonably expected to be invested each year of the term of the contract. For this purpose, present value is computed using the taxable discount rate used by the parties to compute the commission or, if not readily ascertainable, the yield to the issuer on the investment contract or other reasonable taxable discount rate.

* * * * *

Par. 12. In § 1.148–6, paragraph (d)(3)(iii)(C) is revised to read as follows:

§ 1.148–6 General allocation and accounting rules.

* * * * *

(d) * * *

(3) * * *

(iii) * * *

(C) *Qualified endowment funds treated as unavailable.* For a 501(c)(3) organization, a qualified endowment fund is treated as unavailable. A fund is a qualified endowment fund if—

(*1*) The fund is derived from gifts or bequests, or the income thereon, that were neither made nor reasonably expected to be used to pay working capital expenditures;

(*2*) Pursuant to reasonable, established practices of the organization, the governing body of the 501(c)(3) organization designates and consistently operates the fund as a permanent endowment fund or quasi-endowment fund restricted as to use; and

(*3*) There is an independent verification that the fund is reasonably necessary as part of the organization's permanent capital.

* * * * *

Par. 13. In § 1.148–9, paragraphs (c)(2)(ii)(B) and (h)(4)(vi) are revised to read as follows:

§ 1.148–9 Arbitrage rules for refunding issues.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(B) *Permissive allocation of non-proceeds to earliest expenditures.* Excluding amounts covered by paragraph (c)(2)(ii)(A) of this section and subject to any required earlier expenditure of those amounts, any amounts in a mixed escrow that are not proceeds of a refunding issue may be allocated to the earliest maturing investments in the mixed escrow, provided that those investments mature and the proceeds thereof are expended before the date of any expenditure from the mixed escrow to pay any principal of the prior issue.

* * * * *

(h) * * *

(4) * * *

(vi) Exception for refundings of interim notes. Paragraph (h)(4)(v) of this section need not be applied to refunding bonds issued to provide permanent financing for one or more projects if the prior issue had a term of less than 3 years and was sold in anticipation of permanent financing, but only if the aggregate term of all prior issues sold in anticipation of permanent financing was less than 3 years.

* * * * *

Par. 14. Section 1.148–10 is amended as follows:

1. Paragraphs (b)(2), (c)(2)(viii) and (c)(2)(ix) are revised.

2. Paragraph (c)(2)(x) is added.

3. Paragraph (e) is revised.

The revised and added provisions read as follows:

§ 1.148–10 Anti-abuse rules and authority of Commissioner.

* * * * *

(b) * * *

(2) *Application.* The provisions of this paragraph (b) only apply to the portion of an issue that, as a result of actions taken (or actions not taken) after the issue date, overburdens the market for tax-exempt bonds, except that for an issue that is reasonably expected as of the issue date to overburden the market, those provisions apply to all of the gross proceeds of the issue.

(c) * * *

(2) * * *

(viii) Replacement proceeds in a sinking fund for the refunding issue;

(ix) Qualified guarantee fees for the refunding issue or the prior issue; and

(x) Fees for a qualified hedge for the refunding issue.

* * * * *

(e) *Authority of the Commissioner to clearly reflect the economic substance of a transaction.* If an issuer enters into a transaction for a principal purpose of obtaining a material financial advantage based on the difference between tax-exempt and taxable interest rates in a manner that is inconsistent with the purposes of section 148, the Commissioner may exercise the Commissioner's discretion to depart from the rules of § 1.148–1 through § 1.148–11 as necessary to clearly reflect the economic substance of the transaction. For this purpose, the Commissioner may recompute yield on an issue or on investments, reallocate payments and receipts on investments, recompute the rebate amount on an issue, treat a hedge as either a qualified hedge or not a qualified hedge, or otherwise adjust any item whatsoever bearing upon the investments and expenditures of gross proceeds of an issue. For example, if the amount paid for a hedge is specifically based on the amount of arbitrage earned or expected to be earned on the hedged bonds, a principal purpose of entering into the contract is to obtain a material financial advantage based on the difference between tax-exempt and taxable interest rates in a manner that is inconsistent with the purposes of section 148.

* * * * *

Par. 15. Section 1.148–11 is amended as follows:

1. Paragraphs (a), (b)(1), (c)(1), and (g) are revised.

2. Paragraph (b)(3) is added.

3. Paragraphs (h) and (i) are removed.

The revised and added provisions read as follows:

§ 1.148–11 Effective dates.

(a) *In general.* Except as otherwise provided in this section, §§ 1.148–1 through 1.148–11 apply to bonds sold on or after July 8, 1997.

(b) *Elective retroactive application in whole*—(1) *In general.* Except as otherwise provided in this section, and subject to the applicable effective dates for the corresponding statutory provisions, an issuer may apply the provisions of §§ 1.148–1 through 1.148–11 in whole, but not in part, to any issue that is outstanding on July 8, 1997, and is subject to section 148(f) or to sections 103(c)(6) or 103A(i) of the Internal Revenue Code of 1954, in lieu of otherwise applicable regulations under those sections.

* * * * *

(3) *No elective retroactive application for hedges of fixed rate issues.* The provisions of § 1.148–4(h)(2)(i)(B) (relating to hedges of fixed rate issues) may not be applied to any bond sold on or before July 8, 1997.

(c) *Elective retroactive application of certain provisions and special rules—(1) Retroactive application of overpayment recovery provisions.* An issuer may apply the provisions of § 1.148–3(i) to any issue that is subject to section 148(f) or to sections 103(c)(6) or 103A(i) of the Internal Revenue Code of 1954.

* * * * *

(g) *Provisions applicable to certain bonds sold before effective date.* Except for bonds to which paragraph (b)(1) of this section applies—

(1) Section 1.148–11A provides rules applicable to bonds sold after June 6, 1994, and before July 8, 1997; and

(2) Sections 1.148–1 through 1.148–11 as in effect on July 1, 1993 (see 26 CFR part 1 as revised April 1, 1994), and § 1.148–11A(i) (relating to elective retroactive application of certain provisions) provide rules applicable to

certain issues issued before June 7, 1994.

Par. 16. In newly designated § 1.148–11A, paragraph (i) is revised to read as follows:

§ 1.148–11A Effective dates.

* * * * *

(i) *Transition rules for certain amendments—(1) In general.* Section 1.103–8(a)(5), §§ 1.148–1, 1.148–2, 1.148–3, 1.148–4, .148–5, 1.148–6, 1.148–7, 1.148–8, 1.148–9, 1.148–10, 1.148–11, 1.149(d)–1, and 1.150–1 as in effect on June 7, 1994 (see 26 CFR part 1 as revised April 1, 1997), and §§ 1.148–1A through 1.148–11A, 1.149(d)–1A, and 1.150–1A apply, in whole, but not in part—

(i) To bonds sold after June 6, 1994, and before July 8, 1997;

(ii) To bonds issued before July 1, 1993, that are outstanding on June 7, 1994, if the first time the issuer applies §§ 1.148–1 through 1.148–11 as in effect on June 7, 1994 (see 26 CFR part 1 as revised April 1, 1997), to the bonds under § 1.148–11 (b) or (c) is after June 6, 1994, and before July 8, 1997;

(iii) At the option of the issuer, to bonds to which §§ 1.148–1 through 1.148–11, as in effect on July 1, 1993 (see 26 CFR part 1 as revised April 1, 1994), apply, if the bonds are outstanding on June 7, 1994, and the issuer applies § 1.103–8(a)(5), §§ 1.148–1, 1.148–2, 1.148–3, 1.148–4, 1.148–5, 1.148–6, 1.148–7, 1.148–8, 1.148–9, 1.148–10, 1.148–11, 1.149(d)–1, and 1.150–1 as in effect on June 7, 1994 (see 26 CFR part 1 as revised April 1, 1997), and §§ 1.148–1A through 1.148–11A, 1.149(d)–1A, and 1.150–1A to the bonds before July 8, 1997.

(2) *Special rule.* For purposes of paragraph (i)(1) of this section, any reference to a particular paragraph of §§ 1.148–1T, 1.148–2T, 1.148–3T, 1.148–4T, 1.148–5T, 1.148–6T, 1.148–9T, 1.148–10T, 1.148–11T, 1.149(d)–1T, or 1.150–1T shall be applied as a reference to the corresponding paragraph of §§ 1.148–1A, 1.148–2A, 1.148–3A, 1.148–4A, 1.148–5A, 1.148–6A, 1.148–9A, 1.148–10A, 1.148–11A, 1.149(d)–1A, or 1.150–1A, respectively.

(3) *Identification of certain hedges.* For any hedge entered into after June 18, 1993, and on or before June 6, 1994, that would be a qualified hedge within the meaning of § 1.148–4(h)(2), as in effect on June 7, 1994 (see 26 CFR part 1 as revised April 1, 1997), except that the hedge does not meet the requirements of § 1.148–4A(h)(2)(ix) because the issuer failed to identify the hedge not later than 3 days after which the issuer and the provider entered into the contract, the requirements of § 1.148–4A(h)(2)(ix) are treated as met if the contract is identified by the actual issuer on its books and records maintained for the hedged bonds not later than July 8, 1997.

Par. 17. Section 1.149(d)–1 is amended as follows:

1. Paragraph (f)(3) is revised.
2. Paragraph (g)(3) is added.

The revised and added provisions read as follows:

§ 1.149(d)–1 Limitations on advance refundings.

* * * * *

(f) * * *

(3) *Application of savings test to multipurpose issues.* Except as otherwise provided in this paragraph (f)(3), the multipurpose issue rules in § 1.148–9(h) apply for purposes of the savings test. If any separate issue in a multipurpose issue increases the aggregate present value debt service savings on the entire multipurpose issue or reduces the present value debt service losses on that entire multipurpose issue, that separate issue satisfies the savings test.

(g) * * *

(3) *Special effective date for paragraph (f)(3).* Paragraph (f)(3) of this section applies to bonds sold on or after July 8, 1997 and to any issue to which the election described in § 1.148–11(b)(1) is made. See §§ 1.148–11A(i) for rules relating to certain bonds sold before July 8, 1997.

§ 1.149(d)–1T [Redesignated as § 1.149(d)–1A]

Par. 18. Section 1.149(d)–1T is redesignated as § 1.149(d)–1A, is transferred immediately following § 1.148–11A, and the section heading is amended by removing the language ''(temporary)''.

Par. 19. Section 1.150–1 is amended as follows:

1. Paragraph (a)(2) is revised.
2. Paragraphs (c)(1) and (c)(4)(iii) are revised.
3. Paragraph (c)(6) is added.

The revised and added provisions read as follows:

§ 1.150–1 Definitions.

(a) * * *

(2) *Effective date*—(i) *In general.* Except as otherwise provided in this paragraph (a)(2), this section applies to issues issued after June 30, 1993 to which §§ 1.148–1 through 1.148–11 apply. In addition, this section (other than paragraph (c)(3) of this section) applies to any issue to which the election described in § 1.148–11(b)(1) is made.

(ii) *Special effective date for paragraphs (c)(1), (c)(4)(iii), and (c)(6).* Paragraphs (c)(1), (c)(4)(iii), and (c)(6) of this section apply to bonds sold on or after July 8, 1997 and to any issue to which the election described in § 1.148–11(b)(1) is made. See § 1.148–11A(i) for rules relating to certain bonds sold before July 8, 1997.

* * * * *

(c) *Definition of issue*—(1) *In general.* Except as otherwise provided in this paragraph (c), the term *issue* means two or more bonds that meet all of the following requirements:

(i) *Sold at substantially the same time.* The bonds are sold at substantially the same time. Bonds are treated as sold at substantially the same time if they are sold less than 15 days apart.

(ii) *Sold pursuant to the same plan of financing.* The bonds are sold pursuant to the same plan of financing. Factors material to the plan of financing include the purposes for the bonds and the structure of the financing. For example, generally—

(A) Bonds to finance a single facility or related facilities are part of the same plan of financing;

(B) Short-term bonds to finance working capital expenditures and long-term bonds to finance capital projects are not part of the same plan of financing; and

(C) Certificates of participation in a lease and general obligation bonds secured by tax revenues are not part of the same plan of financing.

(iii) *Payable from same source of funds.* The bonds are reasonably expected to be paid from substantially the same source of funds, determined without regard to guarantees from parties unrelated to the obligor.

* * * * *

(4) * * *

(iii) *Certain general obligation bonds.* Except as otherwise provided in paragraph (c)(2) of this section, bonds that are secured by a pledge of the issuer's full faith and credit (or a substantially similar pledge) and sold and issued on the same dates pursuant to a single offering document may be treated as part of the same issue if the issuer so elects on or before the issue date.

* * * * *

(6) *Sale date.* The sale date of a bond is the first day on which there is a binding contract in writing for the sale or exchange of the bond.

* * * * *

§ 1.150–1T [Redesignated as § 1.150–1A]

Par. 20. Section 1.150–1T is redesignated as § 1.150–1A, is transferred immediately following § 1.149(d)–1A, and the section heading

is amended by removing the language ''(temporary)''.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 21. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 22. In § 602.101, paragraph (c) is amended by adding an entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(c) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.150–1	1545–1347
* * * * *	

Margaret Milner Richardson,

Commissioner of Internal Revenue.

Approved: May 1, 1997.

Donald C. Lubick,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 97–12062 Filed 5–8–97; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD09–97–008]

RIN–2115–AE47

Drawbridge Operation Regulations; Grand River, MI

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The District Commander has authorized a temporary 90-day deviation from the current bridge operating regulations for the U.S. Route 31 highway bridge at mile 2.9 over the Grand River in Grand Haven, MI. The deviation will test a proposed operating schedule that would be in effect between March 16 and December 14 each year. The schedule would reduce the number of bridge openings for recreational vessels to relieve vehicular traffic congestion during these months.

DATES: The deviation will be in effect on May 15, 1997 and will end on August 15, 1997. Comments must be received on or before July 15, 1997.

ADDRESSES: Comments may be mailed or delivered to: Commander (obr), Ninth Coast Guard District, 1240 East Ninth Street, Room 2019, Cleveland, OH 44199–2060 between 6:30 a.m. and 3:00 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Bloom, Chief, Bridge Branch at (216) 902–6084.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to submit comments on the operating schedule during the temporary deviation. Persons submitting comments should include their name, address, identify this notice (CGD09–97–008), and the reason(s) for each comment. The Coast Guard requests that all comments and attachments be submitted in an 8½″ × 11″ unbound format suitable for copying and electronic filing. If that is not practical, a second copy of any bound material is requested. Persons wanting acknowledgement of receipt of comments should enclose a stamped self-addressed post card or envelope. Persons may submit comment by writing to the Commander (obr), Ninth Coast Guard District, listed under **ADDRESSES.**

Background and Purpose

In July, 1996, the city of Grand Haven, MI, requested the Coast Guard approve a temporary deviation to the regulations which govern the U.S. Route 31 highway bridge at mile 2.9 over the Grand River in Grand Haven, MI. The city sought to reduce bridge openings to relieve vehicular traffic congestion and still provide for the needs of navigation, particularly during rush-hour times. A trial schedule was devised and the temporary deviation was published in September, 1996. Under this schedule, the bridge was required to open on signal for recreational vessels from 6 a.m. to 9 p.m., once an hour from 3 minutes before to 3 minutes after the half-hour; except the bridge was not required to open for the passage of recreational traffic at 7:30 a.m., 12:30 p.m., 4:30 p.m., or 5:30 p.m.

The Coast Guard received five letters with comments from the public in response. All comments were from recreational vessel operators, or their representatives, who opposed the revised schedule. The primary exception to the revised schedule involved the ''blackout'' periods during afternoon rush-hour when the bridge was not required to open for vessel traffic. Specifically, the 5:30 p.m. blackout time on Wednesday interfered with the scheduled activities of vessel operators.

The City of Grand Haven City Council conducted meetings on November 18, 1996, January 6, 1997, January 27, 1997, and February 10, 1997 to collect input from concerned parties and discuss alternatives to the temporary schedule used in 1996. Additionally, the cities of Ferrysburg and Spring Lake conducted similar public meetings to discuss the issue. As a result of these joint meetings, the three municipalities submitted a request to the Coast Guard on February 11, 1997 for a permanent change to the regulations and a new operating schedule.

The combined efforts of the three municipalities served on Grand River has resulted in a proposed bridge operating schedule that satisfies the needs and desires of recreational vessel operators on Grand River, relieves vehicular traffic congestion, and provides for the anticipated increase of commercial vessel traffic in the area. The Coast Guard published this operating schedule in a notice of proposed rulemaking on April 18, 1997 (62 FR 19082).

The District Commander also authorized the bridge owner to temporarily deviate from the operating regulations in 33 CFR 117.633(c) from May 15, 1997 to August 15, 1997, to test the part of the proposed schedule that would be in effect from March through December each year. The deviation will allow the proposed bridge schedule to be tested for part of the boating season while seeking comments from the public on the proposed changes.

During the deviation period, the bridge will only be required to open for recreational vessel traffic once an hour, on the half-hour, 7 days a week, from 6:30 a.m. to 8:30 p.m., except the bridge need not open at 7:30 a.m., 12:30 p.m., and 5:30 p.m. on Mondays, Tuesdays, Thursdays, and Fridays. On Wednesdays, the bridge need not open at 7:30 a.m., 12:30 p.m., and 4:30 p.m. This schedule will apply to recreational vessel traffic only. The bridge will open on signal for commercial vessel traffic.

Dated: April 23, 1997.

G.F. Woolever,

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

[FR Doc. 97–12253 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF EDUCATION

34 CFR Part 685

RIN 1840–AC19

William D. Ford Federal Direct Loan Program

AGENCY: Department of Education.

ACTION: Final regulations; Correction.

SUMMARY: This document corrects an omission in the final regulations for the William D. Ford Federal Direct Loan Program published in the **Federal Register** on June 19, 1996 (61 FR 31358).

EFFECTIVE DATE: July 1, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. Rachel Edelstein, Program Specialist, Direct Loan Policy, Policy Development Division, U.S. Department of Education, Room 3045, ROB–3, 600 Independence Avenue, SW., Washington, DC 20202–5400. Telephone: (202) 708–8242. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: As published, the final regulations amending § 685.208(f)(2) inadvertently omitted the existing text of paragraphs (f)(2) (i) and (ii). This correction is necessary to add the missing text.

List of Subjects in 34 CFR Part 685

Administrative practice and procedure, Colleges and universities, Education, Loan programs-education, Reporting and recordkeeping requirements, Student aid, Vocational education.

Dated: April 28, 1997.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

Accordingly, 34 CFR part 685 is corrected by making the following correcting amendments:

PART 685—WILLIAM D. FORD FEDERAL DIRECT LOAN PROGRAM

1. The authority citation for part 685 continues to read as follows:

Authority: 20 U.S.C. 1087a *et seq.*, unless otherwise noted.

§ 685.208 [Corrected]

2. Section 685.208(f)(2) is amended by adding paragraphs (f)(2) (i) and (ii) to read as follows:

§ 685.208 Repayment plans.

* * * * *

(f) * * *

(2) * * *

(i) The Secretary amends the regulations relating to a borrower's monthly repayment amount under the income contingent repayment plan; and

(ii) The borrower submits a written request that the amended regulations apply to the repayment of the borrower's Direct Loans.

* * * * *

[FR Doc. 97–12197 Filed 5–8–97; 8:45 am]

BILLING CODE 4000–01–P

POSTAL SERVICE

39 CFR Part 20

Implementation of Global Package Link Service

AGENCY: Postal Service.

ACTION: Interim rules with request for comments.

SUMMARY: Global Package Link Service (formerly known as International Package Consignment Service) is an international mail service designed for companies sending merchandise to other countries. The People's Republic of China (the PRC) is now being added as an additional destination country. To use Global Package Link (GPL) Service, a customer is required to mail at least 10,000 packages a year to GPL destination countries and agree to link its information systems with the information systems of the Postal Service. This linkage is necessary so that the Postal Service can extract certain information about the contents of the customer's packages for customs clearance and other purposes. One level of service will be offered to customers for the PRC. Service will be available only to the cities of Beijing, Guangzhou, and Shanghai. Interim regulations have been developed and are set forth below for comment and suggested revision prior to adoption in final form.

DATES: The interim regulations take effect June 9, 1997. Comments must be received on or before June 9, 1997.

ADDRESSES: Written comments should be mailed or delivered to the International Business Unit, Global Package Link Service, U. S. Postal Service, 475 L'Enfant Plaza SW Room 370 IBU, Washington, DC 20260–6500. Copies of all written comments will be available for public inspection and photocopying at the above address between 9:00 a.m. and 4:00 p.m., Monday through Friday, at the address above.

FOR FURTHER INFORMATION CONTACT: Robert Michelson at the above address, (202) 268–5731, or Marc B. Solnick at the above address, (202) 268–3916.

SUPPLEMENTARY INFORMATION:

I. Introduction

In late 1994, with implementation of International Package Consignment Service, later renamed Global Package Link (GPL), to Japan (59 FR 65961 December 22, 1994), the Postal Service announced that, when feasible, it would expand the service to other destination countries based on customer requests. The Postal Service later expanded GPL by adding Canada, the United Kingdom, Brazil, Chile, and Germany as destination countries for qualifying customers. The Postal Service is hereby further expanding GPL by adding the People's Republic of China (the PRC) as a destination country for qualifying customers.

II. GPL to the People's Republic of China

A. Qualifying Criteria

A customer wishing to use GPL to the PRC will be required to enter into a service agreement with the Postal Service providing for the following. First, the customer must commit to mail at least 10,000 GPL packages a year. (Volumes to all GPL countries are counted toward this minimum.) Second, the customer must designate the Postal Service as its carrier of choice to each country for which it uses GPL service. Third, the customer must agree to link its information systems with the information systems of the Postal Service so that the Postal Service and the customer can exchange data transmissions concerning the customer's packages. The Postal Service must be able to extract, on an as-needed basis, certain information about the packages by scanning the customer-provided barcode on each package.

In general, the information that must be made available to the Postal Service includes: the order number; the package identification number; the buyer's name and address; the recipient's name and address; the total weight of the package; the total value of the package contents; the number of items in the package; and, for each item in the package, its SKU number, its value, and its country of origin. In practice, this requirement means that the customer will have to begin the necessary systems work by the time it begins using GPL and will have to assist the Postal Service in completing and maintaining the information systems linkages. The Postal Service will use the extracted information to prepare the necessary customs forms and package labels and

to provide user-friendly tracking and tracing.

Arrangements between the Postal Service and the customer that are technical in nature may also appear in the GPL service agreement. For instance, the service agreement may describe the electronic data interface (EDI) or proprietary file format that will be used to transmit data between the customer and the Postal Service, as well as the frequency and schedule of transmissions. Similarly, the service agreement may describe the formats and frequencies for any exception and performance reports that the Postal Service will provide to the customer.

B. Processing and Acceptance

If the plant at which the customer's GPL packages originate is located within 500 miles of a GPL processing facility, the Postal Service will verify and accept the packages at the customer's plant and transport them to the GPL processing facility according to a schedule agreed upon by the Postal Service and the customer.

If the plant at which the customer's GPL packages originate is located more than 500 miles from a GPL processing facility, the customer may choose one of two processing options:

Option One: The customer will be required to present the packages to the Postal Service for verification at the customer's plant and transport them as a drop shipment to a GPL processing facility according to a schedule agreed upon by the Postal Service and the customer.

Option Two: The customer will process the packages using Postal Service provided computer system workstations and sort and prepare the packages as required by the Postal Service. Then, the Postal Service will verify and accept the packages at the customer's plant according to a schedule agreed upon by the Postal Service and the customer, and will transport the packages to a designated GPL processing facility for dispatch.

C. Customs Forms

Normally, Postal Service computer workstations will automatically generate all necessary Chinese customs forms. Packages mailed to the PRC through a GPL facility will not be required to bear customs forms when they are tendered to the Postal Service. As part of the processing operation at the GPL processing facility, the Postal Service will scan the customer-printed barcode on each package, correlate the barcode with the package-specific information transmitted by the customer, and print the necessary customs/GPL labels. The Postal Service will then affix the labels to the customer's packages. If the customer is more than 500 miles from a designated GPL facility and chooses option two, then the customs/GPL labels will be affixed by the customer using Postal Service provided workstations.

D. Customs Clearance

The Postal Service has developed the Customs Pre-Advisory System (CPAS) as part of GPL processing. As the packages are processed, this electronic system collects the package-specific data necessary to satisfy customs requirements. CPAS uses the USPS computer workstations located at a GPL facility. The system electronically advises both the USPS delivery agent and the customs agency of the contents of each package mailed. Since this advisory information arrives before the mail, CPAS facilitates and simplifies customs clearance. Electronic pre-notification of the package contents and automatic preparation of required customs declarations assures the fastest clearance through Chinese customs and reduces costs for the customer and the Postal Service. To use CPAS, recipients of merchandise must designate the Postal Service and its customs broker as their agents for customs clearance. The USPS delivery agent in the PRC will collect customs fees and any other taxes from the recipient of the shipment.

E. Delivery Options

The only delivery option the Postal Service offers to the PRC is Premium Service. To provide consistent service, the USPS offers GPL only to the cities of Beijing, Guangzhou, and Shanghai. The Premium Service option includes home delivery. The weight limit for packages is 70 pounds. The sum of the length and the greatest circumference measured in a direction other than the length shall not exceed 118 inches. The maximum size for any one dimension is 59 inches. The Premium Service provides tracking.

The Postal Service will transport GPL packages from the customer's plant, or from the designated GPL processing facility, to the PRC, where the packages will receive expeditious customs clearance and be released to the delivery agent. Once the delivery agent receives the packages, they will be delivered in from one to two days. Normal delivery times will be 4 to 5 business days from dispatch from the U. S. to final delivery. Insurance up to $500 is included at no additional cost.

The Postal Service intends to expand this service to other areas in the PRC outside the cities of Beijing, Guangzhou, and Shanghai. This will proceed as the delivery agent expands its ability to provide an expedited, secure delivery service with tracking for individual packages. The Postal Service requests comments from customers regarding the destination areas needed in the PRC.

F. Rates

The base rates for GPL service to the PRC are set forth below. The Postal Service will charge the base rates, in one pound increments, for all packages mailed to the PRC.

GLOBAL PACKAGE LINK TO THE PEOPLE'S REPUBLIC OF CHINA RATE CHART *

Weight not to exceed (pounds)	Rate (all volumes)
1	12.75
2	15.50
3	18.30
4	21.10
5	26.85
6	29.65
7	32.45
8	35.20
9	38.00
10	40.80
11	43.60
12	46.40
13	49.20
14	51.95
15	54.75
16	57.55
17	60.35
18	63.15
19	65.95
20	68.70
21	71.50
22	74.30
23	77.10
24	79.90
25	82.70
26	85.45
27	88.25
28	91.05
29	93.85
30	96.65
31	99.45
32	102.20
33	105.00
34	107.80
35	110.60
36	113.40
37	116.20
38	118.95
39	121.75
40	124.55
41	127.35
42	130.15
43	132.95
44	135.70
45	138.50
46	141.30
47	144.10
48	146.90
49	149.70
50	152.45
51	155.25
52	158.05
53	160.85

GLOBAL PACKAGE LINK TO THE PEOPLE'S REPUBLIC OF CHINA RATE CHART *—Continued

Weight not to exceed (pounds)	Rate (all volumes)
54	163.65
55	166.45
56	169.25
57	172.00
58	174.80
59	177.60
60	180.40
61	183.20
62	186.00
63	188.75
64	191.55
65	194.35
66	197.15
67	199.95
68	202.75
69	205.50
70	208.30

*Service to the People's Republic of China is limited to the cities of Beijing, Shanghai, and Guangzhou.

III. Conclusion

Accordingly, the Postal Service hereby adopts GPL service to the PRC, on an interim basis, at the rates set forth in the schedules above. Although 39 U.S.C. 407 does not require advance notice and opportunity for submission of comments, and the Postal Service is exempted by 39 U.S.C. 410(a) from the advance notice requirements of the Administrative Procedure Act regarding proposed rule making (5 U.S.C. 553), the Postal Service invites interested persons to submit written data, views, or arguments concerning this interim rule.

The Postal Service adopts the following amendments to the International Mail Manual, which is incorporated by reference in the Code of Federal Regulations. See 39 CFR 20.1.

List of Subjects in 39 CFR Part 20

International postal service, Foreign relations.

PART 20—[AMENDED]

1. The authority citation for 39 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 401, 404, 407, 408.

2. Effective June 9, 1997, subchapter 620 of the International Mail Manual Issue 17 is amended as follows:

6 Special Programs

* * * * *

620 Global Package Link

* * * * *

621.3 Availability.

Global Package Link service is available only to Brazil, Canada, Chile, Germany, Japan, the United Kingdom, and the People's Republic of China. Service to the People's Republic of China is limited to the cities of Beijing, Shanghai, and Guangzhou.

* * * * *

623.3 Size and Weight Limits.

The weight limits for Global Package Link service are 70 pounds for Chile, Germany, and the People's Republic of China; 66 pounds for Brazil, Canada, and the United Kingdom; and 44 pounds for Japan for Premium service and 6 pounds for Standard service.

The maximum length of GPL packages is 60 inches and the maximum length and girth combined is 108 inches with the following exceptions: maximum size for Germany is length 47 inches, height 23 inches, width 23 inches; maximum size for the People's Republic of China for any one dimension is 59 inches; the sum of the length and the greatest circumference measured in a direction other than the length shall not exceed 118 inches; Japan Standard packages weighing less than 1 pound, the maximum length is 24 inches with a height and depth and length combined maximum of 36 inches. All packages must be large enough to accommodate the necessary labels and customs forms on the address side.

* * * * *

626.432 Japan and the People's Republic of China.

In Japan and the People's Republic of China, any customs duties and fees will be collected from the recipient at the time of delivery.

* * * * *

Amend the Individual Country Listing for China by adding the following information about Global Package Link to the end of the listing:

CHINA, PEOPLE'S REPUBLIC OF COUNTRY PAGE GLOBAL PACKAGE LINK RATE CHART*

Weight not to exceed (pounds)	Rate (all volumes)
1	12.75
2	15.50
3	18.30
4	21.10
5	26.85
6	29.65
7	32.45
8	35.20
9	38.00
10	40.80
11	43.60
12	46.40

CHINA, PEOPLE'S REPUBLIC OF COUNTRY PAGE GLOBAL PACKAGE LINK RATE CHART*—Continued

Weight not to exceed (pounds)	Rate (all volumes)
13	49.20
14	51.95
15	54.75
16	57.55
17	60.35
18	63.15
19	65.95
20	68.70
21	71.50
22	74.30
23	77.10
24	79.90
25	82.70
26	85.45
27	88.25
28	91.05
29	93.85
30	96.65
31	99.45
32	102.20
33	105.00
34	107.80
35	110.60
36	113.40
37	116.20
38	118.95
39	121.75
40	124.55
41	127.35
42	130.15
43	132.95
44	135.70
45	138.50
46	141.30
47	144.10
48	146.90
49	149.70
50	152.45
51	155.25
52	158.05
53	160.85
54	163.65
55	166.45
56	169.25
57	172.00
58	174.80
59	177.60
60	180.40
61	183.20
62	186.00
63	188.75
64	191.55
65	194.35
66	197.15
67	199.95
68	202.75
69	205.50
70	208.30

*Service to the People's Republic of China is limited to the cities of Beijing, Shanghai, and Guangzhou.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 97–12019 Filed 5–8–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180

[OPP–300484; FRL–5715–6]

RIN 2070–AB78

Cyfluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This regulation establishes time-limited tolerances with an expiration date of November 15, 1997 for residues of the pyrethroid cyfluthrin in or on the food commodities group citrus fruit and a maximum residue limit for cyfluthrin on citrus oil and dried pulp. A petition was submitted by Bayer Corporation to EPA under the Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting the tolerance. This tolerance will expire and is revoked on November 15, 1997.

DATES: This regulation becomes effective May 9, 1997. Written objections and requests for hearings must be received by July 8, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300484], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300484], should be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM#2, 1921 Jefferson Davis Hwy., Arlington.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: OPP-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300484]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the July 13, 1994 **Federal Register** (59 FR 35717)(FRL–4871–5), which announced that Miles Corporation had submitted a pesticide petition (4F4313) to EPA and a food/feed additive petition (FAP) 4H5687 to EPA. Pesticide petition 4F4313 requests that the Administrator, pursuant to section 408(d) of the Federal Food, Drug an Cosmetic Act, 21 U.S.C. 346a(d), amend 40 CFR 180.436 to establish tolerances for residues of the insecticide cyfluthrin, ([cyano-[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dicloroethenyl]-2,2-dimethylcyclopropanecarboxylate]; CAS No. 68359–37–5; EPA Chemical No. 128831) in or on the food commodities group citrus, fruits at 0.2 parts per million (ppm). Food/feed additive petition 4H5687 requests that the Administrator, pursuant to section 409(e) of the FFDCA (21 U.S.C. 348), amend 40 CFR parts 185 and 186 by establishing a food/feed additive regulation for cyfluthrin in or on the process commodities citrus oil and citrus dried pulp at 0.3 ppm. The Agency was unable to publish a final rule prior to the enactment of the Food Quality and Protection Act (FQPA) of 1996. Because of new procedures under FQPA Bayer Corporation was required to submit a new notice of filing requesting issuance of these tolerances in compliance with FQPA.

In the **Federal Register** of March 14, 1997 (62 FR 12182)(FRL–5990–2) EPA issued a second notice of filing to bring the notice into conformity with the FQPA. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and assessments to support its conclusion that the petition complied with FQPA.

There were no comments received in response to the notices of filing.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures.

New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Section 408(b)(2)(D) specifies factors EPA is to consider in establishing a tolerance. Section 408(b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408(b)(4) requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level.

II. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of

pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (NOEL).

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose significant risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FQPA requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Consistent with sections 408(b)(2)(C)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has also assessed the toxicology data base for cyfluthrin its evaluation of application for registration on citrus. EPA has sufficient data to assess the hazards of cyfluthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for granting time-limited tolerances for residues of cyfluthrin on citrus at 0.2 ppm, and citrus oil and dried pulp at 0.3 ppm. EPA's assessment of the database, dietary exposures and risks associated with establishing these tolerances follows:

A. Toxicology Database

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by cyfluthrin are discussed below.

1. *Acute studies*. A battery of acute toxicity studies placing technical cyfluthrin in toxicity category II.

2. *Chronic studies*. i. A 12–month chronic feeding study in dogs with a no-observed effect level (NOEL) of 4 milligram per kilogram per day (mg/kg/day). The lowest effect level (LEL) for this study is established at 16 mg/kg/day, based on slight ataxia, increased vomiting, diarrhea and decreased body weight.

ii. A 24–month chronic feeding/carcinogenicity study in rats with a NOEL of 2.5 mg/kg/day and LEL of 6.2 mg/kg/day, based on decreased body weights in males, decreased food consumption in males, and inflammatory foci in the kidneys in females.

iii. A 24–month carcinogenicity study in mice. There were no carcinogenic effects observed under the conditions of the study.

3. *Developmental and reproductive effects studies*. i. An oral rat developmental toxicity study, the maternal (systemic) NOEL is 3 mg/kg/day. The maternal (systemic) lowest observed effect level (LOEL) of 10 mg/kg/day was based on behavioral changes in gait and coordination. The developmental (fetal) NOEL is 30 mg/kg/day (highest dose tested). No developmental effects were noted.

ii. An oral rat developmental toxicity study, the maternal (systemic) NOEL is 10 mg/kg/day (highest dose tested). The developmental (fetal) NOEL is 10 mg/kg/day (highest dose tested). No developmental effects were noted.

iii. A rat inhalation developmental toxicity study, the maternal (systemic) NOEL is 0.46 mg/m^3. The maternal (systemic) LOEL 2.55 mg/m^3 was based on decreased body weight gain and reduced food efficiency. The developmental (fetal) NOEL is 0.46 mg/m^3. The developmental (fetal) LOEL of 2.55 mg/m^3 is based on reduced fetal and placental weight, reduced ossification in the phalanges, metacarpals and vertebrae.

iv. An oral rabbit developmental toxicity study, the maternal (systemic) NOEL is 20 mg/kg/day. The maternal (systemic) LOEL of 60 mg/kg/day was based on decreased body weight gain and food consumption during the dosing period. The developmental (fetal) NOEL is 20 mg/kg/day. The developmental (fetal) LOEL is 60 mg/kg/day based on statistically significant increase in the numbers of resorptions and statistically significant post-implantation loss.

v. An oral 3-generation reproduction study, the systemic NOEL is 1.5 mg/kg/day. The systemic LOEL of 4.5 mg/kg/day was based on body weight decrease in pups. The reproductive (fetal) NOEL is 4.5 mg/kg/day. The reproductive (fetal) LOEL is 7.5 mg/kg/day based on decreased pup viability.

4. *Other studies.* i. Mutagenicity tests were conducted, including several gene mutation assays (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary(CHO)/HGPRT assay); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis assay in rat hepatocytes. All tests were negative for genotoxicity.

ii. A metabolism study in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed. The NOEL for dermal and systemic toxicity was 1,000 mg/kg/day (limit dose). New Zealand White strain rabbits were given 15 dermal applications at 0, 100, 500, or 1,000 mg/kg/day for 21 days. Under the conditions of the test, there was no evidence of treatment-related toxicity from dermal application at doses up to 1,000 mg/kg/day.

The toxicity database for cyfluthrin is essentially complete. Data lacking but desirable are a new 21–day subchronic dermal study, an acute neurotoxicity study in rats, a 90–day neurotoxicity study in rats, and a dermal sensitization study on the end-use product, Baythroid 2. These studies have been submitted to the Agency and are currently under review, with the exception of the acute and 90–day neurotoxicity studies. Bayer Corporation has committed to submit the results of these neurotoxicity studies to the Agency by July 1997. Although these data are lacking, the Agency believes it has sufficient toxicity data to support the proposed tolerance and these additional studies will not significantly change its risk assessment.

B. Toxicological Profile

1. *Toxicity endpoints for dietary exposure*— i. *acute.* To assess acute dietary risk, the Agency used an endpoint of 20 mg/kg/day, the NOEL from the oral developmental toxicity study in rabbits. This risk assessment will evaluate acute dietary risk to females 13+ years and older.

ii. *Chronic.* A reference dose (RfD) of 0.025 mg/kg/day has been estimated by the Agency. The RfD was established based on the rat chronic feeding/carcinogenicity study with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100.

iii. *Carcinogenicity*. Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Agency. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

2. *Toxicity endpoints for non-dietary exposure—i. short and intermediate term residential dermal and/or inhalation exposure.* For short-and intermediate term dermal exposure, the agency used the dermal toxicity NOEL of 250 mg/kg/day (highest dose tested) from the 21–day dermal rabbit toxicity study. For short- and intermediate-term inhalation exposure, the Agency used the inhalation developmental study in rats, where the maternal threshold NOEL was 0.00046 based on decreased body weight gain and reduced relative food efficiency at the LOEL of 0.0025 milligrams per liter (mg/L). The developmental NOEL of 0.00046 mg/l was based on reduced fetal weights, reduced placental weights, and reduced ossification in the phalanx, metacarpals and vertebrae at the LOEL of 0.0025 mg/L (0.46 mg/kg/day).

ii. *Chronic residential exposure.* Based upon the registered indoor/outdoor uses of cyfluthrin, exposure from these uses are expected to be from inhalation and/or dermal contact. EPA has no quantitative data on dermal absorption for the formulations of this pesticide, nor does it have reliable data for indoor/outdoor exposures. Estimations of outdoor residential exposure have been required for cyfluthrin in a data call-in issued in 1995. These data are being generated by the Outdoor Residential Exposure Task Force. Without these data EPA cannot determine the risk to the public exposed by the non-dietary uses of this pesticide. For this reason EPA is using a maximum default assumption of 20% of the RfD (0.025 mg/kg/day) as the exposure for these uses.

iii. *Dermal penetration*. The default value of 100% is being used for dermal penetration in the absence of actual data.

C. Aggregate Exposure

1. *From food and feed uses.* The primary source of human exposure to cyfluthrin will be from ingestion of both raw and processed food commodities treated with cyfluthrin. These commodities include the current citrus fruit group plus citrus oil and dried pulp and other commodities listed in 40 CFR 180.436, 185.1250 and 186.1250. Any secondary residues occurring in cattle meat, meat byproducts, milk and fat from the addition of the feed items citrus dried pulp will be covered by existing tolerances. There is no reasonable expectation of finite residues in poultry and swine, therefore the necessity or adequacy of tolerances for these commodities is not an issue relevant to the use on citrus.

The Agency has requested additional confirmatory animal feeding study data on levels of the metabolite DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid) in animal commodities.

2. *From potable (drinking) water.* There is no established Maximum Concentration Level for residues of cyfluthrin in drinking water. Although data indicate little potential for soil mobility or leaching, cyfluthrin is moderately persistent. In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in indoor/outdoor residential sites.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause cyfluthrin to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with cyfluthrin in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary uses.* Cyfluthrin is registered for use on non-food sites including golf courses, lawns, ornamental shrubs, indoor foggers, and wood surfaces. Upon considering the registered uses, formulation types, persistence, and toxicological endpoints, and in accordance with the Agency's Interim Decision Logic (PR

97–1, Jaunary 31, 1997), EPA has determined that, in the absence of exposure data, the registered non-dietary, non-occupational uses of cyfluthrin should be assigned a default value of 20% of the acceptable aggregate chronic; and short- and intermediate-term risk.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Cyfluthrin is a member of the synthetic pyrethroid class of pesticides. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Although cyfluthrin is structurally similar to other members of the synthetic pyrethroid class of insecticides, EPA does not have, at this time, available data to determine whether cyfluthrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that cyfluthrin has a common mechanism of toxicity with other substances.

D. Aggregate Risk Assessment

1. *Acute aggregate risk.* The acute dietary (food only) risk assessment used tolerance level residues and assumed 100% crop-treated. Thus, this acute dietary exposure estimate is considered conservative; refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate. A Monte Carlo analysis is a probabilistic risk assessment methodology in which a distribution of expected residues (also consumption estimates) is considered, instead of a single value such as the tolerance level. The estimated acute dietary risk, using a high-end exposure of 0.03 mg/kg/day, resulted in an MOE = 666 for the population of concern (females, 13+ years).

The acute aggregate risk assessment takes into account exposure from dietary food only. As indicated above, although EPA has not identified a water exposure figure based upon available environmental data, cyfluthrin is not expected to be mobile in soil or water environments and poses relatively little threat to drinking water. Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from food and water. However, the Agency does not believe that aggregating multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a 1 day exposure is a reasonably probable event. It is highly unlikely that, in 1 day, an individual would have multiple high-end exposures to the same pesticide by treating their lawn and garden, treating their house via crack and crevice application, swimming in a pool, and be maximally exposed in the food and water consumed. Additionally, the concept of an acute exposure as a single exposure does not allow for including post-application exposures, in which residues decline over a period of days after application. Therefore, the Agency believes that residential exposures are more appropriately included in the short-term exposure scenario.

An acute dietary MOE of greater than 100 would not be of concern to EPA. As indicated above, the MOE for females 13+ years was calculated to be 666. Under any bounding assumption EPA is considering for exposure from drinking water, this MOE would not be reduced to less than 100. Therefore, EPA has no acute aggregate concern due to exposure to cyfluthrin through food and drinking water.

2. *Short- and intermediate term aggregate risk.* In the absence of exposure data, EPA is reserving a default value of 20% for residential exposures. However, as non-quantifiable exposures can not be included in MOE calculations, the short-term MOE will include only dietary exposure. Since the short term NOEL is based on a 21 day dermal exposure toxicity, the dermal exposure will be adjusted for a dietary endpoint (from the developmental study). The NOEL from the developmental study (20 mg/kg/day) is 12.5-fold lower than that of the 21–day dermal study (250 mg/kg/day). The adjusted chronic dietary exposure is thus 0.339 mg/kg/day (TMRC of 0.0271 mg/kg/day multiplied by 12.5). As the calculated MOE for children (1 to 6 years old) is 737 (short term NOEL of 250 mg/kg/day divided by adjusted dietary exposure of 0.339 mg/kg/day), the addition of any bounding assumption EPA is considering for exposures from dietary water and residential sources is unlikely to result in a MOE of <100. EPA thus considers the short- and intermediate term risk to be acceptable for the purposes of establishing the proposed tolerances.

3. *Chronic aggregate risk.* The chronic dietary (food only) risk assessment used anticipated residues and percent crop treated for certain crops. Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using the upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations, including several regional groups, to pesticide residues. The resulting exposure

estimates should therefore be viewed as partially refined. Further refinement using anticipated residues and percent crop treated for all commodities would result in lower dietary exposure estimates. For chronic dietary (food only) risk estimates, the population subgroup with the largest percentage of the RfD occupied is children (non-nursing infants, <1 years old) at 13% of the RfD.

Section 408 (b)(2)(E) requires that, if EPA relies upon anticipated residue levels in setting a tolerance, EPA must require that data be submitted 5 years after approval of the tolerance on whether the anticipated residue level remains accurate. Because this tolerance is limited to less than 1 year, data are not being required at this time.

The aggregated chronic risk is equal to the sum of the chronic risk for food, drinking water, and indoor and outdoor residential exposures. For cyfluthrin, residential exposure data are lacking although the potential for exposure does exist. Therefore, residential exposure was also aggregated with dietary exposure in the chronic risk assessment. The aggregated chronic risk for the population subgroup non-nursing infants less than 1 year old from combined sources is 33% of the RfD (dietary = 13% + non-occupational = 20%). Under any bounding assumptions EPA is considering for exposure from drinking water, exposure to cyfluthrin would not exceed the RfD. EPA therefore concludes that there is reasonable certainty that no harm will result to consumers, including infants and children, from aggregate exposure to cyfluthrin residues.

4. *Determination of safety for infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOEL in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor not the additional tenfold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor.

In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, EPA considered data from oral developmental toxicity studies in the rat and rabbit, as well data from a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to the mothers. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

5. *Pre-natal effects.* In the oral rat developmental toxicity studies, maternal (systemic) effects consisting of behavioral changes in gait and coordination were the basis of the maternal LOEL of 10 mg/kg/day. No developmental (fetal) effects were noted in doses up to 30 mg/kg/day (highest dose tested). In the oral rabbit developmental study, no developmental toxicity was observed at doses where maternal toxicity was noted. The maternal (systemic) NOEL is 20 mg/kg/day and the maternal (systemic) LOEL of 60 mg/kg/day was based on decreased body weight gain and food consumption. The developmental (fetal) NOEL is 20 mg/kg/day and the developmental (fetal) LOEL of 60 mg/kg/day was based on increases in the numbers of resorptions and post-implantation loss.

In an inhalation developmental toxicity study, the maternal (systemic) and developmental (fetal) NOELs are 0.46 mg/m^3 and the maternal (systemic) and developmental (fetal) LOELs are 2.55 mg/m^3. The maternal (systemic) LOEL was based on decreased body weight gain and reduced food efficiency. The developmental (fetal) LOEL was based on reduced fetal and placental weight and reduced ossification. The weight of the evidence from this study would suggest that cyfluthrin exposure caused developmental toxicity indirectly through bradypnea (abnormal slowness of breathing) in the dams.

6. *Post-natal effects.* In the rat 2-generation reproduction study, parental toxicity was observed at 4.5 mg/kg/day based on body weight decrease in pups (weaned for the next generation). The reproductive (fetal) NOEL is 4.5 mg/kg/day. The reproductive (fetal) LOEL is 7.5 mg/kg/day based on decreased pup viability.

These data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased pre- or post-natal sensitivity. Therefore, EPA concludes that reliable data support use of a hundredfold safety factor, and an additional tenfold safety factor is not needed to protect the safety of infants and children.

E. Other Considerations

1. *Endocrine effects.* No evidence of such effects were reported in the toxicology studies described above. There is no evidence at this time that cyfluthrin causes endocrine effects.

2. *Metabolism and nature of the residue.* The nature of the residue in plants and animals is adequately understood. The residue of concern is parent cyfluthrin. Any secondary residues occurring in cattle meat, meat by-products, milk and fat from the consumption of cyfluthrin treated citrus will be covered by the existing tolerances for these commodities.

3. *Analytical methodology.* Adequate enforcement methodology (gas chromatography/electron capture detector) for plant and animal commodities is available to enforce the tolerances. EPA has provided information on this method to the Food and Drug Adminstration. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–5805.

4. *International tolerances.* There are no Codex, Canadian or Mexican maximum residue limits (MRLs) for residues of cyfluthrin in/on citrus.

F. Summary of Findings

Tolerances are time-limited to allow for development and review of supplemental toxicity data; animal feeding data for a metabolite of cyfluthrin; and residential, water and cumulative exposure data. These tolerances will expire and be revoked by EPA on November 15, 1997. After that November 15, 1997, EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

EPA concludes that the time-limited tolerances will be safe. Therefore the tolerances are established as set forth.

III. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''Object'' to a tolerance regulation issued by EPA under the new section 408(d) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which given the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use its current procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 8, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

IV. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number OPP–300484 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number OPP–300484. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

V. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 30, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.436 is amended by revising the introductory text to paragraph (a), by revising the column headings to the table in paragraph (a), and by alphabetically adding entries for citrus crop group; citrus oil; and citrus dried pulp.

§ 180.436 Cyfluthrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS Reg. No. 68359–37–5) in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation date
* * *	* * *	* * *
Citrus crop group.	0.2	Nov. 15, 1997

Commodity	Parts per million	Expiration/ Revocation date
Citrus dried pulp.	0.3	Do.
Citrus oil	0.3	Do.
*	* *	* *

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[FR Doc. 97–12195 Filed 5–8–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 180

[OPP–30113; FRL–5714–1]

Tolerance Processing Fees

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule increases fees charged for processing tolerance petitions for pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA). The change in fees reflects a 3.33 percent increase in locality pay for civilian Federal General Schedule (GS) employees working in the Washington, DC/Baltimore, MD metropolitan area in 1997.

EFFECTIVE DATE: June 9, 1997.

FOR FURTHER INFORMATION CONTACT: For information concerning this rule: By mail: Edward Setren, Immediate Office, Resources Management Staff (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 700–I, CM#2, 1921 Jefferson Davis Highway, Arlington, VA (703–305–5927), e-mail:setren.Edward@epamail.epa.gov. For further information concerning tolerance petitions and individual fees contact: Sonya Brooks at the same address, telephone (703) 308–6428, e-mail: brooks.sonya@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The EPA is charged with administration of section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 408 authorizes the Agency to establish tolerance levels and exemptions from the requirements for tolerances for food commodities. Section 408(o) requires that the Agency collect fees as will, in the aggregate, be sufficient to cover the costs of processing petitions for pesticide products, i.e., that the tolerance process be as self-supporting as possible.

The current fee schedule for tolerance petitions (40 CFR 180.33) was published in the **Federal Register** on May 3, 1996 (61 FR 19850)(FRL–5365–2) and became effective on June 3, 1996. At that time the fees were increased 2.54 percent in accordance with a provision in the regulation that provides for automatic annual adjustments to the fees based on annual percentage changes in Federal salaries. The specific language in the regulation is contained in paragraph (o) of § 180.33 and reads in part as follows:

(o) This fee schedule will be changed annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale.... When automatic adjustments are made based on the GS pay scale, the new fee schedule will be published in the **Federal Register** as a final rule to become effective 30 days or more after publication, as specified in the rule.

The Federal Employees Pay Comparability Act of 1990 (FEPCA) initiated locality-based comparability pay, known as ''locality pay''. The intent of the legislation is to make Federal pay more responsive to local labor market conditions by adjusting General Schedule salaries on the basis of a comparison with non-Federal rates on a geographic, locality basis.

The processing and review of tolerance petitions is conducted by EPA employees working in the Washington, DC/ Baltimore, MD pay area. The pay raise in 1997 for Federal General Schedule employees working in the Washington, DC/Baltimore, MD metropolitan pay area is 3.33 percent; therefore, the tolerance petition fees are being increased 3.33 percent. The entire fee schedule, § 180.33, is presented for the reader's convenience. (All fees have been rounded to the nearest $25.00.)

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements

Dated: April 30, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.33 is revised to read as follows:

§ 180.33 Fees.

(a) Each petition or request for the establishment of a new tolerance or a tolerance higher than already established, shall be accompanied by a fee of $64,025, plus $1,600 for each food commodity more than nine on which the establishment of a tolerance is requested, except as provided in paragraphs (b), (d), and (h) of this section.

(b) Each petition or request for the establishment of a tolerance at a lower numerical level or levels than a tolerance already established for the same pesticide chemical, or for the establishment of a tolerance on additional food commodities at the same numerical level as a tolerance already established for the same pesticide chemical, shall be accompanied by a fee of $14,650 plus $975 for each food commodity on which a tolerance is requested.

(c) Each petition or request for an exemption from the requirement of a tolerance or repeal of an exemption shall be accompanied by a fee of $11,800.

(d) Each petition or request for a temporary tolerance or a temporary exemption from the requirement of a tolerance shall be accompanied by a fee of $25,575 except as provided in paragraph (e) of this section. A petition or request to renew or extend such temporary tolerance or temporary exemption shall be accompanied by a fee of $3,625.

(e) A petition or request for a temporary tolerance for a pesticide chemical which has a tolerance for other uses at the same numerical level or a higher numerical level shall be accompanied by a fee of $12,750 plus $975 for each food commodity on which the temporary tolerance is sought.

(f) Each petition or request for repeal of a tolerance shall be accompanied by a fee of $8,000. Such fee is not required when, in connection with the change sought under this paragraph, a petition or request is filed for the establishment of new tolerances to take the place of those sought to be repealed and a fee is paid as required by paragraph (a) of this section.

(g) If a petition or a request is not accepted for processing because it is technically incomplete, the fee, less $1,600 for handling and initial review, shall be returned. If a petition is withdrawn by the petitioner after initial processing, but before significant Agency scientific review has begun, the fee, less $1,600 for handling and initial review, shall be returned. If an unacceptable or withdrawn petition is resubmitted, it shall be accompanied by the fee that would be required if it were being submitted for the first time.

(h) Each petition or request for a crop group tolerance, regardless of the number of food commodities involved, shall be accompanied by a fee equal to

the fee required by the analogous category for a single tolerance that is not a crop group tolerance, i.e., paragraphs (a) through (f) of this section, without a charge for each commodity where that would otherwise apply.

(i) Objections under section 408(d)(5) of the Act shall be accompanied by a filing fee of $3,200.

(j)(1) In the event of a referral of a petition or proposal under this section to an advisory committee, the costs shall be borne by the person who requests the referral of the data to the advisory committee.

(2) Costs of the advisory committee shall include compensation for experts as provided in § 180.11 and the expenses of the secretariat, including the costs of duplicating petitions and other related material referred to the committee.

(3) An advance deposit shall be made in the amount of $31,975 to cover the costs of the advisory committee. Further advance deposits of $31,975 each shall be made upon request of the Administrator when necessary to prevent arrears in the payment of such costs. Any deposits in excess of actual expenses will be refunded to the depositor.

(k) The person who files a petition for judicial review of an order under section 408(d)(5) or (e) of the Act shall pay the costs of preparing the record on which the order is based unless the person has no financial interest in the petition for judicial review.

(l) No fee under this section will be imposed on the Inter-Regional Research Project Number 4 (IR-4 Program).

(m) The Administrator may waive or refund part or all of any fee imposed by this section if the Administrator determines in his or her sole discretion that such a waiver or refund will promote the public interest or that payment of the fee would work an unreasonable hardship on the person on whom the fee is imposed. A request for waiver or refund of a fee shall be submitted in writing to the Environmental Protection Agency, Office of Pesticide Programs, Registration Division (7505C), Washington, DC 20460. A fee of $1,600 shall accompany every request for a waiver or refund, except that the fee shall not be imposed on any person who has no financial interest in any action requested by such person under paragraphs (a) through (k) of this section. The fee for requesting a waiver or refund shall be refunded if the request is granted.

(n) All deposits and fees required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Environmental Protection Agency. All deposits and fees shall be forwarded to the Environmental Protection Agency, Headquarters Accounting Operations Branch, Office of Pesticide Programs (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. The payments should be specifically labeled ''Tolerance Petition Fees'' and should be accompanied only by a copy of the letter or petition requesting the tolerance. The actual letter or petition, along with supporting data, shall be forwarded within 30 days of payment to the Environmental Protection Agency, Office of Pesticide Programs, Registration Division, (7504C) Washington, DC 20460. A petition will not be accepted for processing until the required fees have been submitted. A petition for which a waiver of fees has been requested will not be accepted for processing until the fee has been waived or, if the waiver has been denied, the proper fee is submitted after notice of denial. A request for waiver or refund will not be accepted after scientific review has begun on a petition.

(o) This fee schedule will be changed annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale. In addition, processing costs and fees will periodically be reviewed and changes will be made to the schedule as necessary. When automatic adjustments are made based on the GS pay scale, the new fee schedule will be published in the **Federal Register** as a Final Rule to become effective 30 days or more after publication, as specified in the rule. When changes are made based on periodic reviews, the changes will be subject to public comment.

[FR Doc. 97–12194 Filed 5–8–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Parts 159, 160, and 199

[CGD 85–205]

RIN 2115–AC51

Inflatable Liferafts

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising its regulations for the approval and servicing of inflatable liferafts, and adding provisions for the approval of inflatable buoyant apparatuses. This final rule implements the 1983 Amendments to the International Convention for the Safety of Life at Sea, 1974 (SOLAS), adds provisions for approval of a new ''Coastal Service'' liferaft for use on certain uninspected fishing vessels, introduces requirements for the stability of liferafts, and reduces direct Coast Guard involvement in inspections of liferaft production and servicing. This final rule will bring liferafts approved by the Coast Guard into compliance with SOLAS, improve the seaworthiness of approved liferafts, and increase manufacturers' flexibility in scheduling liferaft inspections while reducing the associated burden on the Coast Guard.

DATES: This final rule is effective June 9, 1997. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register on June 9, 1997.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G–LRA/3406), U.S. Coast Guard Headquarters, 2100 Second Street SW., room 3406, Washington, DC 20593–0001, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–267–1477.

FOR FURTHER INFORMATION CONTACT: Mr. Kurt J. Heinz, Lifesaving and Fire Safety Standards Division (G–MSE–4), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001, telephone 202–267–1444, fax 202–267–1069, E-mail ''kheinz@comdt.uscg.mil''.

SUPPLEMENTARY INFORMATION:

Regulatory History

On October 18, 1994, the Coast Guard published a notice of proposed rulemaking entitled Inflatable Liferafts in the **Federal Register** (59 FR 52590). The Coast Guard received 51 letters commenting on the proposed rulemaking. These comprised 12 letters from commercial fishermen and a commercial fishermen's association, 17 form letters also apparently from commercial fishermen, 9 letters from liferaft servicing facilities, 4 letters from marine inspection and District offices of the Coast Guard, 2 letters from marine suppliers, a letter from the National Transportation Safety Board (NTSB), letters from an association representing U.S. liferaft manufacturers and servicing facilities and an association representing European lifesaving appliance manufacturers, a letter from a liferaft manufacturer, a letter from a vessel classification society, and a letter from the Icelandic maritime

administration. One letter, from the vessel classification society, suggested a public meeting on whether third parties involved in liferaft inspections should have the qualifications and quality control required for membership in IACS (International Association of Classification Societies). The Coast Guard does not believe that such a public meeting would aid this rulemaking, and accordingly will not conduct one.

Background and Purpose

On June 17, 1983, the International Maritime Organization (IMO) Maritime Safety Committee (MSC) approved the 1983 Amendments to the International Convention for the Safety of Life at Sea, 1974 (SOLAS). The amended SOLAS, commonly referred to as ''SOLAS 74/83,'' included a new Chapter III, ''Life-saving Appliances and Arrangements.''

Since no contracting governments objected, SOLAS 74/83 was deemed to be accepted on January 1, 1986, and subsequently came into force for the United States and all other contracting governments on July 1, 1986. Ships whose keels were laid or which were at a similar stage of construction on or after that date must comply with SOLAS 74/83 in order to qualify for a SOLAS Safety or Safety Equipment Certificate. Coast Guard-approved inflatable liferafts on these ships are also required to meet the inflatable liferaft requirements of SOLAS 74/83. In addition, any ship with a SOLAS Safety or Safety Equipment Certificate replacing a liferaft on or after July 1, 1986, is required to replace the raft with one meeting SOLAS 74/83.

Implementation of SOLAS 74/83 (hereinafter referred to simply as SOLAS for clarity) has been the subject of a series of Coast Guard rulemaking documents and public meetings, culminating in an NPRM published on October 18, 1994. This NPRM reflected most of the comments submitted in response to the previous rulemaking documents and those discussed at public meetings.

The Coast Guard announced the first series of meetings in the July 30, 1984, **Federal Register** (49 FR 30339) (CGD 84–051). These meetings were held in conjunction with the U.S. Lifesaving Manufacturers Association (now the United States Marine Safety Association) to discuss the impending implementation of SOLAS, including the implications of the new Chapter III requirements for Coast Guard-approved lifeboats, inflatable liferafts, and their launching equipment. Guidelines were also developed for lifesaving equipment manufacturers regarding the additions and deviations from current Coast Guard regulations necessary to meet the new Chapter III requirements.

On December 31, 1984, the Coast Guard published an Advance Notice of Proposed Rulemaking (ANPRM) (49 FR 50745) describing major changes under consideration for implementation of SOLAS. The ANPRM proposed a revision of the regulations involving inflatable liferafts, but did not describe the revisions in detail.

On September 27, 1984, the Coast Guard published an NPRM which proposed rules for the approval and production testing of lifeboats, liferafts, and lifeboat launching equipment (49 FR 38151) (CGD 83–030). A public hearing on the proposal was also held at Coast Guard Headquarters in Washington, DC, on February 19, 1985. The NPRM published on October 18, 1994, incorporated the written comments submitted in response to CGD 83–030 and the comments made at the public hearing, and consequently, included approval and production testing procedures which replaced proposals made for inflatable liferafts under CGD 83–030. Separate rulemaking documents, to be published at a later date, will propose revisions to regulations involving inspection of lifeboats, davits, and winches.

Possible changes in liferaft servicing procedures were initially raised in an ANPRM published on August 14, 1986 (51 FR 29117) (CGD 81–010), and discussed at public meetings held on January 27, 1987, and March 20, 1987. The primary objectives of the changes to inspection and servicing of liferafts were to minimize the role of Coast Guard inspectors while maintaining Coast Guard oversight for quality control, and to allow private industry the flexibility necessary to meet the changing needs of the marine industry. An additional objective was to update Coast Guard regulations by implementing the relevant SOLAS requirements related to servicing. The proposals related to liferaft servicing which were contained in the October 18, 1994, NPRM addressed the issues discussed in the 1986 ANPRM. The comments at the public meetings were also considered in the development of these proposals.

Proposals concerning improved liferaft stability first appeared in an ANPRM in the **Federal Register** published on June 29, 1981 (46 FR 33341) (CGD 80–113). That ANPRM presented a summary of research efforts, sea trials, and yachting casualties from the U.S. and Europe, and invited comments from the public. A public hearing was held on September 1, 1981. An NPRM published on January 11, 1985 (50 FR 1558) summarized the comments received on this ANPRM, and also proposed specific design and testing requirements to improve stability of inflatable liferafts. The proposals contained in the January 11, 1985, NPRM, as well as the comments to such proposals were refined and used as a basis for those contained in the October 18, 1994, NPRM. The Coast Guard notes that all subsequent references to an NPRM relate to the October 18, 1994, NPRM.

Discussion of Comments and Changes

General Approval Procedures

Confidentiality of Information

Proposed § 159.005–5(a)(4) required that a manufacturer submitting commercial information that could cause substantial commercial harm if released to the public, include a statement to that effect with the information. One comment suggested that a system should be developed within the Coast Guard to ensure that such information remains confidential. It is unclear what sort of a system the comment envisions; however, the Coast Guard does not and will not release proprietary commercial information to any party other than the original submitting party, except as may be required under the Freedom of Information Act [5 U.S.C. 552]. Exemption b(4) of the Freedom of Information Act, which is specifically referred to in § 159.005–5(a)(4), clearly exempts the release of material that could cause substantial competitive harm to the party submitting it. Consequently, in this final rule, new § 159.005–5(a)(4) is retained as proposed in the NPRM.

Approval of Equivalents

One comment questioned whether, in view of the lengthy and comprehensive process by which regulations are drafted, the Coast Guard needed provisions allowing for approval of equipment and material not meeting the letter of the regulations but having ''equivalent performance characteristics.'' It further recommended that, in instances where the Coast Guard does approve materials or equipment on the basis of equivalency to the regulatory requirements, the Coast Guard notify members of the industry holding similar approvals to allow them the opportunity to exercise the same equivalency determination in their products if they desire.

The current situation in the liferaft industry is a good example of the need

to approve equivalents. The existing specifications for structural fabrics of liferafts are a combination of design and performance requirements. A majority of liferaft manufacturers currently use fabrics in their approved products that do not meet all of the design requirements specified in the regulations but provide equivalent performance. Those manufacturers have chosen to use these recently developed fabrics to reduce weight and manufacturing cost and to improve the performance of their products. The Coast Guard fully expects that future research may lead to the development of new fabrics and other materials and designs that, although they do not specifically comply with the design requirements in the regulations, have at least equivalent performance characteristics. By allowing the approval of equivalents, the Coast Guard can accommodate technological improvements without the need for cumbersome and lengthy regulatory changes. However, at the same time, the Coast Guard is working with the International Organization for Standardization (ISO) and other consensus standards organizations to develop suitable performance standards to replace existing design (and combined design-and-performance) standards to the extent possible, with the expectation of making approval of equivalents obsolete.

The Coast Guard already had the authority to approve equivalents to inflatable liferafts and liferaft components in existing regulations (46 CFR 160.051–2). The new § 159.005–7 merely streamlines the regulations by allowing a provision applicable to many items of approved equipment to be stated in a single location.

Concerning the suggestion that equivalency determinations be disseminated to the industry to allow a ''level playing field,'' the Coast Guard agrees, and will develop a system internally to disseminate them. In view of the importance of dissemination as a means to ensure uniform application of the regulations by the Coast Guard, manufacturers should be aware that designs and materials submitted as ''equivalents'' cannot be considered confidential in terms of new § 159.005–5(a)(4).

Inflatable Buoyant Apparatuses

Design and Performance Requirements

The NPRM specified design and performance requirements for inflatable buoyant apparatuses in terms of the differences between it and the Coastal Service inflatable liferaft, the requirements for which were, in turn, defined in terms of the differences between it and the SOLAS liferaft. This convention of defining inflatable buoyant apparatuses in terms of exceptions to exceptions was confusing, and so in this final rule, the design and performance requirements for inflatable buoyant apparatuses in § 160.010–3(a) are specified as direct exceptions to the corresponding SOLAS liferaft requirements in subpart 160.151. There are some editorial and paragraph numbering changes as a result of this change, but the substance of the affected paragraphs is unchanged.

Floor Drains

Proposed § 160.010–3(a)(3) required that every inflatable buoyant apparatus with a capacity of 25 or more persons be equipped with self-bailing floor drains. Citing the requirement for functionally similar inflatable liferafts to be equipped with bailers but not with floor drains, and the added cost of providing floor drains, one comment suggested that the Coast Guard permit inflatable buoyant apparatuses to be equipped with either bailers or floor drains.

The Coast Guard contends that it is not valid to compare a large inflatable liferaft, which is almost completely sheltered by a canopy, with an open inflatable buoyant apparatus, which has no protection against waves. It is very easy for an inflatable buoyant apparatus to be swamped by a single wave, after which a large apparatus (for example, one of 25 persons or more capacity) can have a substantial depth of water (well in excess of 1 meter) in its center. Bailers are of little use in removing such a quantity of water, particularly as more water is likely to be coming in during the process. However, floor drains, which are generally in the form of simple fabric tubes secured through the floor, are capable of quickly removing such a quantity of water on a continuous basis. In calm seas, where such heavy water-removing capability is not needed, the floor drains can be secured to prevent small quantities of water from entering the buoyant apparatus through them. Because floor drains are not capable of removing all water from the buoyant apparatus, bailers are needed as well.

The proposed requirement for floor drains is less stringent than the only corresponding international requirement, which is that for ''open reversible liferafts'' contained in the IMO International Code Of Safety For High-Speed Craft (HSC Code). The HSC Code requires an apparatus with a capacity of up to 30 persons to be equipped with one floor drain, and an apparatus with a capacity of greater than 30 persons to be equipped with two floor drains. Since there is no evidence that water depth in an inflatable buoyant apparatus when swamped is a significant problem for an apparatus with a capacity of less than 25 persons, § 160.010–3(a)(7) in the final rule retains the floor drain requirements as proposed in the October 18, 1994, NPRM.

Boarding Ladders

One comment suggested that boarding ladders on inflatable buoyant apparatuses should meet construction standards similar to those required for SOLAS inflatable liferafts. They already do, since § 160.010–3(a) in the NPRM (the substance of which remains unchanged in the final rule) requires an inflatable buoyant apparatus to generally meet the design and performance requirements for SOLAS inflatable liferafts in subpart 160.151.

Position-Indicating Lamps

Several comments suggested that the wording of § 160.010–3(a)(8)(ii) was unclear as to whether one or two lamps are required on each side of a reversible inflatable buoyant apparatus. The Coast Guard agrees that the wording is ambiguous, and § 160.010–3(a)(11) in the final rule clarifies that one lamp is required on each of the two reversible sides of the apparatus.

Sea Anchors

Proposed § 160.010–3(a)(10), which prescribed required equipment for an inflatable buoyant apparatus, did not include a sea anchor. However, all manufacturers of currently approved inflatable buoyant apparatuses include sea anchors with those apparatuses, although the Coast Guard has not specifically required them. In addition, a sea anchor is required for ''open reversible liferafts'' under the IMO HSC Code. Therefore, in keeping with longstanding industry practice, and the comments on the NPRM supporting consistency with international requirements, § 160.010–3(a)(12) in the final rule includes a requirement that inflatable buoyant apparatuses be fitted with a sea anchor.

''Overloading'' of Inflatable Buoyant Apparatuses

Proposed § 160.010–3(a)(11) required that the IMO Swamp Test be conducted on an inflatable buoyant apparatus with the apparatus loaded to 50% in excess of its rated capacity, rather than just to its rated capacity (as specified in the test procedure). This requirement was

proposed in anticipation of rulemaking projects (since completed) establishing, for some protected routes, carriage requirements based on the possibility of such overloading contained in 46 CFR subchapters K, T, and W.

Citing National Transportation Safety Board (NTSB) recommendations in the wake of the grounding of the PILGRIM BELLE in 1985 and the sinking of the COUGAR in 1988, one comment opposed this concept on the grounds that it would ''make the out-of-water flotation device an in-water flotation device.'' The comment cautioned that overloading of survival equipment should not be acceptable in any waters, no matter how protected.

The Coast Guard disagrees with the premise of the comment concerning the effect of 50 percent overloading on an inflatable buoyant apparatus. The cases cited in the comment involved rigid buoyant apparatuses, not the inflatable type. Like an inflatable liferaft, an inflatable buoyant apparatus is designed with at least 100 percent excess buoyancy. Consequently, it remains an out-of-water flotation device even in conditions of overload far more extreme than anticipated in the proposed rule. Multiple swamp tests of inflatable buoyant apparatuses which have been conducted under the conditions specified in the proposed rule have verified that the devices remain effective under such conditions.

However, subsequent to the publication of the NPRM, the IMO MSC approved a change to Resolution A.689(17) which would effectively render the proposed overload test meaningless. Specifically, in order to address the potential personnel hazard and logistical problems associated with swamp testing of a large survival craft loaded with people, the Committee revised the Swamp Test procedure to require that the device be completely swamped, but without people inside, during the test. In view of the buoyancy of people wearing lifejackets, this test is considered to be at least as strenuous a test of the device in the swamped condition as the previous test. However, since the revised procedure calls for the device to be completely swamped, it is not possible to ''overload'' it as specified in the NPRM. Consequently, in view of the extensive successful test experience already obtained for a variety of inflatable buoyant apparatuses under overload conditions, and in the interest of remaining consistent with internationally accepted testing procedures, proposed § 160.010–3(a)(11) has not been included in this final rule. This will have the effect of requiring an inflatable buoyant apparatus to be subjected to the same Swamp Test as an inflatable liferaft.

''Open Reversible Liferafts'' Under the IMO HSC Code

On January 1, 1996, the IMO HSC Code entered into force. Annex 10 to the HSC Code contains requirements for an ''open reversible liferaft'' which are similar, but not identical to the requirements for inflatable buoyant apparatuses as specified in this final rule. Although the timing of the publication of the HSC Code did not allow for discussion of it in the NPRM, a new § 160.010–3(e) has been added to this final rule to provide guidance to those who wish to obtain approval for inflatable buoyant apparatuses which also comply with the requirements for open reversible liferafts under the HSC Code. This new section merely provides an alternative path to approval which manufacturers may utilize as they see fit.

Inflatable Liferafts

Incorporation by Reference

Proposed § 160.151–1 incorporated a number of technical documents by reference. One comment suggested that all material incorporated by reference should be published as an appendix with the final rules.

The Coast Guard contends that the purpose of incorporating lengthy technical documents by reference is to reduce repetition and, in keeping with ongoing government reinvention initiatives, to reduce the bulk of the Code of Federal Regulations. It would completely defeat the purpose of incorporating materials by reference to publish them as annexes to the final rule. Consequently, proposed § 160.151–1 is retained unchanged as § 160.151–5 (due to editorially interchanging § 160.151–1 and § 160.151–5) in the final rule.

Definitions

Proposed § 160.151–3 contained a definition of ''SOLAS'' which incorporated all amendments through the 1983 amendments. In the final rule, this definition has been revised to incorporate amendments through the 1988 Global Maritime Distress and Safety System (GMDSS) amendments. This will simplify SOLAS references for the user, since the most common published version of SOLAS is a 1992 Consolidated Edition which includes the 1988 amendments. The only substantive effect is that, as was discussed in the preamble to the NPRM, the GMDSS amendments removed the requirement for liferafts to be fitted with portable lifeboat radio siting and securing arrangements as of August 1, 1993. The paragraph numbering in SOLAS regulation III/38.3 was slightly altered as a result.

Liferaft Capacity

One comment questioned why capacity requirements for liferafts were not included in the standards for design, performance, and construction contained in proposed §§ 160.151–7 and 160.151–15. The comment also questioned whether Navigation and Vessel Inspection Circular (NVIC) 1–92 would remain valid for capacity conversion of unapproved liferafts ''grandfathered'' for use on commercial fishing vessels.

Like many of the requirements in the NPRM, the capacity requirements for liferafts are included by reference to the corresponding SOLAS regulation—in this case, by reference to regulation III/39 in proposed § 160.151–7(c), which remains unchanged for this final rule. The standards for design, performance, and construction in the final rule apply only to new construction of approved liferafts, so all issues pertaining to the ''grandfathering'' of unapproved liferafts on commercial fishing vessels will continue to be covered by NVIC 1–92.

Liferafts of Less Than 6 Persons Capacity

Proposed § 160.151–7 prescribed construction requirements for SOLAS A and SOLAS B inflatable liferafts. By reference to SOLAS regulation III/38 (specifically regulation III/38.2.1), this section restricted inflatable liferafts to a minimum capacity of 6 persons, except as otherwise specified in the subpart (for example, for coastal service liferafts).

One comment noted that the Coast Guard has long approved, and that there continues to be a need for, 4-person liferafts as capable as SOLAS A and SOLAS B liferafts. These liferafts have particular application on some commercial fishing vessels, which are technically required to carry SOLAS A or SOLAS B liferafts but which have been permitted to carry approved 4-person liferafts if they carry 4 or fewer persons on board. In the past, the Coast Guard has allowed 4-person liferafts with the equivalent of SOLAS A and SOLAS B equipment packs to be marked as having ''A'' or ''B'' packs, avoiding the use of the term ''SOLAS''. These rafts were issued approval numbers in the 160.051/XXX series, as opposed to liferafts complying with SOLAS, which have been issued approval numbers in the 160.151/XXX series. The Coast Guard agrees that there continues to be

a need for approved 4-person liferafts comparable to SOLAS A and SOLAS B liferafts. Consequently, to maintain the longstanding approval-numbering convention, the final rule does not completely remove 46 CFR subpart 160.051 as was proposed in the NPRM. Instead, in the final rule existing subpart 160.051 is replaced by a new subpart 160.051, which covers standards for design, construction, performance, and equipment for liferafts not complying with SOLAS but which are approved for use in some domestic services. These include ''A'' and ''B'' inflatable liferafts of less than 6 persons capacity, and coastal service inflatable liferafts, which were addressed in §§ 160.151–19, 160.151–23, and portions of 160.151–27 in the NPRM. This is merely an editorial change; it does not affect the substance of the moved sections.

Oversight of Approval Testing

Proposed § 160.151–13 (c)–(f) required that approval testing of prototype liferafts be carried out under the oversight of a Coast Guard marine inspector. One comment suggested that this oversight be provided by qualified third parties such as classification societies that are members of the IACS, and noted that such third parties were competent to perform this function.

As discussed in the NPRM, the proposed rules struck a careful balance between delegation of suitable functions to third parties under Coast Guard oversight and direct Coast Guard participation in certain critical areas in order to fulfill our responsibility for the approval of equipment used on U.S. ships and for maintaining the knowledge and experience necessary to provide adequate oversight. The proposed rules allow for third-party involvement in inspection of prototype construction and in production inspection after approval. However, in light of the other proposed changes to the approval procedures, it is essential that the Coast Guard maintain its direct involvement in the required prototype testing to validate the basic design submitted for approval. Consequently, §§ 160.151–13 (c) through (f) are retained in the final rule as proposed in the NPRM.

Liferaft Design and Performance

Proposed § 160.151–15(c) required that a protective liner or baffling arrangement be provided inside each inflatable compartment at the inflation gas inlet in order to protect the compartment fabric from the damaging effects of cold inflation gas. One comment suggested that advances in the technology of thermoplastic-coated fabrics may result in the development of fabrics not as susceptible to damage from cold exposure as the fabrics currently used. Consequently, a liner or baffling arrangement would not necessarily be needed on rafts constructed of such fabrics. The comment suggested that the Coast Guard adopt a performance criterion to allow approval of such designs, but did not propose a specific test.

The Coast Guard agrees that the requirement as proposed is unnecessarily design-restrictive, and has revised the wording of § 160.151–15(c) in the final rule to allow means other than a liner or baffling arrangement to achieve the performance objective of protecting the compartment fabric from damaging effects of cold inflation gas. However, the Coast Guard does not have sufficient data to specify in this final rule a particular test to evaluate the adequacy of designs not incorporating a liner or baffling arrangement. The Coast Guard will evaluate such designs on a case-by-case basis to ensure that they provide performance equivalent to that of conventional designs using liners or baffling arrangements. It will be the responsibility of the manufacturer, in consultation with the Coast Guard, to develop a suitable test protocol to demonstrate such equivalence. The Coast Guard will notify all manufacturers of any designs approved under this system, and of the testing performed to validate them.

Color

Proposed § 160.151–15(e) required that the exterior of the liferaft canopy be of a highly visible color, such as vivid reddish orange. However, in a departure from existing § 160.051–4(e), which requires that the underside of the floor be of a dark color, the NPRM did not address the color of the outside of the raft other than the canopy. One comment, citing SOLAS regulation III/30.2.6, which requires that life-saving appliances be of a highly visible color ''on all parts where this will assist detection,'' commented that both sides of the raft, and not just the canopy, should be of a color contrasting with the marine environment. The comment mentioned instances where a rescue unit was not able to detect a liferaft, because it had overturned.

The Coast Guard agrees that application of a highly visible color to the bottom of a liferaft can assist in detection if the liferaft is overturned. This concept recently gained the support of the international community as well. In the wake of the sinking of the Baltic ferry ESTONIA in September 1994, where a number of casualties occurred due to difficulty in locating overturned liferafts, the 26th session of the IMO Lifesaving, Search and Rescue Sub-Committee in March 1995, adopted a proposal to require that water pockets affixed to the bottom of liferafts be of a highly visible color. This new requirement will take effect in July 1998, as part of the latest set of amendments to SOLAS Chapter III, and has been incorporated in § 160.151–17(a)(2)(vii) of this final rule. The effective date of the requirement in this final rule has been deferred to coincide with the effective date of the corresponding provision of SOLAS Chapter III.

Towing Connections

Proposed § 160.151–15(g), like existing § 160.051–7(b)(12), required towing connections at opposite ends of the inflatable liferaft. SOLAS regulation III/38.1.4 does not specify a number of towing connections, but rather requires only that the raft be so constructed as to enable it to be towed under specified conditions. Several comments suggested that there is no need for more than one towing connection on a liferaft since liferafts are maneuverable and can be repositioned for towing if necessary. One of these comments also noted that a requirement for two towing locations would add unnecessary costs and require further testing of the product.

The Coast Guard contends that one towing connection is not sufficient. Under SOLAS regulation III/20.3, the lifesaving arrangements for passenger ships include the ''marshalling'' of liferafts, i.e., using a rescue boat to gather liferafts together for the purpose of connecting them in order to facilitate their detection and long-term survival. In some cases, a single rescue boat can be assigned to marshall up to nine liferafts. However, it can be unwieldy to connect a liferaft with only one towing connection to many other liferafts. A second towing connection would considerably facilitate marshalling.

The Coast Guard also contends that the provision of a second towing connection would not necessitate any further testing of the product, or add any significant additional cost. Where multiple towing connections are provided, they are generally identical in design, and testing of one (which is required in any case) can stand for testing of both, or all. The only cost associated with a second towing connection is the cost of the materials involved and their assembly and installation. This cost would not represent any increase over present requirements, since existing 46 CFR 160.051–7(b)(12) already requires a

towing connection at each end of a liferaft.

Despite the above discussion, the Coast Guard has amended § 160.151–15(g) in the final rule to remove the requirement for towing connections at both ends of a liferaft in keeping with its policy of not imposing unilateral requirements in excess of SOLAS. However, the Coast Guard does intend to approach IMO with the concerns discussed above in order to generate discussion whether a future amendment to the relevant IMO requirement may be warranted.

Weight

Proposed § 160.151–15(h) would limit the weight of liferafts not served by launching appliances to 185 kilograms (kg) (407.8 pounds (lb)), a very slight increase from the 400-lb limit in existing 46 CFR 160.051–3(b). One comment noted the problems associated with manually launching a heavy liferaft, citing an NTSB recommendation pursuant to the fire and explosion on the tankship PUERTO RICAN in 1984, that liferafts be installed so that manual launching does not require any unnecessary lifting, such as over a railing. The Coast Guard is aware of the difficulties associated with launching liferafts near the weight limit when they are not served by launching appliances. However, the proposed increase in the allowable weight is trivial, essentially resulting from a metric conversion. Consequently, in the final rule § 160.151–15(h) is not changed from the NPRM. The issue of installing liferafts to avoid the necessity of lifting was addressed in the Subchapter W rulemaking project (CGD 84–069), and is now covered in 46 CFR 199.130(a)(7).

Strength of Lifeline Attachments

Proposed § 160.151–15(i) required that lifeline attachment patches have a minimum breaking strength of 1.5 kN (350 lb) pull exerted in a direction perpendicular to their bases. One comment contended that this breaking strength is excessive, since liferafts should be lifted out of the water by the towline rather than the lifelines, and since the buoyancy of human bodies reduces a liferaft's weight in the water.

The Coast Guard disagrees. This is not a new requirement, stemming as it does from paragraph 3.6.19 of military specification MIL–L–19496, which is referred to (for design guidance) in existing § 160.051–1(a)(1). In addition, the comment does not take into account that buoyancy effects are minimal when a person in the water pulls himself into a liferaft using the internal lifelines, that external lifelines may be used to carry an inflated liferaft, and that the weight of a liferaft can make it difficult to handle (for example, while placing it in the water) by a towline attached at a single point. Although SOLAS does not specifically discuss using lifelines to carry a liferaft, the ability to do so is required by other responsible maritime safety administrations, such as in the European Free Trade Association's (EFTA) *Scheme for the Reciprocal Recognition of Tests and Inspections Carried Out on Ships' Equipment.* That document requires that, beyond being suitable for use as a lifeline, the grablines ''be suitably arranged for carrying the inflated raft.'' For all of these reasons, § 160.151–15(i) is retained in the final rule as proposed in the NPRM.

Painter Length

The preamble to the NPRM discussed a pending change to SOLAS Chapter III which would reduce the painter length required by SOLAS to the greater of 15 meters or the liferaft's stowage height plus 10 meters. The NPRM indicated that if the change received final approval by the IMO MSC, it would be incorporated into the final rule. The change was approved as part of the most recent set of SOLAS amendments, to take effect July 1, 1998, and has been incorporated into the final rule as § 160.151–15(j). The effective date of the requirement is July 1, 1998, which conforms to the SOLAS effective date. However, manufacturers are encouraged to comply at the earliest possible date so as to reduce the operational problems associated with excessive painter lengths.

Boarding Ladders

Proposed § 160.151–15(l) required that the steps of a boarding ladder ''be of rigid or semi-rigid tubing and secured against rotation to provide a suitable foothold.'' One comment suggested that this requirement is unnecessarily design restrictive, and that boarding ladders should be evaluated by their performance rather than on certain design properties. The comment noted that more critical than the design of the footholds themselves is that they be placed to prevent the user's legs from going underneath the hull, thereby preventing a vertical climb into the liferaft. The comment also noted that, although boarding ladders are required, they are a secondary boarding aid to the required boarding ramp.

The Coast Guard agrees with the general approach proposed in the comment. In the final rule, proposed § 160.151–15(l) has been replaced by a general performance requirement in § 160.151–15(m) that the steps of the boarding ladder ''must provide a suitable foothold.'' As suggested in the comment, a new § 160.151–27(c)(4) has been added to the final rule to require that the IMO Boarding Test be performed using the boarding ladder (if installed) as well as the boarding ramp. The IMO Boarding Test is considerably more stringent than that in current § 160.051–5(e)(7) and so will ensure, through demonstrated performance, that boarding arrangements are adequate for those liferafts and inflatable buoyant apparatuses for which the boarding ladder is the primary means of boarding.

Liferaft Stability

Proposed § 160.151–17(a), and the associated requirements on prototype testing in proposed § 160.151–29(a) and (b), prescribed stability standards for SOLAS inflatable liferafts based upon the performance of currently approved designs of ''heavily ballasted'' liferafts. A number of comments disagreed with the proposed stability standards in their entirety. The comments questioned whether the benefits of improved liferaft stability would outweigh the costs, cited the adverse effect the proposed stability standards would have upon the cost-competitiveness of U.S.-manufactured liferafts in the international market, and questioned whether the available casualty history indicates that the stability of existing liferaft designs is inadequate. One of the comments noted that adoption of the standards would increase the weight of liferafts substantially. In many cases, the weight could increase to the extent that some shipowners would need to install launching appliances or expensive rack-mounting arrangements when they replace their current rafts, for which such appliances are not needed.

One comment agreed with the Coast Guard's position that international standards for liferafts are appropriate, and suggested that, if there is a stability problem with liferafts, it should be identified by the Coast Guard at the appropriate international forum and a solution reached based on input from the international community. Several related comments suggested adoption of the ''European Liferaft Stability System'' detailed in the EFTA *Scheme for the Reciprocal Recognition of Tests and Inspections Carried Out on Ships' Equipment.* Finally, one comment proposed that, if the Coast Guard were to unilaterally adopt a stability standard, it should be based on the volume (a minimum of 25 percent of buoyancy-tube volume) currently required for Coastal Service liferafts.

The Coast Guard agrees with the view that any regulatory requirements for liferaft stability should be based upon standards developed and accepted internationally. This is consistent with the Coast Guard's general position that U.S. requirements should not exceed the requirements of SOLAS. Until recently, however, SOLAS has been vague on the issue of liferaft stability, requiring only that liferafts be ''stable in a seaway.''

In that regard, the proposals made in the NPRM have been overtaken by international events. At its 26th session in March 1995, the IMO Lifesaving, Search and Rescue Sub-Committee approved standards for liferaft stability to include in the latest set of SOLAS amendments, which will become effective in 1998. These requirements are based upon a proposal by the United Kingdom (UK), and are generally consistent with those in the EFTA Scheme, which have been in effect in many countries (including most of Northern Europe) since the 1980–81 UK/Icelandic stability testing discussed in the NPRM. By U.S. intervention, the most design-restrictive portions of the original UK proposal were eliminated. The resulting SOLAS regulation requires stability appendages with an aggregate volume one fourth of that proposed in the NPRM, or 20 liters (.02 cubic meters) per person of capacity, for liferafts with a capacity of greater than 10 persons. This is around 20 percent of the required buoyancy-tube volume—slightly less than was proposed in the comments. For smaller liferafts, the regulation requires a minimum aggregate capacity of 220 liters (.22 cubic meters).

In this final rule, in place of the stability requirements proposed in the NPRM in proposed §§ 160.151–17(a) and 160.151–29(a)–(b), the Coast Guard has decided to incorporate the new SOLAS stability requirements, in their entirety, into § 160.151–17(a). In doing so, the Coast Guard adopts the comments received supporting conformance with international standards. The SOLAS requirements also substantially conform to the specific proposals in the comments concerning stability appendage volume. The effective date of the domestic requirements is July 1, 1998, to conform with the SOLAS effective date.

In addition to opposing the proposed stability requirements in the NPRM, several comments also opposed the Lift-Out Force Test and At-Sea Test, both of which were proposed to evaluate compliance with those requirements. Since the SOLAS requirements upon which the stability requirements in this final rule are based do not cover either test, neither test is retained in this final rule. Instead, there is a test in § 160.151–29(a) to evaluate the filling time of the stability appendages against the standard in § 160.151–17(a)(2)(vi). The Coast Guard intends to continue research into test methods to evaluate liferaft stability, perhaps including some variation of the Lift-Out Force and At-Sea Tests, so it can evaluate, for equivalence to the regulatory requirements, the performance of novel stability designs that may be developed in the future.

One comment supported self-righting capability for liferafts ''as required by SOLAS, the righting test specified in IMO Resolution A.689(17), and proposed 46 CFR 160.151–27(a).'' However, none of those three documents requires self-righting capability, only the capability for the inverted liferaft to be righted by a single person in the water. Consistent with them, the final rule does not require that liferafts be self-righting. The same comment suggested that there should be a requirement that rafts always inflate right side up when deployed in water. This requirement already existed in proposed § 160.151–27(a), by reference to the Drop Test in IMO Resolution A.689(17), para. 1/5.1, which requires that the tested rafts inflate upright. This requirement is retained in the final rule. It should be recognized, however, that even a raft that inflates upright during approval testing may not always inflate upright if it has subsequently been packed incorrectly, for example, during servicing.

A number of identical comments suggested that the Coast Guard make a videotape of the various rafts in heavy seas available so that mariners can see how they react and select one they ''feel comfortable with.'' This suggestion has not been adopted in the final rule. Such a comparative demonstration would entail essentially the same costs and logistical difficulties as the heavy weather sea trial strongly opposed by the liferaft industry, and further, would focus on only one aspect of a liferaft's performance when there are others which are also very important. The Coast Guard's position is that liferaft manufacturers are in the best position to market and establish brand differentiation for their products based on all of their features, and in fact actively do so.

Boarding Arrangements for Coastal Service Liferafts

Proposed § 160.151–19(f) indicated that boarding ramps are not required on Coastal Service liferafts if the combined diameter of the buoyancy chambers is 500 millimeters (mm) or less. One comment suggested that, although boarding ramps may not be necessary under these circumstances, some sort of boarding aid, such as strategically placed hand holds, may be.

The Coast Guard acknowledges the importance of adequate boarding arrangements for liferafts, particularly in light of the NTSB's investigation of the sinking of the bulk carrier MARINE ELECTRIC in 1983. As suggested by the NTSB, the NPRM proposed, and the final rule requires, by reference to SOLAS regulation III/39 (specifically regulation III/39.4.3 thereunder) in § 160.151–7, that ''there shall be means inside the liferaft to assist persons to pull themselves into the liferaft from the ladder.'' In addition, the IMO Boarding Test required by reference to IMO Resolution A.689(17), para. 1/5.8, in § 160.151–27(a) is considerably more stringent than the existing test in § 160.051–5(e)(7), and is rigorous enough to ensure that boarding arrangements are adequate.

Fabric Valise Containers

Proposed § 160.151–19(i) allowed the use of fabric valise-type containers with Coastal Service inflatable liferafts, and by extension, with inflatable buoyant apparatuses. This provision has been deleted from the final rule, since it was substantially similar to § 160.151–15(n)(7) in the NPRM (retained as § 160.151–15(o)(7) in the final rule).

Liferaft Equipment

In an editorial change throughout § 160.151–21, for internal consistency and consistency with the terminology in Subchapter W, all references to specific subparts under which particular items of equipment are approved have been replaced with references to the ''approval series'' under which the item is approved.

One comment suggested that proposed § 160.151–21 may lead to confusion because it lists all of the equipment required for SOLAS A liferafts and implies that the same equipment is needed for SOLAS B liferafts. The comment suggested a clarification of the difference between SOLAS A and SOLAS B equipment packs, much as SOLAS regulation III/38.5.3 identifies those items in a SOLAS A Pack not required for a SOLAS B Pack.

Proposed § 160.151–21 was not intended to set forth a list of the required contents of equipment packs. The required contents of the SOLAS A and SOLAS B equipment packs are specified in proposed § 160.151–7(b), by reference to SOLAS regulation III/38.

Proposed § 160.151–21 is intended only to facilitate compliance by liferaft manufacturers and servicing facilities by supplementing the minimal descriptions of the various individual items of equipment in the SOLAS regulation. Consequently, it is retained generally intact in the final rule, subject to revisions to various individual subsections as discussed below.

Proposed § 160.151–21(b) contains requirements for jackknives carried in equipment packs. One comment questioned whether folding knives complied with the SOLAS requirements, since SOLAS regulation III/38.5.1.2 specifically requires a non-folding knife.

By reference in § 160.151–7, the proposed rules incorporated all of regulation III/38, including regulation III/38.5.1.2, which requires a buoyant non-folding knife. However, regulation III/38.5.1.2 also requires that liferafts of 13 persons or more capacity be equipped with a second knife, which may be of the folding variety. The requirement in § 160.151–21(b), which is retained unchanged in the final rule, applies only to situations where these allowable folding knives are permitted.

Proposed §§ 160.051–21(f) and 160.151–23(f) required that two paddles of the type used to pass the IMO Maneuverability Test be included in the equipment packs. A number of identical comments objected to the inclusion of paddles, since they provide no maneuverability on ocean waters and will only increase the pack size and increase the purchase price.

The Coast Guard disagrees. Paddles are essential to move away from burning wreckage, to avoid the turbulence associated with a sinking ship, and to assemble with other liferafts to facilitate survival. The fact that the required paddles are of the size and type used to pass the Maneuverability Test clearly demonstrates that they do provide for a degree of maneuverability. Since paddles have always had to be provided with inflatable liferafts, their inclusion in the equipment required by the NPRM does not represent any increase in the cost or the size of the equipment pack over those of existing liferafts. Consequently, §§ 160.051–9(f) (which was § 160.151–23(f) in the NPRM) and 160.151–21(f) are retained in the final rule as proposed in the NPRM.

Regulation III/38.5.1.7 of SOLAS, which was incorporated by reference into the NPRM, with a minor modification, in proposed § 160.151–21(g), requires the equipment pack of a SOLAS A liferaft to include three tin openers. One comment, while supporting the modification in proposed § 160.151–21(g) requiring sharp parts of tin openers to be fitted with guards, commented that tin openers should not be required unless a manufacturer specifies the carriage of canned water in its liferaft.

The Coast Guard disagrees. SOLAS does not provide for such an exemption; and in discussions on this issue at IMO it was agreed that, even if canned water is not packed in a liferaft, it is reasonable to assume that persons abandoning ship into liferafts will attempt to bring along as much canned food as possible, whereupon a tin opener will be indispensable. Consequently, the requirements for tin openers, and the associated modification, are retained in this final rule as originally proposed.

Pursuant to IMO MSC Circular (Circ.) 447, proposed § 160.151–21(n) waived the SOLAS requirement for liferafts to be equipped with an ''efficient radar reflector.'' The reason for the effective waiver in the 1983 IMO document was that no radar reflector suitable for packing in inflatable liferafts was known to be available at that time. One comment suggested that MSC/Circ. 447 is an ''antiquated ruling that has been overcome by time and technology,'' and that a radar reflector should be a fundamental piece of required equipment for all liferafts.

The Coast Guard disagrees. There have not been any significant advances in radar reflector technology since 1983. The Coast Guard is still not aware of any ''efficient'' radar reflectors suitable for extended storage in the tight confines of packed inflatable liferafts, and several proposals to cancel MSC/Circ. 447 have been rejected by the IMO Lifesaving, Search and Rescue Sub-Committee for that reason. It should be noted as well that, since 1983, the implementation of the GMDSS, incorporating portable satellite Emergency Position Indicating Radio Beacons (EPIRBs) and Search and Rescue Transponders (SARTs) on many ships, has largely overshadowed radar reflectors as locating aids.

A number of identical comments suggested requiring a ''tape'' on liferaft canopies that would make them more visible to radar. This suggestion has not been adopted in the final rule, since the principles of radar propagation and reflection would render such a product ineffective as a radar reflector.

Proposed § 160.151–21(u) required that the anti-seasickness medicine required by SOLAS regulation III/38.5.1.21 be one of two specified medicines carried onboard. Several comments noted that, because the two specified medicines are available only by prescription, this provision would require a servicing facility to obtain DEA registration to distribute controlled substances. The comments also noted that the specified medicines can have serious side effects making their use dangerous without medical supervision.

The Coast Guard agrees that it would be impracticable to require liferaft-servicing facilities to handle controlled substances, and has amended § 160.151–21(u) in the final rule to remove the requirement for specific medicines. Any readily available over-the-counter medicine for motion sickness such as dimenhydrinate (generic formulation of Dramamine®) will be suitable.

Proposed § 160.151–21 (v) and (w) required instructions for survival and immediate action to be provided in English. One comment noted that in many areas the crews do not read or speak English, and suggested that the required instructions be in a language the crew understands.

The Coast Guard is very aware of the linguistic diversity of ships' crews, particularly in the fishing industry. However, it would not be practical to require liferaft manufacturers to make the required instructions available in whatever language a particular customer (or his crew) may be able to read, particularly in view of the fact that the manufacturer generally does not know who the customer (let alone his crew) is until long after the liferaft is packed. We encourage liferaft manufacturers to make practical efforts to satisfy the linguistic needs of their customers, and have revised § 160.151–21 (v) and (w) in the final rule to make it clear that providing instructions in other languages along with English is acceptable.

Proposed § 160.151–21(x) required SOLAS A and SOLAS B inflatable liferafts to be equipped with thermal protective aids approved under approval series 160.174. One comment noted that these aids provide critical survival capability not currently available in Ocean Service or Limited Service equipment packs. The same comment further recommended either that those packs be replaced by the SOLAS A and SOLAS B packs, respectively, or that they have to be upgraded by the addition of thermal protective aids.

While the Coast Guard agrees that thermal protective aids can significantly enhance survival prospects in certain situations, the upgrading of existing approved liferafts is beyond the scope of this rulemaking. Consequently, the final rule does not include any requirement to upgrade such liferafts. At present, a liferaft owner desiring to add thermal

protective aids to its equipment pack may, so long as the addition is addressed in the manufacturer's servicing manual. Even notwithstanding such optional carriage, the Coast Guard anticipates that the proportion of liferafts equipped with thermal protective aids will slowly increase as existing Ocean and Limited Service liferafts are taken out of service and replaced by SOLAS A or SOLAS B liferafts equipped with these aids. It should be noted, however, that these aids are not a panacea for exposure, since a SOLAS liferaft need carry them for only ten percent of its rated capacity.

One comment questioned who would decide how many thermal protective aids would be provided in each liferaft, and how the addition of these protective aids would affect the re-packing of the liferaft. As discussed briefly above, the number of these aids in a SOLAS liferaft is specified by SOLAS regulation III/38.5.24 as the greater of ten percent of its rated capacity or two. This information would be included in the manufacturer's service manual, along with instructions for packing the aids in the equipment pack. The manufacturer would have performed all approval testing of a SOLAS liferaft with the required aids packed in the equipment pack.

Proposed § 160.151–21(y) required a repair kit called for by SOLAS regulation III/39.10.1.1 to include six or more sealing clamps or serrated conical plastic plugs, along with patches, cement, and a roughing tool for making more permanent repairs. The NPRM specifically requested comments concerning appropriate contents for repair kits, since SOLAS does not specify its contents.

One comment suggested that a combination of serrated plugs and sealing clamps should be accepted. The comment added that the serrated plugs should not have to be of plastic material, and that the Coast Guard should consider the possibility of using a quick-repair material such as a suitable self-adhesive tape in lieu of tube patches and cement. Two comments contended that tube patches and cement are virtually useless for making repairs on the water. One comment suggested that conical plugs should not be approved as substitutes for sealing clamps until they have been proven as effective as the clamps. Another comment suggested that sealing clamps are superior to serrated repair plugs, and should be used.

The Coast Guard does not agree that sealing clamps are superior to plugs in all instances. The thickness and textures of fabrics of tubes of inflatable liferafts vary widely. In light of the disparate effectiveness of sealing clamps and plugs with different fabrics for inflatable tubes, the Coast Guard contends that liferaft manufacturers are best able to determine a suitable combination for use with their liferafts through testing and operational experience. It expects that manufacturers will take effectiveness as well as economics into account when determining suitable contents for a repair kit. It agrees that wooden plugs should be accepted as well as plastic ones (and may be desirable in some cases), and that a suitable quick-repair material such as self-adhesive tape would be an acceptable and perhaps preferable substitute for patches, cement, and a roughing tool. Consequently, the wording of § 160.151–21(y) has been revised in the final rule to require six or more sealing clamps or serrated conical plugs, or a combination of the two; five or more tube patches at least 50 mm (2 inches (in.)) in diameter, compatible with the liferaft fabric; a roughing tool, if necessary to apply the patches; and, unless the patches are self-adhesive, cement as specified in the NPRM. The Coast Guard would like to be kept informed of the progress of manufacturers in developing or identifying suitable self-adhesive patches.

Float-Free Arrangements

One comment noted that there is no specific reference to float-free arrangements in the proposed rules other than by reference to SOLAS regulation III/38 (specifically regulation 38.6 thereunder) in proposed § 160.151–7, and that there is no mention of wire weak links for inflatable buoyant apparatuses. The comment also questioned whether hydrostatic release units used in float-free arrangements would have to be approved by the Coast Guard (as is the equipment in § 160.151–21).

As is the case in the bulk of the proposed rules, the requirements for float-free arrangements are not explicitly stated, but rather are incorporated by reference to the corresponding SOLAS requirements. Weak links for inflatable buoyant apparatuses are covered in § 160.010–3(a) in the NPRM (retained substantially unchanged in the final rule), which requires an inflatable buoyant apparatus to generally meet the standards of design and performance for SOLAS inflatable liferafts contained in subpart 160.151. Since they are of similar function and packed buoyancy to inflatable liferafts, the NPRM and the final rule require that buoyant apparatuses be fitted with the same weak links used with inflatable liferafts, rather than the weaker weak links used with life floats and rigid buoyant apparatuses.

The requirement that hydrostatic releases used in float-free arrangements be approved is a vessel requirement which is beyond the scope of this equipment subpart and this rulemaking, but appears in the recently updated vessel regulations at §§ 28.125(c), 117.130 (b), 180.130(b), and 199.130(c)(7) of this part.

Carriage of Additional Equipment

Proposed § 160.151–25 provided guidelines for the carriage of additional equipment, beyond that required by the regulations, in liferaft equipment packs. The proposed rule required that such equipment be covered in the liferaft manufacturer's approved drawings and servicing manual, and that specified items meet the applicable Federal Communications Commission (FCC) regulations in 47 CFR part 80.

Two comments questioned the inclusion of the Class S EPIRB and the omission of the Class B EPIRB in the items specified in the proposed rule, since the class S EPIRB is not commonly used in liferafts. One comment questioned why only certain items were specified in the proposed rule, and two comments suggested substituting a generic statement that any additional equipment must meet any applicable Coast Guard or FCC requirements. The Coast Guard agrees that wording to that effect confers a more flexible approach. Accordingly, it has revised § 160.151–25 to require that any additional equipment for which performance or approval standards are prescribed in 46 CFR part 160 or 47 CFR part 80 must comply with those standards.

Although the proposed regulations permitted optional carriage of an EPIRB, ten identical comments suggested that EPIRB's should be required to be included in liferaft equipment packs. These comments noted that adding an EPIRB would result in quicker location of the liferaft, so that stability would not be as significant a factor. Several comments suggested adding a waterproof VHF radio.

The Coast Guard does not agree that EPIRBs and VHF radios should have to be included in liferaft equipment packs. As discussed above, the proposed rules allowed for adding equipment to that specifically required in the equipment pack. Anyone who wants to include an EPIRB, a VHF radio, or both in a liferaft may do so, provided that their packing is addressed in the liferaft manufacturer's service manual. However, portable versions of these

items generally already have to be carried on a ship outside of the liferaft, and a trained crew should know to retrieve them in the event of an emergency so as to be ready to carry them into the liferaft. Consequently, the final rule does not mandate the inclusion of EPIRBs or VHF radios in liferaft equipment packs.

Approval Inspections and Tests

By reference to IMO Resolution A.689(17), proposed § 160.151–27(a) required that all liferafts and inflatable buoyant apparatus be subjected to the same Cold Inflation Test, at a test temperature of −30°C. The preamble to the NPRM solicited comments as to whether the Coast Guard should approve Coastal Service liferafts and inflatable buoyant apparatus tested at a higher temperature, such as −18°C, since other countries approve them. One comment supported this suggestion, while another supported an increase in the testing temperature to −12°C in order to reduce costs by reducing the sizes of inflation cylinders and the dimensions of raft containers.

The Coast Guard agrees that an increase in the testing temperature for Coastal Service liferafts and inflatable buoyant apparatus is warranted, but finds the proposal to increase the testing temperature to −12°C excessive for the following reasons. These products are often used in areas where the temperature falls below −12°C. In addition, the HSC Code specifies a range of operational temperatures down to −18°C for open reversible liferafts, which are functionally similar to inflatable buoyant apparatus, and countries with climates similar to ours have substantial and successful operational experience with the test temperature of −18°C. Therefore, § 160.051–5(l) of the final rule has been revised to require the Cold Inflation Test in IMO Resolution A.689(17), para. 1/5.17.3.3.2, to be conducted at a test temperature of −18°C for Coastal Service inflatable liferafts, and § 160.010–3(a)(16) allows the same for inflatable buoyant apparatus.

The Cold Inflation Test in IMO Resolution A.689(17), para. 1/5.17.3.3.2, requires that the liferaft be exposed to the test temperature for at least 24 hours before the test. The Hot Inflation Test in para. 1/5.17.3.3.3 requires that the liferaft be exposed to the test temperature for at least 7 hours before the test. The existing procedures for these tests in 46 CFR 160.051–5(e)(11) require that the liferaft be fitted with thermocouples and exposed to the appropriate test temperature until the interior of the liferaft reaches that test temperature, which often takes considerably in excess of 24 hours. One comment suggested that this ''weakening'' of the test procedure is unjustified and may not be an accurate determinant of the raft's ability to inflate hot or cold.

The Coast Guard disagrees. The tests in the IMO recommendation have been used worldwide for approval of liferafts for many years, and there has been no indication that the liferafts approved according to those or similar tests are deficient in hot or cold performance. In fact, it is misleading to evaluate these tests in terms only of the changes in the required temperature exposures. The IMO Cold Inflation Test, for example, is a more stringent test than the test in existing regulation, since it requires the raft to reach design pressure (as opposed to design shape) in the specified time. Most rafts approved to existing U.S. requirements will fail this test without upgrading of the gas charge. Similarly, the IMO Hot Inflation Test requires that the pressure-relief valves be sufficient to prevent the liferaft from reaching twice working pressure. There was no corresponding requirement in existing regulations. For these reasons, the Hot and Cold Inflation Tests are retained in the final rule as proposed by § 160.151–27(a), with reference to IMO Resolution A.689(17), paragraph 5.17.

Also with reference to IMO Resolution A.689(17), proposed § 160.151–27(a) would require a Towing Test at a speed of 3 knots, rather than 5 knots as at present. One comment questioned the validity of revising the requirement since no justification was provided for lowering the speed.

The Coast Guard does not agree that the lower speed of the Towing Test as proposed represents a drop of standards. The existing test in 46 CFR 160.051–5(e)(8) requires towing at 5 knots, but does not include any minimum distance. The IMO test, while at a lower specified speed, also includes a stringent minimum distance. Especially since it is extremely unlikely that a loaded liferaft would ever be towed at speeds in excess of 3 knots, the IMO test is a more realistic and more repeatable test. The test is retained in the final rule as proposed.

Proposed § 160.151–27(c)(5) would require that, when the Canopy Closure Test is performed, the accumulated water in the liferaft must not exceed 4 liters. One comment suggested that this requirement is extreme and unnecessary, since this quantity of water is so insignificant that it cannot even be bailed from the liferaft. The comment proposed that the wording in the IMO testing recommendation, that there be no ''significant accumulation'' of water within the liferaft, be retained by reference without any elaboration.

The Coast Guard disagrees. The term ''significant accumulation'' is subjective and so is essentially meaningless. The Coast Guard considers that SOLAS regulation III/38.1.5.3, which requires that the canopy ''exclude seawater,'' dictates that the canopy closure be watertight. The Coast Guard realizes, however, that complete watertightness is practically impossible for a product constructed of fabric, and that the nature of the test procedure dictates that a small amount of water will likely enter the raft if only as the canopy is opened to check the raft at the conclusion of the test. The specified 4-liter maximum is intended to be a generous allowance for this inevitable minor leakage, not to define the limit of a dangerous amount. The suggestion in the comment that this would not even be enough water to bail indirectly supports the choice of this figure, since the presence of enough water to require bailing would, based on experience with numerous tests performed in conjunction with other maritime safety administrations, certainly constitute a failure of the test. For these reasons, proposed § 160.151–27(c)(5) is retained unchanged in the final rule.

Production Tests and Inspections

By reference to IMO Resolution A.689(17), proposed § 160.151–31(d) would require each production liferaft to undergo an overpressure test at 1.5 times working pressure. The preamble to the NPRM noted that a change to this test, to make it consistent with the ''Necessary Additional Pressure (NAP) Test'' done during servicing, had been tentatively approved by the Lifesaving, Search and Rescue Sub-Committee of IMO, and would be incorporated in the final rule if it obtained final approval. That approval was given by the 66th session of the IMO MSC in Resolution MSC.54(66) of 30 May 1996.

One comment supported the reference to the existing overpressure test in Resolution A.689(17), and commented that the Coast Guard should ensure that the NAP Test is at least equivalent to that test before adopting it. Since the overpressure test currently in the IMO recommendation is at 1.5 times working pressure, and the NAP Test is at a minimum of twice working pressure, the Coast Guard is confident that the NAP Test is at least equivalent, and has incorporated it in this final rule by updating the incorporation by reference of Resolution A.689(17) to include amendments through and including Resolution MSC.54(66). Consequently,

the reference to Resolution A.689(17), part 2, paragraph 5.1.4 in § 160.151–31(d) now covers the updated test.

By reference to IMO Resolution A.689(17), proposed § 160.151–31 (d) and (e) would require inflatable compartments of liferafts to undergo a 1-hour air-holding test with an allowable pressure drop of 5 percent, rather than the 6-hour, 10 percent test in existing 46 CFR 160.051–5(c)(3). One comment suggested that the existing test should be retained unless the Coast Guard can show that the revised test will provide the same assurance of the liferaft's airtightness.

The Coast Guard has several years of experience with the IMO test, because it has been allowed for liferafts approved to the SOLAS requirements since its adoption by the IMO. The Coast Guard knows of no problems associated with the reduction of the testing period, and believes that the 1-hour test is an adequate measure of the airtightness of a liferaft, especially combined with the required NAP test. Consequently, the test is retained in the final rule in §§ 160.151–31 (d) and (e) as proposed in the NPRM.

Proposed § 160.151–31(a) would require that liferaft production inspections be performed under the oversight of an accepted independent laboratory. One comment strongly supported the use of third parties for this purpose, and suggested that such parties should be required to have the qualifications and quality control required for IACS membership.

Section 160.151–31(a) has been retained in this final rule as proposed. The Coast Guard does not intend to restrict acceptance as third parties for production inspections to classification societies or IACS members. The Coast Guard considers that the existing independent laboratory acceptance standards in § 159.010, which have been used successfully for years to accept numerous third parties to inspect a variety of approved products, are sufficient to evaluate and accept third parties for liferaft production inspections.

The Coast Guard recognizes that manufacturers will likely not be able to comply immediately with the requirement in proposed § 160.151–31(g) to arrange for periodic inspections by an accepted independent laboratory. Consequently, § 160.151–31(g) in the final rule has been revised to give manufacturers up to one year to comply with this requirement. A new § 160.151–31(h) has been added to the final rule to address procedures for the transitional period while manufacturers arrange for independent laboratory inspection. This paragraph is similar to existing § 160.051–5(a), except that it allows the OCMI the option of attending or not when notified of final production inspections.

Liferaft Servicing

Servicing Intervals

Proposed § 160.151–35(a) would require that inflatable liferafts (and by extension, inflatable buoyant apparatus) be serviced ''periodically'' at a servicing facility approved by the Coast Guard. One comment suggested that the servicing interval should be definitively stated, perhaps by reference to SOLAS regulation III/19, which requires servicing annually.

A more definitive statement of servicing intervals appears in proposed § 160.151–57(n). Under § 160.151–57(n) in the NPRM and in this final rule, annual servicing is no longer applicable in all cases, since the first servicing of a new liferaft on a non-SOLAS ship can be delayed until the raft is two years old provided that dated survival equipment in the liferaft will not expire before the next servicing due date.

Multiple comments suggested that that annual servicing is unnecessary and costly. In support of this view, several of these comments cited the fact that most of the equipment in a liferaft's equipment pack remains serviceable for far longer than a year. One comment suggested that servicing intervals could be extended considerably by the placement of the liferaft equipment in a waterproof container. Nine of the comments proposed alternative servicing intervals, ranging from biennially to once every 5 years; however, none of these comments provided any justification for the proposed intervals or any evidence that they would not adversely affect the performance of the liferaft. One letter cited the difficulty of removing the liferaft from the vessel for servicing, and the potential for damage when doing so. Several comments noted that the choice of servicing facilities is limited, and the prices they charge exorbitant.

The Coast Guard does not agree that annual servicing is unnecessary. Servicing intervals do not derive exclusively from the need to examine and replace dated equipment, although some equipment, such as flashlight batteries and cement in repair kits, does typically require annual replacement. During servicing, in addition to having its emergency equipment examined, the liferaft itself is unfolded, inflated with air and tested for airtightness, and repaired if needed. The cylinder is weighed, and the liferaft fabric and structure examined for damage and deterioration. The liferaft is then refolded and repacked, which serves to extend the life of the liferaft fabric by relocating the creases. This procedure has been the requirement in the U.S. for some decades, and is also the norm internationally, required by SOLAS regulation III/19.8.1. Although some manufacturers have done some developmental work on methods of extending service intervals, the Coast Guard is not currently aware of any methods shown to provide the same level of assurance of a raft's operational readiness as the currently required annual servicing. The Coast Guard is also not aware of any other maritime safety administrations currently allowing extension of servicing intervals. Consequently, the final rule does not extend intervals for liferaft servicing beyond those contained in existing regulation and in SOLAS, except for new liferafts on ships not certificated under SOLAS. This minimal extension was first permitted by 46 CFR 28.140(b) for new liferafts on commercial fishing vessels, as a way of mitigating the expense of compliance with the new regulations for safety of vessels in the commercial fishing industry. The Coast Guard considers this extension to be low-risk in view of the stringent production testing to which new liferafts are subjected, and so these final rules extend its application to new liferafts on all vessels not SOLAS-certificated. The Coast Guard may reexamine this position in the future with further experience and research by the industry.

One comment opposed allowing the first servicing of new liferafts to be extended to two years, citing dated items in the liferaft. Section 160.151–57(n) in the NPRM and in this final rule addresses this comment by permitting such extensions only if dated survival equipment in the liferaft will not expire before the next due date for servicing.

Servicing Costs

A number of comments discussed the limited choice of servicing facilities and the prices charged for servicing. The Coast Guard notes these comments, however the Coast Guard does not have any authority to regulate the economics of the liferaft-servicing industry. It would advise consumers to investigate the availability and suitability of servicing facilities before purchasing a liferaft. Although liferaft manufacturers are required as a condition of approval to demonstrate some reasonable geographic coverage of servicing facilities, the Coast Guard cannot require or guarantee that a servicing

facility will be conveniently located for every liferaft owner.

One comment suggested that liferaft servicing should be performed by the manufacturer, with servicing costs and schedules provided at the time of liferaft purchase. The final rule does not shift the burden of service onto the manufacturer. Most liferaft manufacturers are equipped primarily to manufacture liferafts, not to service them, and the costs and time associated with transporting the liferafts to the manufacturer for servicing would be enormous. The existing system better serves the owner of the liferaft by providing for reasonably local access to liferaft servicing. Advance notice of recurring servicing costs would be impossible to provide with any degree of certainty, since these costs vary from liferaft to liferaft depending on how and where the liferaft is stored and numerous other factors that cannot be determined in advance with any certainty.

Manufacturers' Responsibilities

Proposed § 160.151–35(b)(3) would require a manufacturer to make the servicing manual, servicing manual revisions, service bulletins, liferaft plans, and any unique parts and tools that may be necessary to service the manufacturer's liferafts available to each technician who has successfully completed the manufacturer's initial or refresher training course within the periods specified in § 160.151–41(e). Several comments opposed this requirement, since it implies that the specified items are the property of the technician rather than the servicing facility (which likely paid for the training). Several of the comments further noted that individual technicians may have no vested interest in the liferaft-servicing business, since not all facility owners are qualified technicians, and that the manufacturer has no relationship with or recourse against an individual technician. One comment suggested that it would be unduly burdensome for manufacturers to have to provide each technician, rather than each approved servicing facility, with updates. Two comments proposed that the wording of § 160.151–35(b)(3) be changed to require that the manufacturer make the specified items available to approved service facilities staffed by technicians who have been trained within the specified periods, rather than to the technicians themselves.

The Coast Guard agrees in concept with the suggested change to proposed § 160.151–35(b)(3), since it will accomplish substantially the same end as the proposal in the NPRM. The change has been incorporated in § 160.151–35(b)(3) of the final rule with one minor revision; since § 160.151–41(e) already requires an approved servicing facility to employ at least one currently trained technician, it is not necessary to include that as a condition in this regulation. Consequently, § 160.151–35(b)(3) of the final rule requires that the items specified in the NPRM be made available to ''each approved servicing facility'' servicing the manufacturer's liferafts.

Proposed § 160.151–39(b) would require that the manufacturer ''conduct a refresher training program for recertification of previously trained servicing technicians.'' Several comments disagreed with this requirement, since they do not believe a technician should have a right in perpetuity to be trained. One of the comments proposed wording that would indicate that the manufacturer will conduct a refresher training program ''by invitation.'' Another comment suggested that manufacturers should have to open up their training courses to any technician from a facility approved by the Coast Guard, to ensure that the approval of servicing facilities is based upon the qualifications of the facility and its technicians, not upon business considerations. One comment suggested that a servicing technician's certification should be linked to a particular approved facility.

As indicated in the preamble to the NPRM, the proposed rule did not intend to mandate who must receive training, or that a manufacturer must provide training on demand. It intended to require only that a manufacturer have an established refresher-training program so that it is possible to maintain an approved servicing network in compliance with the training requirements in § 160.151–41(e). The Coast Guard does not intend to get involved in whom a manufacturer invites to attend the program. It has slightly refined the wording of § 160.151–39(b) in the final rule to clarify its intent.

The suggestion that a technician's certification be linked to a particular approved facility has not been adopted in the final rule. Subject to relevant legal considerations, a manufacturer can include such a linkage in its certifications, but the Coast Guard does not agree that there is any compelling reason why certification to service a particular make of liferaft should not be portable.

Approval Process for Servicing Facilities

Proposed § 160.151–41(b) would revise the process by which servicing facilities obtain Coast Guard approval. Rather than the manufacturer's designating a selected facility as at present under 46 CFR 160.051–6(d), a servicing facility would apply directly to the OCMI for approval. There would no longer be an explicit requirement for advance authorization by a manufacturer of a servicing facility.

A number of comments opposed this change. The reasons cited in the comments were that the proposed change does not allow for a manufacturer's ''approval'' of a servicing facility as is effectively the case at present, and does not require ''manufacturer support as outlined in IMO Resolution A.761(18), Annex 2.'' One of the comments noted that it appeared the proposed rules would mandate a reduction in the manufacturer's control over the servicing of its product. One comment noted that any manufacturer must retain the right to determine who will distribute its products. One comment suggested that technicians must have manufacturer training, and suggested that the manufacturer should periodically visit a servicing facility to train and observe the servicing technicians.

The Coast Guard generally disagrees with all of the comments cited above. First, the IMO Resolution referred to does not require, as the comments wish, that servicing facilities be ''accredited'' by the manufacturer. The wording of the resolution was crafted carefully to avoid such a result. It does require that the manufacturer establish a servicing network by accrediting a sufficient number of servicing stations, that each of those stations be staffed with qualified personnel, and that the manufacturer provide the Administration with a list of them. However, it does not require that every facility approved by the Administration be so accredited.

The proposed rules have no effect on a manufacturer's selection of distributors for its products. They address only servicing facilities, which may or may not also be distributors. Distribution and servicing are distinct activities.

As it indicated in the NPRM, the Coast Guard desires to focus on the technical qualifications of the servicing facility, and not on the facility's business arrangements with the manufacturer. The IMO resolution upon which the proposed rules were based

clearly spells out the technical requirements for approval of a servicing facility: a suitable space, parts, tools, manuals, and appropriately trained personnel. If those requirements are met, there is no significant value added by an explicit business relationship with the manufacturer. Since such a relationship is not essential to the adequate functioning of a servicing facility, the Coast Guard sees no need to allow the liferaft manufacturing industry to control which members of the servicing industry have access to the program of Coast Guard approval.

Manufacturers' support of approved servicing facilities is required by the IMO recommendation on servicing and by § 160.151–35(b)(3) of the NPRM and the final rule. This rule actually represents a strengthening of the requirements for such support, not, as several comments implied, an abandonment of them.

One comment noted that ''to remove the manufacturer approval would remove the manufacturer's quality control abilities.'' However, neither existing regulations nor the proposed rules give the manufacturer any explicit responsibility for control of quality of facilities servicing their liferafts. In fact, to do so, or to require, as suggested in one comment from a facility, that manufacturers visit all of their servicing facilities periodically to train and observe servicing technicians, could be burdensome to manufacturers. Under such requirements, manufacturers would have to give the same degree of attention to remote and overseas facilities that they give to local ones. Quality control is the responsibility of the facility itself, and the Coast Guard intends to continue adequate oversight over the facilities to ensure that quality control is adequate. Note that nothing in this final rule prevents a manufacturer from entering into or maintaining a relationship with an approved facility, which relationship may include quality-control arrangements.

Several comments suggested that if all servicing facilities had to compete with each other, a black market for manuals and parts would appear, and facilities would cut corners to maintain profits.

The Coast Guard disagrees. The Coast Guard has no authority or desire to restrict competition among liferaft-servicing facilities, and believes that the oversight required by these final rules will serve to inhibit those facilities from cutting corners for financial reasons. Concerning the creation of a black market for servicing manuals and parts, § 160.151–37(c) in the NPRM and in the final rule requires each manual to bear the original signature of a manufacturer's representative attesting its consistency with the manual approved by the Commandant. Consequently, ''bootleg'' copies of manuals of questionable accuracy, as may be in circulation at present, should no longer exist. Provided that replacement parts used are genuine parts as specified in the manual, the Coast Guard is not concerned with where a facility obtains them. However, this should not be a problem in any case since, as discussed above, § 160.151–35(b)(3) of the final rule requires that the manufacturer make unique parts or tools required for servicing available to each facility approved by the Coast Guard to service the manufacturer's liferafts.

One comment noted that it appeared the proposed changes to the approval process for facilities may be driven in part by Coast Guard concern that current regulations may foster a monopoly in the servicing industry, and explained in detail how this is not the case at all at present. However, the premise of the comment is incorrect, since the Coast Guard is not concerned with nor has any authority over the regulation of business practices in the servicing industry.

One comment suggested that the proposed rules appeared to indicate that the Coast Guard would hold a facility qualified to service one manufacturer's rafts qualified to service all manufacturer's rafts, and supported retaining the manufacturer in the approval process to ensure that proper repair techniques are used. The same comment pointed out the importance of manufacturers' knowing the identity of the facilities that service their rafts.

Under the proposed rules, servicing facilities would continue to be approved separately for each individual make of liferaft. For each make for which approval is sought, a facility would still need to have appropriately manufacturer-certified personnel, servicing manuals, and all parts and tools required by the manufacturer, and to demonstrate the proficiency of its technicians. The requirements for training would be strengthened from those at present by requiring that the training be current. Overall, the proposed rules strengthen the technical requirements for approval of a facility, so the Coast Guard is confident that the ability of facilities to properly service and repair liferafts will not be adversely affected by the removal of the requirement for a formal manufacturer's authorization. To keep manufacturers apprised of the facilities servicing their liferafts, the Coast Guard would continue the present practice of sending a copy of each facility-approval letter to the manufacturer whose rafts it is approving a facility to service.

One comment suggested that facilities should submit a servicing report describing the servicing of liferafts performed outside of the United States to the Coast Guard. It offered no reason.

The Coast Guard approves servicing facilities outside the United States, and their servicing activities are subject to supervision by OCMIs just the same as servicing at any other approved facility. The Coast Guard does not believe that reporting requirements for liferaft servicing should vary with the geographic location of a servicing facility. The paperwork burden of reporting servicing performed outside the United States would not serve any useful purpose.

For the reasons discussed above, proposed § 160.151–41(b) is retained unchanged in the final rule. The Coast Guard realizes that manufacturers will retain a good deal of practical control over facilities servicing their rafts under that rule, for example through non-compete clauses and control of access to training. However, there will no longer be any reason for the Coast Guard to get involved in these sorts of business arrangements.

Proposed § 160.151–41(c) would require that, for a servicing facility to obtain Coast Guard approval, it would need to demonstrate the complete servicing of a liferaft of the type for which it seeks approval, in the presence of either the cognizant OCMI or a third-party inspector accepted by the OCMI. Several comments suggested that such a demonstration should not be necessary if a technician from the facility has already demonstrated his abilities to a Coast Guard inspector during initial or refresher training held at a different location (such as the manufacturer's plant).

The Coast Guard agrees, and amends § 160.151–41 in the final rule to indicate that certification by a Coast Guard inspector, or by a third-party inspector accepted by the OCMI, of completion of the specified demonstration at the time of initial or refresher training is acceptable in lieu of a demonstration at the facility seeking approval. In addition, this section in final form allows the certification to be made by the manufacturer's trainer, since the trainer would obviously be well enough qualified to be accepted by the OCMI in any case. However, the provision is not moved to § 160.151–39 as proposed in two comments, since, although § 160.151–39(c) requires notification of the cognizant OCMI before holding required training, that training may not

always be attended by a Coast Guard inspector. One comment suggested that a Coast Guard inspector should be present at every training course to ensure the thoroughness of the training and to enable the Coast Guard to better oversee liferaft servicing operations. However, resources and priorities of the Coast Guard do not always allow such attendance.

Proposed § 160.151–41(c)(8) would require that, for the Coast Guard to approve a servicing facility, the facility would need to demonstrate that it can repair a leak in a liferaft's main buoyancy chamber and then subject the repaired chamber to ''the inflation test described in IMO Resolution A.689(17), para. 2/5.1.5.'' One comment suggested that the repaired chamber should be subjected to an overpressure test rather than an inflation test.

This comment stems in part from some imprecise wording in the NPRM, since para. 2/5.1.5 of Resolution A.689(17) is a test of leakage at working pressure, not an inflation test. The Coast Guard agrees that an inflation test is not necessary to ensure that a repair has been done properly, and that an overpressure test is a more appropriate test of a repair than either an inflation test or a test of leakage at working pressure. Section 160.151–41(c)(8) in the final rule requires that the repaired chamber be subjected to the Necessary Additional Pressure test in § 160.151–57(k).

Proposed § 160.151–45(a) would require a servicing facility to maintain ''a complete set of the manufacturer's plans for each inflatable liferaft to be serviced.'' Two comments noted that complete sets of plans are generally not held by facilities, and that it is sufficient to have service manuals that give ''all relevant information.''

The Coast Guard agrees that a requirement for a servicing facility to hold a complete set of manufacturing plans would constitute an unnecessary record-keeping burden. The intention is made clearer in § 160.151–35(b)(3) of the NPRM and in the final rule. To eliminate any ambiguity, § 160.151–45(a) in the final rule has been revised to refer to the description of the necessary plans in § 160.151–35(b)(3).

Proposed § 160.151–47 contains requirements for the owner or operator of an approved servicing facility. Two comments suggested that the requirements should include an annual letter from the liferaft manufacturer(s) for which the facility is approved demonstrating their continued technical and consultative support.

The Coast Guard believes that such a letter would serve no useful purpose, and would therefore represent an unnecessary paperwork burden. As discussed above, § 160.151–35(b)(3) of the final rule requires that a manufacturer make certain items available to facilities approved by the Coast Guard. Demonstration by an approved facility that it has those items is more substantive evidence of the required technical and consultative support than a letter. Consequently, the suggested requirement for an annual letter has not been incorporated into the final rule.

Servicing at Remote Sites

Proposed § 160.151–49 would allow for approval of servicing facilities to perform servicing at remote sites, such as on board ships or offshore facilities, rather than at the facilities themselves. One comment suggested that a facility must be specifically authorized in its letter of approval from the manufacturer to conduct servicing at remote sites.

As discussed above, in a change from the current regulation, this final rule does not require explicit manufacturer authorization as a condition for approval of a servicing facility. Consequently, the ''letter of approval from the manufacturer'' on which the comment proposes to require an authorizing endorsement for remote servicing does not exist. Therefore, the suggested requirement for manufacturer authorization to conduct servicing at remote sites has not been incorporated in this final rule. However, § 160.151–49 in the final rule now requires that a facility conducting servicing at remote sites be specifically authorized to do so in its letter of approval from the Coast Guard.

One comment suggested that the provisions on remote-site servicing should be deleted in their entirety, since the intended beneficiaries of those provisions (such as MODUs and quick-turnaround vessels) would in reality see little benefit under the proposed rules. The comment noted that the same difficulties faced by the raft owner in shipping the raft to an approved facility would be faced by the remote-site technician, who would have to import his tools, manuals, parts, etc. at great transportation cost. The comment also cited the difficulty of obtaining work permits in some areas.

The Coast Guard agrees that remote-site servicing may not be practicable or advantageous in many cases. However, the NPRM does not require remote-site servicing; it merely permits it as an option. The argument that it is inherently impracticable is belied by the fact that the Coast Guard has allowed remote-site servicing at the special request of owners of offshore facilities and servicing facilities under existing regulations. Consequently, the suggestion to delete the provisions on remote-site servicing has not been incorporated in the final rule.

Referring to proposed § 160.151–49, one comment suggested that servicing facilities outside the United States should be specifically approved by the manufacturer since they will not be by the Coast Guard. This is incorrect, since the Coast Guard does and will continue to approve facilities outside the United States. For servicing at remote sites such as oil rigs, the facility performing the work will still have to be approved by the Coast Guard, and the provisions in the facility's letter of approval authorizing it to perform servicing at remote sites will signify that the Coast Guard has evaluated the facility's ability to perform proper servicing in the field.

Supervision of Liferaft Servicing

The NPRM proposed replacing the current system of universal Coast Guard witnessing of liferaft servicing with a system of Coast Guard supervision by means of periodic spot checks, with the frequency of the spot checks at the discretion of the OCMI.

One comment suggested that, rather than change its current system of inspection of servicing to use its resources more efficiently, the Coast Guard should ask Congress for additional personnel.

The Coast Guard does not believe it is realistic or desirable to maintain an existing inspection program that can be carried out just as effectively with a more efficient use of fewer resources of the Coast Guard. The proposed conversion from universal inspection of servicing to spot checks would not take place in a vacuum. Although Coast Guard presence at actual servicing would become less frequent under the rules proposed in the NPRM, the technical requirements for facility approval would be significantly strengthened, as would the training requirements for servicing technicians. Overall, the Coast Guard expects that the changes proposed in the NPRM, taken together, will ensure that liferaft servicing continues to be done properly and under adequate supervision.

One comment completely supported the conversion to spot checks, since servicing technicians at facilities are well trained and qualified, and scheduling a Coast Guard inspector to witness every liferaft servicing is not only burdensome on the Coast Guard's personnel resources but also a financial burden to facilities and an operational burden on ship operators awaiting

liferaft servicing. The comment also noted that the NPRM is consistent with ongoing efforts toward Maritime Regulatory Reform and with the shifting of appropriate activities to the private sector.

One comment suggested that there should be a stated minimum frequency of spot checks, and that in no case should the number of spot checks be less than two a year. Another comment suggested that Coast Guard inspectors should observe the servicing or oversee the performance of third-party inspectors in some reasonable percentage of instances.

The Coast Guard agrees that spot checks by the OCMI must be at some minimum frequency to provide adequate oversight. However, the Coast Guard does not believe that it is appropriate to impose an inflexible requirement upon itself through these regulations. It intends that, when this final rule takes effect, the Commandant will provide appropriate internal guidance to field units to implement the system of supervision by spot checks. In this way, the Coast Guard can take into account any unusual requirements or conditions of particular OCMI zones, and can refine its administration of the program as it gains experience with the new system.

Proposed § 160.151–53(a) would require that a servicing facility taking in a liferaft to be serviced under its Coast Guard approval notify the OCMI of the make, size, and age of the liferaft, and whether the liferaft is due for a 5-year inflation test. Acting on that information, the OCMI would decide whether the servicing of the liferaft must be witnessed by an inspector.

One comment suggested that providing the specified information before servicing would be unnecessarily costly, since many vessels operate on extremely tight schedules. The comment proposed that the facility be required only to notify the OCMI of its intent to service a liferaft, and to provide any information available at the time of notice (but not any particular information). Two comments suggested that proposed § 160.151–53 adds uncertain costs to the servicing of a liferaft, since a facility has no way of knowing in advance whether an individual raft will be subject to inspection where a user fee or third-party-inspection fee will be added. One of these comments suggested that the Coast Guard perform random inspections of every facility at no cost to that facility. Another comment suggested that, to make costs involved with servicing inspections predictable, the Coast Guard make periodic (e.g., quarterly or semi-annual) inspections, with or without notice.

None of these comments have been incorporated in the final rule. Because of constraints on the resources of the Coast Guard, the NPRM proposed to replace the current system of universal Coast Guard witnessing of liferaft servicing for inspected vessels with a system of spot checks by the OCMI. Overall, that system should substantially decrease, for all servicing facilities, the burden associated with scheduling of Coast Guard inspectors for every liferaft servicing and, for foreign facilities, the travel and subsistence expenses of Coast Guard inspectors. However, for spot checks to provide effective supervision of liferaft servicing, it is essential that the Coast Guard focus its resources in the areas of greatest risk. In the case of liferaft servicing, the greatest risk will likely be in the areas of the oldest rafts, particularly those undergoing the five-year inflation test, and perhaps on makes of liferafts that have demonstrated reliability problems in the past. The required information should not be difficult to obtain, since it is all marked on the outside of the liferaft container. A facility called by a ship for the servicing of one of its liferafts would merely need to request that the ship provide the information marked on the outside of the container, whereupon the facility would pass that information to the OCMI when giving the required notice of servicing.

The suggestions for random periodic inspections have not been adopted, because they do not allow for the Coast Guard's resources to be focused on the areas of highest risk. In addition, such a system would result in the lowest-volume facilities' being subjected to a proportionally much greater degree of supervision than the higher-volume facilities.

One comment questioned whether a servicing facility must notify the OCMI when it plans to service a liferaft from a commercial fishing vessel. The NPRM and the final rule require notice whenever a facility is to service a liferaft for which it is approved by the Coast Guard, regardless of the source of the liferaft.

Proposed § 160.151–53(c)(2) would allow a servicing facility, when a Coast Guard marine inspector is not available in a timely manner to witness a servicing that needs to be witnessed, to engage a third-party inspector accepted by the OCMI to witness the servicing on behalf of the OCMI. Third-party inspection would be at the expense of the facility.

Two comments suggested that the OCMIs should retain sole responsibility for supervision of servicing of liferafts in their respective zones to maintain the Coast Guard's level of expertise in this area. Another comment stressed the importance of maintaining the Coast Guard's expertise, and suggested that Coast Guard inspectors should observe the servicing or oversee the performance of third-party inspectors in some reasonable percentage of instances.

The Coast Guard agrees with the comments that it is essential that the Coast Guard maintain its base of knowledge and experience in this highly specialized area. It is anticipated that most spot checks would in fact be conducted by Coast Guard marine inspectors. However, the nature of the spot-check system, in targeting areas of greatest risk, means there may be instances when the witnessing of a particular event is necessary and yet when the Coast Guard does not have adequate resources to attend in a timely manner. To minimize the scheduling burden on servicing facilities and ship operators, the proposed rule affords some flexibility in those instances. Therefore, the suggestion that all spot checks be conducted by a Coast Guard inspector has not been incorporated in the final rule.

One comment opposed third-party inspections, since unlike the Coast Guard, third-party inspectors would have an economic interest in the outcome of the inspection. A ship operator could influence a third-party inspector's decision about whether the liferafts fail the inspection because, if the liferafts fail the inspection, the operator may not hire the inspector again.

This comment appears to be based on a misunderstanding of what was proposed in the NPRM. A third-party inspector as described in the NPRM would be hired not by a ship operator but rather by the servicing facility; an operator might not even be aware that a third-party inspector is involved. The third-party inspector's function would be to oversee the performance of the facility, not to evaluate the condition of the liferaft. The presence of an independent third-party inspector during liferaft servicing would be expected to discourage a facility from allowing economic considerations to influence its evaluation of a liferaft, since the inspector would ensure adherence of the facility to the objective and quantitative criteria in the relevant regulations and in the manufacturer's servicing manual.

Four comments suggested that third-party inspection based on fee for profit

would greatly increase the cost of liferaft servicing, and one further commented that it would be an unfair system in terms of fees unless a nationwide fee could be agreed upon.

These rules have no effect on the cost of Coast Guard inspections; inspections at domestic servicing facilities continue to be provided at no charge, and foreign facilities continue to be billed for the inspector's travel and subsistence. The cost of any third-party inspections as allowed by these rules will be borne by the facility in all cases. However, these rules do not require such inspections; they are merely an option available to facilities in cases where constraints on resources of the Coast Guard may not allow response in time to meet a facility's desired delivery schedule. The Coast Guard does not have the authority to regulate fees for such services, and does not believe a uniform fee would be reasonable given the wide variety of parties who could be accepted as inspectors and the worldwide distribution of approved facilities in sometimes-remote locations.

Three comments expressed concern that untrained personnel might be assigned to oversee liferaft servicing, and asked what training or qualifications a third-party inspector would have to have in order to be able to perform this work.

As was discussed in the NPRM, third-party inspectors engaged to oversee liferaft servicing would be subject to acceptance by the OCMI. Like the proposed rule, this final rule does not require a third-party inspector to necessarily represent an independent laboratory fully compliant with 46 CFR subpart 159.010. Individuals such as experienced marine surveyors with appropriate practical training or background could be employed. And, like the proposed rule, this final rule gives OCMIs the authority to accept third-party inspectors in their respective zones (as opposed to central approval by the Commandant), since OCMIs will be better able, taking into account their local knowledge and conditions, to evaluate prospective local third-party inspectors of less-than-national scope. To maintain some uniformity of requirements, the Commandant will provide OCMIs with general guidelines for use in evaluating and accepting third-party inspectors where they are used.

One comment suggested that performance monitoring of accepted third-party organizations would have to be done by the OCMI, and questioned how this relationship would be any different from the current situation between facilities and the OCMI. The difference is that, under the current system, the OCMI is in the facility for every servicing of a liferaft from an inspected vessel. Under the system proposed in the NPRM, the Coast Guard would be in the facility only for periodic spot checks, at which time it could audit records pertaining to any third-party inspections that may have been performed.

The same comment noted that problems may arise between a facility and third-party inspector, such as conflicts over personality, scheduling, and payment. Obviously, the Coast Guard has neither any intention nor any authority to regulate these areas. Since the facility selects and hires a third-party inspector, it can ''fire'' the inspector as well in the event of an irreconcilable conflict.

One comment suggested that the Coast Guard would need to establish a ''complaint board'' to address instances of ''unfair actions taken by third party inspectors.'' The Coast Guard does not agree that such a dedicated body is needed in view of established appeal procedures in current regulations. Allegations of actions taken by a third-party inspector that are contrary to the terms of the OCMI's acceptance of the inspector would be evaluated by the OCMI, and corrective action (which could include termination of acceptance) taken as appropriate. A party reporting such allegations who is not satisfied with the OCMI's response can appeal the OCMI's decision to the District Commander and then to the Commandant, if necessary.

One comment suggested that the Coast Guard should attend every servicing of a ''grandfathered'' liferaft whose carriage on an uninspected commercial-fishing-industry vessel is permitted under 46 CFR part 28, because these rafts were not manufactured under supervision of the Coast Guard and thus their construction is suspect. The comment also suggests that the Coast Guard should assume the responsibility for monitoring the condition of these rafts, since it is allowing them to continue in use until they are no longer serviceable.

The Coast Guard disagrees. The guidelines used by the Coast Guard to allow grandfathering of these liferafts are very stringent, including a gas inflation test and a Necessary Additional Pressure Test, both at the first servicing. The Coast Guard considers these tests sufficient to screen out any rafts of questionable construction. In addition, although grandfathered rafts themselves are not formally approved by the Coast Guard, they have to be serviced at servicing facilities approved by the Coast Guard. Since proposed § 160.151–53(a) would require a servicing facility to notify the OCMI of every liferaft taken in for servicing under its Coast Guard approval, grandfathered liferafts would be just as subject to an OCMI's spot check as any other liferaft.

The Coast Guard also disagrees that grandfathered rafts should be subject to special supervision because it lets them be used until they are no longer serviceable. This condition is not unique to grandfathered liferafts, since any liferaft may continue to be used until it is no longer serviceable.

Deviations From Procedures in the Servicing Manual

Proposed § 160.151–53(d) would allow servicing facilities to deviate from servicing manual procedures with the approval of the OCMI. As discussed in the NPRM preamble, this provision would include substitution of comparable equipment when survival equipment approved by the Coast Guard is not available for some reason. One comment suggested that equipment substitution should be permitted only if the substituted equipment meets or exceeds the Coast Guard-approved equipment, and also meets SOLAS approval requirements.

The Coast Guard agrees in principle with this comment. It is the Coast Guard's intention that any substitute survival equipment be at least comparable to Coast Guard-approved equipment. As was discussed in the NPRM, however, the wide variety of equipment available and the approval requirements for some types of equipment do not always allow for a definitive determination in the field whether a particular piece of equipment would meet all applicable requirements of the Coast Guard. Although it is anticipated that equipment substitutions will be quite rare in any case, there will no doubt be instances where the OCMI has to use his judgment and experience in determining whether a particular deviation is acceptable. Section 160.151–53(d) is retained in the final rule as proposed, since it adequately describes the general procedure for handling deviations subject to the OCMI's discretion.

Suspension and Withdrawal of Approval of Servicing Facilities

Proposed § 160.151–55 specifies conditions under which the Coast Guard can suspend or withdraw the approval of a servicing facility. Two comments suggested that this section should be revised to give manufacturers the right to withdraw approvals from facilities.

The Coast Guard does not agree. As discussed earlier, SOLAS requires a servicing facility to be approved by the Administration (i.e., the Coast Guard), not by the manufacturer. Under § 160.151–35(b)(3) of this final rule (which varies from the NPRM language because of a comment by the same association commenting on this provision), a manufacturer must provide technical support to each service station approved by the Coast Guard to service that manufacturer's liferafts. If a manufacturer is aware that a facility is not properly servicing liferafts, the manufacturer can report that to the Coast Guard; the Coast Guard will take appropriate action under § 160.151–55(a)(2). Alternatively, a manufacturer can discontinue providing refresher training for the facility's technician(s). However, this final rule does not allow a manufacturer to arbitrarily or unilaterally cause the withdrawal of a servicing facility's approval by the Coast Guard.

Servicing Procedures

Proposed § 160.151–57(b)(3) would require that, during annual servicing, an inflatable floor be inflated until firm, allowed to stand for one hour, then still be firm after two hours. Three comments suggested that this test is excessive, and proposed that the test should last one hour. The Coast Guard agrees that there is no reason why the floor test should last longer than the working pressure leakage test to which the rest of the liferaft is subjected, and § 160.151–57(b)(3) has been revised in the final rule to require only a one-hour test.

In place of the annual test currently required by 46 CFR 160.051–6(e), proposed § 160.151–57(f) would require a davit-launched liferaft to be subjected to a launching-load test at every other servicing. This is the same interval specified in IMO Resolution A.761(18). One comment suggested that this interval would be sufficient for newer liferafts, but suggested that the requirement should be annual testing for rafts over ten years old due to the possibility of deterioration of the materials.

The Coast Guard has not incorporated this comment in the final rule. Its policy is not to impose requirements in excess of SOLAS on U.S.-flag ships, and we are not aware of any data to suggest that the biennial test in § 160.151–57(f) is inadequate to identify, in a timely manner, liferafts deteriorating due to age. Consequently, § 160.151–57(f) is retained in the final rule as proposed in the NPRM.

Proposed § 160.151–57(g) would require that the 5-year gas inflation test be conducted with the liferaft still secured in its container, rather than after being removed from its container as required by current 46 CFR 160.051–6(f)(2). Several comments suggested that, because of the increased bottle charges and higher nitrogen content in the gas mixture necessary to comply with the requirements of SOLAS, performing the test in this manner raises concerns about safety as well as about unnecessary damage to the liferaft. Both comments proposed that the final rule allow the raft to be removed from its container for this test as is the current practice.

As was explained in the NPRM, the forces on a liferaft are significantly different when it is inflated in its container with the retaining bands in place from when it is removed from the container first. The Coast Guard continues to believe that performing the gas inflation test with the liferaft packed in its container is a useful means of detecting marginal or unsatisfactory structural connections in the liferaft in a realistic operating environment. However, the current IMO recommendation on servicing requires that the liferaft be removed from its container before performing the test. Because of concerns about the increased risk of damage to a liferaft when inflating it on the shop floor instead of in the water, there has been little support at IMO for modifying the test as proposed in the NPRM. Consequently, to remain consistent with the current internationally accepted requirement, § 160.151–57(g) in the final rule requires removing the folded raft from its container before actuating the inflation system, as was suggested in the comments.

Proposed § 160.151–57(i) would require that, when a liferaft ten or more years past its date of manufacture leaks extensively or shows fabric damage after a gas inflation test, it must be condemned. One comment suggested that ''fabric damage'' is a vague description, and that it is not unusual for liferafts exhibiting some signs of porosity to successfully pass all required testing.

The Coast Guard agrees that minor porosity, although it might technically be considered to be ''fabric damage,'' should not necessarily mandate the condemnation of a liferaft that otherwise passes all of the required servicing tests. Particularly with the addition of the annual Necessary Additional Pressure test for liferafts over ten years old, the normal testing procedure between gas-inflation tests should be adequate to identify fabric deficiencies serious enough to adversely affect the operational performance of the liferaft. The Coast Guard is concerned, though, about fabric damage other than minor porosity, such as cold cracking. Such damage would tend to be more aggressive and more progressive than simple porosity, and the fact that a liferaft with cold cracking might pass all of the required servicing tests would not necessarily guarantee that it would not fail catastrophically at its next inflation by its gas inflation system.

In view of the above, the Coast Guard has decided to partially adopt the suggestion in the comment. Proposed § 160.151–57(i) in the final rule requires that a liferaft more than ten years old that leaks extensively or shows fabric damage ''other than minor porosity'' after the gas-inflation test must be condemned.

Liferaft Markings as an Aid to Search and Rescue

Proposed § 160.151–57(m)(2) would require a servicing facility to mark the liferaft canopy, or the device required by proposed § 160.151–17(c), with the name of the vessel on which the liferaft will be installed or the name of the vessel owner (if the information is known). One comment suggested that providing this marking can be a problem, since companies sometimes trade liferafts among different vessels. Another comment questioned how important it is to know what ship a liferaft is from, since generally only one ship sinks at any particular time. The same comment suggested that the ship identification could not be attached to the painter, since the painter is generally cut at the raft after deployment.

As discussed in the NPRM under heading entitled ''Raft Markings as an Aid to Search and Rescue'', this requirement is pursuant to IMO Resolution A.759(18). Its main intent is to address the too-frequent situation of a liferaft being found adrift with no persons aboard and no identifying markings, e.g., a liferaft which is inadvertently released from a ship in heavy seas. Such a liferaft will obviously have no one aboard to cut the painter, and so an identification device attached to the painter will remain intact to serve its purpose.

Knowing which ship a liferaft found adrift came from lets SAR forces check to ensure that the ship is safe. An unmarked and unmanned liferaft found adrift naturally leads to speculation whether the ship it is from experienced a sudden casualty with no opportunity

to signal distress, which can result in expensive and fruitless searches.

Concerning the trading of liferafts by companies or cooperatives, § 160.151–57(m)(2) requires a servicing facility to apply the marking only if the information is known. However, manufacturers will have to include in their servicing manuals instructions for facilities to retrofit the device required by § 160.151–17(c) on existing liferafts so that vessel operators will have a means of specifying the identity of the vessel on which a liferaft is fitted without the necessity of anyone's opening the liferaft container. Such identification could be easily changed as a liferaft is traded within a company or cooperative.

In view of the above discussion, § 160.151–57(m)(2) is retained in the final rule as proposed in the NPRM. The effective date for the requirement is July 1, 1998, which is the date the requirement will become mandatory under SOLAS.

Inspection Stickers and Certificates

Proposed § 160.151–57(m)(3) would require a servicing facility to affix an inspection sticker to each liferaft it services, indicating the manufacturer of the liferaft, the identification of the facility, and the expiration date of the servicing. This sticker would replace the metal inspection plate currently required by 46 CFR 160.051–8(a).

One comment opposed the replacement of the metal inspection plate by a sticker, since the sticker would not show what kind of equipment is in the liferaft, would wear or fade easily, and would come off the container easily. Two comments suggested that it was unsatisfactory that the sticker would not show the inspection record. Another comment cited the added cost to the customer and noted that, if the sticker were to replace the servicing certificate, the customer would not know the expiration dates of the equipment inside the liferaft.

The Coast Guard disagrees with the substance of these comments in their entirety. First, the sticker would not replace, but would be in addition to, the container markings otherwise required by SOLAS and by proposed § 160.151–33(b), which include specification of the type of equipment pack in the liferaft. The inspection record will continue to appear on the liferaft itself per proposed § 160.151–57(m)(1). The sticker would not replace the servicing certificate, which is required by proposed § 160.151–57(p); however, the certificate need not indicate the expiration dates of the packed equipment in any case. Note that, notwithstanding the information required on the sticker, a manufacturer can require or allow the marking of any other relevant information by including it in the servicing manual. The durability of the sticker and its attachment to the liferaft container are specifically addressed in proposed § 160.151–57(m)(3), which requires the sticker to be of a type that will remain legible for two years in a marine environment and that cannot be removed without being destroyed. Such stickers are readily available, and their cost is nominal.

One comment noted that, since the stickers do not require specific identification by Coast Guard inspector, they could be affixed to liferafts whose servicing was not witnessed by the Coast Guard. Consequently, a facility could affix a sticker to a liferaft that it had not even opened. The same comment also noted that not requiring a Coast Guard inspector's identification on the service record marking required by proposed § 160.151–57(m)(1) would allow a facility to repack a raft without even inflating it.

The Coast Guard believes that the vast majority of servicing facilities are professional organizations dedicated to high-quality liferaft servicing in accordance with all relevant laws, regulations, and manufacturers' instructions, who perform high-quality work whether the Coast Guard witnesses it or not. Nevertheless, there are documented instances where unscrupulous facilities have engaged in acts such as those described in the comment discussed above, even under existing regulations. A facility wishing to avoid supervision by the Coast Guard need only fail to notify the Coast Guard of a liferaft taken in for servicing. A requirement for Coast Guard identification on stickers or on servicing record markings has not deterred in the past, and would not deter in the future, a facility intent on not performing the work for which it is paid.

In view of the above discussion, § 160.151–57(m)(3) is retained in the final rule as proposed in the NPRM. The requirement has an effective date 6 months from the date of publication in the **Federal Register**, so as to allow those manufacturers who have not yet begun using the stickers to obtain and distribute them.

Proposed § 160.151–57(p) would require that a servicing facility issue a certificate to the liferaft owner or owner's agent for each liferaft it services. One comment proposed that this section be revised to require also that the facility provide a copy of the servicing certificate to the manufacturer.

The Coast Guard disagrees. While it is obvious that providing the liferaft owner with a certificate facilitates demonstration to the relevant authorities that a liferaft has been properly serviced, the Coast Guard knows of no compelling reason (and the comment did not offer any) why the certificate should be required by regulation to be provided to the manufacturer as well. If the manufacturer wants a copy of each servicing certificate, that can be arranged by agreement between the manufacturer and the facilities servicing the manufacturer's rafts, or by requiring it in the manufacturer's approved servicing manual. Consequently, the proposal in the comment has not been adopted in the final rule.

One comment suggested that servicing certificates should be supplied, controlled, and serialized by manufacturers to inhibit counterfeiting and to ensure that only approved and authorized facilities conduct servicing. The Coast Guard disagrees that it is necessary to regulate the form and substance of the certificates in such detail. As discussed above, manufacturers desiring to do so can accomplish the same end by agreement between themselves and the facilities servicing their rafts, or by specifying particular certificates in the approved servicing manuals. If a manufacturer demands in the manual particular certificates as part of the servicing procedure, § 160.151–35(b)(3) will require that the manufacturer make those certificates available to approved facilities.

Reporting Damage and Defects

Proposed § 160.151–57(r) would require, in accordance with the IMO recommendation on liferaft servicing, that servicing facilities transmit to the OCMI, at least annually, information concerning damage and defects found in liferafts during servicing and repair. This information would be used by the OCMI and the Commandant to identify recurring problems, and to correct them by requiring manufacturers to make appropriate modifications to their equipment or their procedures.

One comment suggested that the specified information should be provided to the affected manufacturer(s) as well. It also suggested that the information should be provided quarterly rather than annually, though it offered no reason for the increase in frequency.

The Coast Guard disagrees that it is necessary or even desirable for servicing facilities to have to provide the same information to several different parties.

The IMO recommendation requires only that the information be made available to the ''Administration.'' As discussed above, a manufacturer desiring to obtain complete servicing records from facilities servicing its liferafts can accomplish that either by agreement with the affected facilities or by simply requiring it in the approved servicing manual. As was noted in another comment, the Coast Guard expects that OCMIs who identify recurring problems in liferafts or their servicing on the basis of the data submitted to them will inform the Commandant, who will evaluate the information and bring it to the attention of the affected manufacturer(s) for action as appropriate. Consequently, the suggestions in the comment have not been adopted in the final rule.

Penalty for Improper Servicing

One comment noted that there is currently no civil penalty regulation associated with liferaft servicing, and asked what penalty is available for a facility performing improper servicing. When the NPRM was published, there was indeed no established penalty. Since then, section 310 of the Coast Guard Authorization Act of 1996 amended 46 U.S.C. 3318(b) to make servicing or alteration of lifesaving equipment so as to intentionally render that equipment unsafe or unfit for its purpose a Class D felony.

Instructions for Training and Maintenance

Proposed § 160.151–59 would require the manufacturer to prepare ''training and maintenance instructions'' to comply with SOLAS regulations III/18.2, 19.3, 51, and 52. One comment suggested that all references to ''training'' in this section should be modified to ''operating'' or ''operating and maintenance.'' The reason given was that liferaft manufacturers are not in the business of training, and should not be responsible for preparation of training materials.

The Coast Guard believes the suggestion in the comment has merit, since the terminology used in the referenced SOLAS regulations may lead to some confusion. What is required by SOLAS regulation III/51 is the placement in a ship's training manual of not strictly training material but rather ''instructions and information, in easily understood terms illustrated wherever possible'': a simple set of operating instructions for the education and ready reference of the ship's crew. To minimize ambiguity, in the final rule proposed § 160.151–59 is broken into both a new § 160.151–59 (Operating instructions and information for the ship's training manual) and a new § 160.151–61 (Maintenance instructions), and all references in the final rule to ''training material'' have been amended appropriately.

Consequential Revisions

Currently, in 46 CFR 199.190(g)(3) refers to subpart 160.051 for servicing requirements for inflatable liferafts. This final rule revises the reference to subpart 160.151, and expands its application to include inflatable buoyant apparatuses.

Incorporation by Reference

The Director of the Federal Register has approved the material in § 160.151–5 for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. The material is available as indicated in that section.

Regulatory Evaluation

This rulemaking is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11034; February 26, 1979).

A draft Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is available in the docket for inspection or copying where indicated under **ADDRESSES.** A summary of the Evaluation follows.

The draft evaluation estimated a total one-time cost of $710,000 for liferaft manufacturers to comply with the proposed rule, including about $560,000 for them to individually complete the proposed at-sea test for stability. This final rule does not require the at-sea test proposed in the NPRM, and consequently the cost of the test is not included in this final regulatory evaluation. The total anticipated one-time cost for compliance with this rule is therefore $150,000, or approximately $60 per new SOLAS liferaft.

This final rule should result in a net recurring annual cost of about $156,000. Annual saving of almost $500,000 in servicing costs are possible as a result of the revisions to the servicing procedures in this rule, but some of those savings are offset by an increase of $218,000 in the annual cost of new SOLAS equipment that will have to be replaced during annual servicings. New liferafts will incur an annual increase of $214,000 needed to comply with the new SOLAS requirements, and $22,000 in fees for inspections by independent laboratories. In addition, the NPRM projected a cost of $200,000 for stability appendages, which will be reduced to about $100,000 by the revisions to the stability requirements in this rule. All of these increases, totalling $336,000 or about $672 per new SOLAS liferaft, should fall on manufacturers and presumably be passed through to purchasers. With both one-time and recurring costs taken into account, the acquisition cost of a new SOLAS liferaft would be increased by about $732, still one-third less than the $1156 increase projected in the NPRM. The average cost of annual servicing will drop by about $62 per year per liferaft, as projected in the NPRM. The regulatory evaluation discounts costs at 7 percent to determine future costs. On the basis of this analysis, the evaluation estimates that the cost of compliance with this rule will be about $1,264,000 over 10 years. Economic research indicates that $2.7 million per statistical life saved is a reasonable estimate of people's willingness to pay for safety. Therefore, this rule will be cost-effective even if it saves only one life over a 10 year period. The recent history of casualties involving liferafts, such as the MARINE ELECTRIC in 1983 (with loss of life due to difficulty in boarding the liferaft), and the 1992 NETTIE H. and 1993 TRUE LIFE casualties (both with loss of life, where overturned liferafts could not be easily located due to dark bottoms), strongly suggest that liferaft improvements such as the boarding ramps, stability systems, and highly visible coloring on the underside mandated by SOLAS and by this rule will result in the saving of one or more lives.

The regulatory evaluation also discusses other benefits than the saving of lives. First, liferafts approved by the Coast Guard will meet the requirements of SOLAS. This will ensure that U.S.-registered vessels are not being penalized or delayed in foreign ports because of non-compliance. Second, as a signatory to the SOLAS Convention, the United States is obligated to make sure its vessels comply. This final rule will also enhance the lifesaving potential and operational efficiency of inflatable liferafts by making them easier to board from the water, by increasing their stability in heavy seas, and by various other improvements required by the 1983 and subsequent SOLAS amendments.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule will have

a significant economic impact on a substantial number of small entities. ''Small entities'' include small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations less than 50,000. All seven U.S. manufacturers of inflatable liferafts and all (approximately 105) U.S. facilities servicing inflatable liferafts qualify as small entities. (Foreign manufacturers and servicing facilities are not considered small entities for the purposes of this analysis.) This final rule would affect all manufacturers and servicing facilities to about the same degree. U.S. firms (the small entities) may already hold a small cost advantage over their foreign counterparts in that the Coast Guard does not require reimbursement for travel and subsistence expenses to conduct inspections at their facilities. Any additional costs incurred as a result of this rule are expected to be passed through to the consumer, resulting in a negligible economic impact on manufacturers and servicing facilities.

Most consumers of liferafts will probably be small entities as well. As discussed above, the acquisition cost of a new SOLAS inflatable liferaft should increase by less than 20 percent under this rule. This increase should not create a substantial hardship for most consumers. In fact, for the regulated market, liferaft production has shifted predominantly toward liferafts complying with SOLAS since approximately 1987, and the Coast Guard is unaware of any significant adverse effects of any price increases associated with SOLAS compliance. Further, as noted above, the average cost of annual servicing will drop by $62 over the life of the raft, resulting in a negligible difference in lifetime cost.

The Coast Guard has developed these rules to provide for compliance with relevant international treaties and internationally accepted standards at the lowest possible cost to the regulated public. In response to the many comments received on the issue of cost, the most costly provisions in the NPRM, concerning stability testing, were practically eliminated in favor of compliance with relevant international standards. There were no public comments concerning the initial regulatory flexibility analysis in the NPRM, which concluded that the proposed rules would not have a significant economic impact on a substantial number of small entities. This final rule substantially reduces the financial burden on small entities relative to the proposed rules. The reporting, recordkeeping, and other compliance requirements of this rule are substantially similar to those which have been in long standing effect and industry practice, and require no particular professional skills for compliance. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard offers to assist small entities in understanding the rule so it can evaluate its effects on them and allow them to participate in the rulemaking process. If your small business or organization is affected by this rule and you have questions concerning its provisions or options for compliance, please contact Kurt Heinz, at either telephone 202–267–1444, fax 202–267–1069, or E-mail address ''kheinz@comdt.uscg.mil''.

Collection of Information

This final rule provides for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). As required by 5 U.S.C. 3507(d) the Coast Guard has submitted a copy of this rule to the Office of Management and Budget (OMB) for review of the collection of information. The Coast Guard will publish a notice in the **Federal Register** when they have been approved. There were no comments on the information collection requirements proposed in the NPRM, and this final rule does not impose any information collection requirements other than those which were proposed in the NPRM. The section numbers of information collection requirements which are either new or have not yet been approved by OMB are as follows:

a. § 160.151–21((n).
b. § 160.151–21(u).
c. § 160.151–21(y)(4).
d. § 160.151–33.
e. § 160.151–39(c).
f. § 160.151–41(b).
g. § 160.151–45.
h. § 160.151–53.
i. § 160.151–57(m).
j. § 160.151–57(p).
k. § 160.151–57(r).
l. § 160.151–59.
m. § 160.151–61 (was part of § 160.151–59 in the NPRM).

Federalism

The Coast Guard has analyzed this final rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient implications for federalism to warrant the preparation of a Federalism Assessment. The authority to establish standards for the approval of lifesaving equipment to be carried on board vessels has been committed to the Coast Guard by Federal statutes. Further, because liferafts are distributed in a national marketplace, divergent requirements regarding their manufacture would lead to confusion, added expense, and reduced safety. Therefore, the Coast Guard intends to preempt State and local regulations on the same subject that are inconsistent with this rule. There were no comments concerning the federalism implications of this rule as proposed in the NPRM.

Environment

The Coast Guard considered the environmental impact of this final rule and concluded that under section 2.B.2.e(34)(e) of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation. The requirements in this final rule affect the design and servicing of inflatable liferafts. This rule will have a positive impact on safety, and clearly have no impact on the environment. A ''Categorical Exclusion Determination'' is available in the docket for inspection and copying where indicated under **ADDRESSES.** There were no comments concerning the environmental impacts of this rule as proposed in the NPRM.

List of Subjects

46 CFR Part 159

Business and industry, Laboratories, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 160

Marine safety, Reporting and recordkeeping requirements, Incorporation by reference.

46 CFR Part 199

Cargo vessels, Marine safety, Oil and gas exploration, Passenger vessels, Reporting and recordkeeping requirements, Vessels.

For the reasons set out in the preamble, the Coast Guard amends 46 CFR parts 159, 160, and 199 as follows:

PART 159—APPROVAL OF EQUIPMENT AND MATERIALS

1. The authority citation for part 159 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; 49 CFR 1.45, 1.46; Section 159.001–9 also issued under the authority of 44 U.S.C. 3507.

2. In § 159.005–5, add paragraph (a)(4) to read as follows:

§ 159.005–5 Preapproval review: Contents of application.

(a) * * *

(4) If the material submitted under paragraph (a)(2) of this section contains confidential commercial information that could cause substantial competitive harm if released to the public, a statement to the effect that the material is considered privileged and confidential under exemption (b)(4) of the Freedom of Information Act (5 U.S.C. 552), and that it should not be released to anyone other than the original submitter.

* * * * *

3. In § 159.005–7, add paragraph (c) to read as follows:

§ 159.005–7 Preapproval review: Coast Guard action.

* * * * *

(c) An item of equipment or material that does not meet all of the requirements of this subchapter for design or performance may be approved by the Commandant if it has equivalent performance characteristics. The item has equivalent performance characteristics if the application and any approval tests prescribed by the Commandant, in place of or in addition to the approval tests required by this subchapter, demonstrate to the satisfaction of the Commandant that the item is at least as effective as one that meets the requirements of this subchapter.

4. In § 159.005–13, revise the introductory text of paragraph (a) to read as follows:

§ 159.005–13 Equipment or material: Approval.

(a) If from analysis of the material and data required to be submitted under this subpart, the Commandant determines that the equipment or material meets the applicable subpart or has equivalent performance characteristics in accordance with § 159.005–7(c), the Commandant—

* * * * *

5. In § 159.007–9, add paragraph (d) to read as follows:

§ 159.007–9 Production inspections and tests.

* * * * *

(d) The manufacturer shall admit a Coast Guard inspector to any place where approved equipment is manufactured, for the purpose of verifying that the equipment is being manufactured in accordance with the approved plans and the requirements of this subchapter.

PART 160—LIFESAVING EQUIPMENT

6. The authority citation for part 160 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703, and 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

7. In § 160.010–2, remove paragraph designators (a) through (d) and add the definition for *inflatable buoyant apparatus* at the end of the section to read as follows:

§ 160.010–2 Definitions.

* * * * *

Inflatable buoyant apparatus. An inflatable buoyant apparatus is flotation equipment that depends on inflated compartments for buoyancy and is designed to support a specified number of persons completely out of the water.

8. Sections 160.010–3 and 160.010–4 are redesignated, as §§ 160.010–4 and 160.010–5 respectively, and a new § 160.010–3 is added to read as follows:

§ 160.010–3 Inflatable buoyant apparatus.

(a) *Design and performance.* To obtain Coast Guard approval, an inflatable buoyant apparatus must comply with subpart 160.151, with the following exceptions:

(1) *Canopy requirements (SOLAS Chapter III, regulation 38, paragraph 1.5 (III/38.1.5)).* It does not need a canopy.

(2) *Capacity (Regulation III/38.2.1).* The carrying capacity must be not less than four persons.

(3) *Floor insulation (Regulation III/39.2.2).* The floor may be uninsulated.

(4) *Stability (Regulation III/39.5.1).* It does not need stability pockets.

(5) *Righting (Regulation III/39.5.2).* A reversible one does not need arrangements for righting.

(6) One with a capacity of 13 or more persons must be reversible, with the floor arranged between the buoyancy chambers so that the apparatus can, floating either side up, accommodate the number of persons for which it is approved. One with a capacity of 12 or fewer persons must either be reversible in the same manner, or be designed so that it can be readily righted by one person.

(7) One with a capacity of 25 or more persons must be provided with self-bailing floor drains. If the floor of a reversible one includes one or more drains, each drain must be arranged to completely drain the floor of water when the device is fully loaded, and must prevent water from flowing back onto the floor.

(8) If the buoyancy tubes are not vivid reddish orange, vivid yellow, or a fluorescent color of a similar hue, panels of such hue must be secured to the buoyancy chambers so that a minimum of 1 m^2 (11 ft^2) is visible from above the apparatus when it is floating either side up.

(9) *Boarding ramp (Regulation III/39.4.1).* Boarding ramps are not required if the combined cross-section diameter of the buoyancy chambers is 500 millimeters (mm) (19.5 in.) or less. An apparatus with a combined cross-section diameter greater than 500 mm (19.5 in.) requires boarding ramps as follows:

(i) For an apparatus with a capacity of less than 25 persons, at least one ramp must be provided;

(ii) For an apparatus with a capacity of 25 or more persons, at least two ramps must be provided; and

(iii) The boarding ramps required by this paragraph must allow persons to board with either side of a reversible apparatus floating up, or the full number of ramps required must be installed on each side.

(10) *Boarding ladder (Regulation* III/39.4.2). Boarding ladders must be provided on each inflatable buoyant apparatus as follows:

(i) One ladder must be provided on each apparatus with a capacity of less than 25 persons, except that, for an apparatus with a capacity of 13 or more persons that is not equipped with a boarding ramp, two ladders must be provided.

(ii) Two ladders must be provided on each apparatus with a capacity of 25 or more persons.

(iii) The ladders required by this paragraph must allow persons to board with either side of a reversible apparatus floating up, or the full number of ladders required must be installed on each side.

(11) One or more exterior canopy lamps meeting the requirements of § 160.151–15(n) of this subchapter must be provided such that—

(i) On a non-reversible inflatable buoyant apparatus, one lamp is mounted so that it is on the uppermost surface of the floating apparatus; and

(ii) On a reversible apparatus, two lamps are mounted so that one lamp is on the uppermost surface of the apparatus, whichever side is floating up.

(12) *Equipment (Regulation* III/38.5.1). All equipment required by this paragraph must be either packed in a container accessible to the occupants, or otherwise secured to the apparatus. Duplicate equipment must be provided, for each side of a reversible inflatable buoyant apparatus, if the equipment is

not accessible from both sides. In lieu of the equipment specified in § 160.151–7(b) and Regulation III/38.5.1, each apparatus must be provided with—

(i) *Rescue quoit and heaving line.* One rescue quoit and a heaving line as described in § 160.151–21(a) on each apparatus with a capacity of less than 25 persons; or two on each apparatus for a capacity of 25 or more persons. The heaving line(s) must be mounted adjacent to a boarding ramp (or boarding ladder, if no ramps are installed), and ready for immediate use;

(ii) *Knives.* Two buoyant safety knives ready for use near the painter attachment;

(iii) *Bailer.* One bailer as described in § 160.151–21(c) on each apparatus with a capacity of less than 25 persons; or two bailers on each apparatus with a capacity of 25 or more persons, except that no bailers are necessary if both sides of the floor of a reversible apparatus are equipped with drains;

(iv) *Sponge.* One sponge as described in § 160.151–21(d) on each apparatus with a capacity of less than 25 persons, or two sponges on each apparatus with a capacity of 25 or more persons;

(v) *Paddles.* Two paddles as described in § 160.151–21(f) on each apparatus with a capacity of less than 25 persons, or four paddles on each apparatus with a capacity of 25 or more persons;

(vi) *Flashlight.* One flashlight with spare batteries as described in § 160.151–21(m);

(vii) *Signaling mirror.* One signaling mirror as described in § 160.151–21(o);

(viii) *Repair outfit.* One set of sealing clamps or plugs as described in § 160.151–21(y)(1);

(ix) *Pump or bellows.* One pump or bellows as described in § 160.151–21(z); and

(x) *Sea anchor.* One sea anchor as described in § 160.151–21(e), attached so as to be readily deployable when the apparatus inflates.

(13) *Marking and labeling (Regulations III/39.7.3.4, III/39.7.3.5, and III/39.8.6).* Marking and labeling of inflatable buoyant apparatus must be in accordance with the requirements of § 160.151–33, except that the device must be identified as an ''INFLATABLE BUOYANT APPARATUS'', and no ''SOLAS'' markings shall be placed on the container of the apparatus. The capacity marking specified in regulation III/39.8.6 must be applied to the top of each buoyancy tube.

(14) *Drop test.* The drop test required under paragraph 1/5.1 of IMO Resolution A.689(17) and § 160.151–27(a) may be from a lesser height, if that height is the maximum height of stowage marked on the container.

(15) *Loading and seating test.* For the loading and seating test required under paragraph 1/5.7 of IMO Resolution A.689(17) and § 160.151–27(a), the loaded freeboard of the apparatus must be not less than 200 mm (8 in.).

(16) *Cold-inflation test.* The cold-inflation test required under paragraph 1/5.17.3.3.2 of IMO Resolution A.689(17) and § 160.151–27(a) must be conducted at a test temperature of −18°C (0°F).

(b) *Production inspections and tests.* Production inspections and tests for inflatable buoyant apparatus must be performed in accordance with the applicable requirements of § 160.151–31.

(c) *Servicing.* Inflatable buoyant apparatus must be serviced periodically at approved servicing facilities in accordance with the applicable requirements of §§ 160.151–35 through 160.151–57.

(d) *Instruction placard.* An instruction placard meeting the requirements of § 160.151–59(c), giving simple procedures and illustrations for inflating, launching, and boarding the inflatable buoyant apparatus, must be made available to the operator or master of each vessel on which the apparatus is to be carried.

(e) *Requirements for ''open reversible liferafts'' under the IMO International Code of Safety for High-Speed Craft (HSC Code).* To be approved as meeting the requirements for open reversible liferafts in Annex 10 to the HSC Code, an inflatable buoyant apparatus must meet all of the requirements in paragraphs (a) through (d) of this section, with the following exceptions:

(1) The apparatus must be reversible regardless of size.

(2) The surface of the buoyancy tubes must be of a non-slip material. At least 25 percent of the surface of the buoyancy tubes must meet the color requirements of § 160.151–15(e).

(3) The length of the painter should be such that the apparatus inflates automatically upon reaching the water.

(4) An additional bowsing-in line must be fitted to an apparatus with a capacity of more than 30 persons.

(5) The apparatus must be fitted with boarding ramps regardless of size.

(6) An apparatus with a capacity of 30 or fewer persons must be fitted with at least one floor drain.

(7) In addition to the equipment specified in § 160.010–3(a)(12), the apparatus must be provided with—

(i) *Sponge.* One additional sponge as described in § 160.151–21(d) on each apparatus with a capacity of less than 25 persons;

(ii) *First-aid kit.* A first-aid kit approved by the Commandant under approval series 160.054;

(iii) *Whistle.* A ball-type or multi-tone whistle of corrosion-resistant construction;

(iv) *Hand flares.* Two hand flares approved by the Commandant under approval series 160.121.

(8) Marking and labeling of the apparatus must be in accordance with § 160.151–33, except that the device must be identified as a ''NON-SOLAS REVERSIBLE'', and the equipment pack must be identified as an ''HSC Pack''.

9. Subpart 160.051, consisting of §§ 160.051–0 through 160.051–9, is removed, and replaced with a new subpart 160.051 to read as follows:

Subpart 160.051—Inflatable Liferafts for Domestic Service

Sec.
160.051–1 Scope.
160.051–3 Definitions.
160.051–5 Design and performance of Coastal Service inflatable liferafts.
160.051–7 Design and performance of A and B inflatable liferafts.
160.051–9 Equipment required for Coastal Service inflatable liferafts.

Subpart 160.051—Inflatable Liferafts for Domestic Service

§ 160.051–1 Scope.

This subpart prescribes requirements for approval by the Coast Guard of A, B, and Coastal Service inflatable liferafts for use only in domestic service. These liferafts must comply with all of the requirements for SOLAS A and SOLAS B liferafts in subpart 160.151 except as specified in this subpart.

§ 160.051–3 Definitions.

In this subpart, the term:

A or B liferaft means an inflatable liferaft that meets the requirements prescribed in subpart 160.151 for a SOLAS A or SOLAS B liferaft, respectively, except that the capacity is less than 6 persons and the liferaft cannot contain SOLAS markings.

Coastal Service liferaft means a liferaft that does not meet the all of the requirements prescribed in subpart 160.151 for a SOLAS A or SOLAS B liferaft, but that instead meets the requirements of this subpart and is approved for use on certain uninspected vessels under subchapter C of this chapter.

§ 160.051–5 Design and performance of Coastal Service inflatable liferafts.

To obtain Coast Guard approval, each Coastal Service inflatable liferaft must comply with subpart 160.151, with the following exceptions:

(a) *Canopy requirements (Regulation III/38.1.5).* The canopy may—

(1) Be of a type that is furled when the liferaft inflates and that can be set in place by the occupants. A furled canopy must be secured to the buoyancy tubes over 50 percent or more of the liferaft's circumference;

(2) Be of an uninsulated, single-ply design; and

(3) Have an interior of any color.

(b) *Viewing port (Regulation III/38.1.5.5).* The liferaft need not have the viewing port described in Regulation III/38.1.5.5.

(c) *Rainwater collection (Regulation III/38.1.5.6).* The liferaft need not have the means of rainwater collection described in Regulation III/38.1.5.6.

(d) *Capacity (Regulation III/38.2.1).* The carrying capacity must be not less than four persons.

(e) *Floor insulation (Regulation III/39.2.2).* The floor may be uninsulated.

(f) *Boarding ramps (Regulation III/39.4.1).* The liferaft need be provided with boarding ramps only if the combined cross-section diameter of the buoyancy chambers is greater than 500 mm (19.5 in).

(g) *Stability (Regulation III/39.5.1).* Each Coastal Service inflatable liferaft must either meet the stability criteria in § 160.151–17(a) or be fitted with water-containing stability pockets meeting the following requirements:

(1) The total volume of the pockets must be not less than 25 percent of the minimum required volume of the principal buoyancy compartments of the liferaft.

(2) The pockets must be securely attached and evenly distributed around the periphery of the exterior bottom of the liferaft. They may be omitted at the locations of inflation cylinders.

(3) The pockets must be designed to deploy underwater when the liferaft inflates. If weights are used for this purpose, they must be of corrosion-resistant material.

(h) *Lamp (Regulation III/39.6.3).* The liferaft need not have the manually controlled interior lamp described in Regulation III/39.6.3.

(i) *Markings (Regulations III/39.7.3.4 and III/39.7.3.5).* The words ''COASTAL SERVICE'' must appear on the container, and the type of equipment pack must be identified as ''Coastal Service''. No ''SOLAS'' markings may appear on the container.

(j) *Drop test.* The drop test required under paragraph 1/5.1 of IMO Resolution A.689(17) and 160.151–27(a) may be from a lesser height, if that height is the maximum height of stowage marked on the container.

(k) *Loading and seating test.* For the loading and seating test required under paragraph 1/5.7 of IMO Resolution A.689(17) and § 160.151–27(a), the loaded freeboard of the liferaft must be not less than 200 mm (8 in.).

(l) *Cold-inflation test.* The cold-inflation test required under paragraph 1/5.17.3.3.2 of IMO Resolution A.689(17) and § 160.151–27(a) must be conducted at a test temperature of −18°C (0°F).

§ 160.051–7 Design and performance of A and B inflatable liferafts.

To obtain Coast Guard approval, each A and B inflatable liferaft must comply with the requirements in subpart 160.151, with the following exceptions:

(a) *Capacity (Regulation III/38.2.1).* The carrying capacity must be not less than four persons.

(b) *Markings (Regulations III/39.7.3.4 and III/39.7.3.5).* The type of equipment pack must be identified as ''A'' or ''B'', respectively, instead of ''SOLAS A'' or ''SOLAS B''. No ''SOLAS'' markings may appear on the container.

§ 160.051–9 Equipment required for Coastal Service inflatable liferafts.

In lieu of the equipment specified in § 160.151–21, the following equipment must be provided with a Coastal Service inflatable liferaft:

(a) *Rescue quoit and heaving line.* One rescue quoit and a heaving line as described in § 160.151–21(a).

(b) *Knife.* One knife, of a type designed to minimize the chance of damage to the inflatable liferaft and secured with a lanyard.

(c) *Bailer.* One bailer as described in § 160.151–21(c).

(d) *Sponge.* One sponge as described in § 160.151–21(d).

(e) *Sea anchor.* One sea anchor as described in § 160.151–21(e).

(f) *Paddles.* Two paddles of the same size and type as used to pass the maneuverability test in paragraph 1/5.10 of IMO Resolution A.689(17).

(g) *Whistle.* One whistle as described in § 160.151–21(i) of this part.

(h) *Flashlight.* One flashlight with spare batteries as described in § 160.151–21(m).

(i) *Signalling mirror.* One signalling mirror as described in § 160.151–21(o).

(j) *Survival instructions.* Instructions on how to survive as described in § 160.151–21(v).

(k) *Instructions for immediate action.* Instructions for immediate action as described in § 160.151–21(w).

(l) *Repair outfit.* One set of sealing clamps or plugs as described in § 160.151–21(y)(1).

(m) *Pump or bellows.* One pump or bellows as described in § 160.151–21(z).

(n) *Plugs for pressure-relief valves.* Plugs for pressure-relief valves as described in § 160.151–21(aa).

10. Subpart 160.151, consisting of §§ 160.151–1 through 160.151–59, is added to read as follows:

Subpart 160.151—Inflatable Liferafts (SOLAS)

Sec.

160.151–1 Scope.
160.151–3 Definitions.
160.151–5 Incorporation by reference.
160.151–7 Construction of inflatable liferafts.
160.151–9 Independent laboratory.
160.151–11 Approval procedure.
160.151–13 Fabrication of prototype inflatable liferafts for approval.
160.151–15 Design and performance of inflatable liferafts.
160.151–17 Additional requirements for design and performance of SOLAS A and SOLAS B inflatable liferafts.
160.151–21 Equipment required for SOLAS A and SOLAS B inflatable liferafts.
160.151–25 Additional equipment for inflatable liferafts.
160.151–27 Approval inspections and tests for inflatable liferafts.
160.151–29 Additional approval tests for SOLAS A and SOLAS B liferafts.
160.151–31 Production inspections and tests of inflatable liferafts.
160.151–33 Marking and labeling.
160.151–35 Servicing.
160.151–37 Servicing manual.
160.151–39 Training of servicing technicians.
160.151–41 Approval of servicing facilities.
160.151–43 Conditions at servicing facilities.
160.151–45 Equipment required for servicing facilities.
160.151–47 Requirements for owners or operators of servicing facilities.
160.151–49 Approval of servicing facilities at remote sites.
160.151–51 Notice of approval.
160.151–53 Notice to OCMI of servicing.
160.151–55 Withdrawal of approval.
160.151–57 Servicing procedure.
160.151–59 Operating instructions and information for the ship's training manual.
160.151–61 Maintenance instructions.

Subpart 160.151—Inflatable Liferafts (SOLAS)

§ 160.151–1 Scope.

This subpart prescribes standards, tests, and procedures for approval by the Coast Guard of SOLAS A and SOLAS B inflatable liferafts, and for their periodic inspection and repair at approved facilities (''servicing''). Certain provisions of this subpart also apply to inflatable buoyant apparatus as specified in § 160.010–3 and to inflatable liferafts for domestic service as specified in subpart 160.051.

§ 160.151–3 Definitions.

In this subpart, the term:

Commandant means the Commandant (G–MSE), United States Coast Guard, 2100 Second Street, SW., Washington, DC 20593–0001.

Servicing means periodic inspection, necessary repair, and repacking by a servicing facility approved by the Coast Guard. Requirements for periodic inspection and repair of inflatable liferafts approved by the Coast Guard are described in §§ 160.151–35 through 160.151–57.

SOLAS means the International Convention for the Safety of Life at Sea, 1974, as amended by the International Maritime Organization through the 1988 (GMDSS) amendments, dated 9 November 1988.

SOLAS A Liferaft means a liferaft that meets the requirements of this subpart for an inflatable liferaft complying with SOLAS and equipped with a SOLAS A equipment pack.

SOLAS B Liferaft means a liferaft that meets the requirements of this subpart for an inflatable liferaft complying with SOLAS and equipped with a SOLAS B equipment pack.

§ 160.151–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in paragraph (b) of this section, the Coast Guard must publish notice of change in the **Federal Register** and make the material available to the public. All approved material is on file at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC, and at the U.S. Coast Guard, Office of Design and Engineering Standards (G–MSE), 2100 Second Street SW., Washington, DC 20593–0001, and is available from the sources indicated in paragraph (b) of this section.

(b) The material approved for incorporation by reference in this subpart and the sections affected are as follows:

American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103

ASTM F1014—Standard Specification for Flashlights on Vessels, 1986—160.151–21

International Maritime Organization (IMO), Publications Section, 4 Albert Embankment, London SE1 7SR, England

Resolution A.689(17)—Recommendation on Testing of Life-saving Appliances, 27 November 1991, including amendments through Resolution MSC.54(66), adopted 30 May 1996—160.151–21; 160.151–27; 160.151–31; 160.151–57

Resolution A.657(16)—Instructions for Action in Survival Craft, 19 November 1989—160.151–21

Resolution A.658(16)—Use and Fitting of Retro-reflective Materials on Life-saving Appliances, 20 November 1989—160.151–15; 160.151–57.

National Institute of Standards and Technology (formerly National Bureau of Standards), c/o National Technical Information Service, Springfield, VA 22161

NBS Special Publication 440 (Order No. PB265225) Color: Universal Language and Dictionary of Names, 1976—160.151–15

Naval Forms and Publications Center, Customer Service, Code 1052, 5801 Tabor Ave., Philadelphia, PA 19120

MIL–C–17415E—(Ships)—Cloth, Coated, and Webbing, Inflatable Boat and Miscellaneous Use—160.151–15

§ 160.151–7 Construction of inflatable liferafts.

Except as specified in this subpart, each SOLAS A and SOLAS B inflatable liferaft must meet the requirements of Chapter III of SOLAS. To be approved under this subpart, inflatable liferafts must be constructed in accordance with the following provisions of SOLAS:

(a) Chapter III, Regulation 30, paragraph 2 (III/30.2), General requirements for life-saving appliances.

(b) Chapter III, Regulation 38 (III/38) General requirements for liferafts.

(c) Chapter III, Regulation 39 (III/39) Inflatable liferafts.

(d) Chapter III, Regulation 51 (III/51) Training manual.

(e) Chapter III, Regulation 52 (III/52) Instructions for on-board maintenance.

§ 160.151–9 Independent laboratory.

Tests and inspections that this subpart requires to be conducted by an independent laboratory must be conducted by an independent laboratory accepted by the Coast Guard under subpart 159.010 of part 159 of this chapter to perform such tests and inspections. A list of accepted laboratories is available from the Commandant.

§ 160.151–11 Approval procedure.

(a) A manufacturer seeking approval of an inflatable liferaft must comply with the procedures in part 159, subpart 159.005, of this chapter and in this section.

(b) A manufacturer seeking approval of an inflatable liferaft must submit an application meeting the requirements of § 159.005–5 of this chapter for preapproval review. To meet the requirements of § 159.005–5(a)(2) of this chapter, the manufacturer shall submit—

(1) General-arrangement drawing including principal dimensions;

(2) Seating-arrangement plan;

(3) Plans for subassemblies;

(4) Plans for carriage and, in detail, stowage of equipment;

(5) Plans for the inflation system;

(6) Plans for the outer container;

(7) Plans for any lifting shackle or ring, including diameter in cross-section, used for connecting the suspension tackle of a davit-launched inflatable liferaft to the automatic disengaging device used for its hoisting and lowering;

(8) Other drawing(s) necessary to show that the inflatable liferaft complies with the requirements of this subpart;

(9) Description of methods of seam and joint construction;

(10) Samples and identification of each material used in the buoyancy chambers, floor, and canopy, including the identity of their manufacturers, and segments of each type of seam made from such materials; and

(11) Complete data pertinent to the installation and use of the proposed inflatable liferaft, including the maximum proposed height of its installation above the water, and the maximum length of the sea painter installed in the inflatable liferaft.

§ 160.151–13 Fabrication of prototype inflatable liferafts for approval.

If the manufacturer is notified that the information submitted in accordance with § 160.151–11 is satisfactory to the Commandant, fabrication of a prototype inflatable liferaft must proceed in the following sequence:

(a) The manufacturer shall arrange for an independent laboratory to inspect the liferaft during its fabrication and prepare an inspection report meeting the requirements of § 159.005–11 of this chapter. The independent laboratory shall conduct at least one inspection during layup of the buoyancy tubes of the liferaft, at least one inspection of the finished liferaft when fully inflated, and as many other inspections as are necessary to determine that the liferaft—

(1) Is constructed by the methods and with the materials specified in the plans;

(2) Passes the applicable inspections and tests required by § 160.151–31; and

(3) Conforms with the manufacturer's plans.

(b) The manufacturer shall submit the independent laboratory's inspection report to the Commandant for review.

(c) If, after review of the inspection report of the independent laboratory, the Commandant notifies the manufacturer that the liferaft is in compliance with the requirements of this subpart, the manufacturer may proceed with the approval tests required under §§ 160.151–27 and 160.151–29.

(d) The manufacturer shall notify the cognizant OCMI of where the approval tests required under §§ 160.151–27 and 160.151–29 will take place and arrange with the OCMI a testing schedule that allows for a Coast Guard inspector to travel to the site where the testing is to be performed.

(e) The manufacturer shall admit the Coast Guard inspector to any place where work or testing is performed on inflatable liferafts or their component parts and materials for the purpose of—

(1) Assuring that the quality-assurance program of the manufacturer is satisfactory;

(2) Witnessing tests; and

(3) Taking samples of parts or materials for additional inspections or tests.

(f) The manufacturer shall make available to the Coast Guard inspector the affidavits or invoices from the suppliers of all essential materials used in the production of inflatable liferafts, together with records identifying the lot numbers of the liferafts in which such materials were used.

(g) On conclusion of the approval testing, the manufacturer shall comply with the requirements of § 159.005–9(a)(5) of this chapter by submitting the following to the Commandant:

(1) The report of the prototype testing prepared by the manufacturer. The report must include a signed statement by the Coast Guard inspector who witnessed the testing, indicating that the report accurately describes the testing and its results.

(2) The final plans of the liferaft as built. The plans must include—

(i) The servicing manual described in § 160.151–37;

(ii) The instructions for training and maintenance described in §§ 160.151–59 and 160.151–61, respectively;

(iii) The final version of the plans required under § 160.151–11(b), including—

(A) Each correction, change, or addition made during the construction and approval testing of prototypes;

(B) Sufficient detail to determine that each requirement of this subpart is met;

(C) Fabrication details for the inflatable liferaft, including details of the method of making seams and joints; and

(D) Full details of the inflation system.

(h) A description of the quality-control procedures that will apply to the production of the inflatable liferaft. These must include—

(1) The system for checking material certifications received from suppliers;

(2) The method for controlling the inventory of materials;

(3) The method for checking quality of seams and joints; and

(4) The inspection checklists used during various stages of fabrication to assure that the approved liferaft complies with the approved plans and the requirements of this subpart.

§ 160.151–15 Design and performance of inflatable liferafts.

To satisfy the requirements of the regulations of SOLAS indicated in § 160.151–7, each inflatable liferaft must meet the following requirements of this section:

(a) *Workmanship and materials (Regulation III/30.2.1).* Each liferaft must be constructed of the following types of materials meeting MIL–C–17415E, or materials accepted by the Commandant as equivalent or superior—

(1) Type 2, Class B, for the canopy;

(2) Type 8 for seam tape;

(3) Type 11 for the inflatable floor; and

(4) Type 16, Class AA, for all other inflatable compartments and structural components.

(b) *Seams (Regulation III/30.2.1).* Each seam must be at least as strong as the weakest of the materials joined by the seam. Each seam must be covered with tape where necessary to prevent lifting of and damage to fabric edges.

(c) *Protection from cold inflation-gas (Regulation III/30.2.1).* Each inflatable compartment must be provided with a protective liner or baffling arrangement at the inflation-gas inlet, or other equally effective means to prevent damage from exposure to cold inflation-gas.

(d) *Compatibility of dissimilar materials (Regulation III/30.2.4).* Where dissimilar materials are combined in the construction of a liferaft, provisions must be made to prevent loosening or tightening due to differences in thermal expansion, freezing, buckling, galvanic corrosion, or other incompatibilities.

(e) *Color (Regulation III/30.2.6).* The primary color of the exterior of the canopy must be vivid reddish orange (color number 34 of NBS Special Publication 440), or a fluorescent color of a similar hue.

(f) *Retroreflective material (Regulation III/30.2.7).* Each inflatable liferaft must be marked with Type I retroreflective material approved under part 164, subpart 164.018, of this chapter as complying with SOLAS. The arrangement of the retroreflective material must comply with IMO Resolution A.658(16).

(g) *Towing attachments (Regulation III/38.1.4.)* Each towing attachment must be reinforced strongly enough to withstand the towing strain, and marked to indicate its function.

(h) *Weight (Regulation III/38.2.2).* The weight of the liferaft including its container and equipment may not exceed 185 kg (407.8 lb), unless the liferaft is intended for launching into the water directly from its stowed position using an inclined or hand-tilted rack, or is served by a launching appliance approved by the Commandant under approval series 160.163.

(i) *Lifelines (Regulation III/38.3.1).* Each lifeline must be made of nylon tubular webbing with a minimum diameter of 14 mm (9/16-inch), rope with a minimum diameter of 10 mm (3/8-inch), or equivalent. Each lifeline-attachment patch must have a minimum breaking strength of 1.5 kN (350 lb) pull exerted perpendicular to the base of the patch. Each bight of an exterior lifeline must be long enough to allow the lifeline to reach to the waterline of the liferaft when it is afloat.

(j) *Painter length (Regulation III/38.3.2).* On or before July 1, 1998, the length of the liferaft painter shall be not less than 10 meters (33 feet) plus the liferaft's maximum stowage height, or 15 meters (49 feet), whichever is greater.

(k) *Painter system (Regulation III/38.6.1).* The painter protruding from the liferaft container must be inherently resistant, or treated to be resistant, to deterioration from sunlight and salt spray, and resistant to absorption and wicking of water.

(l) *Inflation cylinders (Regulation III/39.2.3).* Each compressed-gas inflation cylinder within the liferaft must meet the requirements of § 147.60 of this chapter, and be installed so that—

(1) Slings and reinforcements of sufficient strength retain the inflation cylinders in place when the liferaft is dropped into the water from its stowage height and during inflation; and

(2) The painter and the inflation cylinders of the liferaft are linked to start inflation when the painter is pulled by one person exerting a force not exceeding 150 N (34 lb).

(m) *Boarding ladders (Regulation III/39.4.2).* The steps of each boarding ladder must provide a suitable foothold.

(n) *Canopy lamps (Regulation III/39.6.2).* The exterior liferaft canopy lamp must be approved by the Commandant under approval series 161.101.

(o) *Containers (Regulation III/39.7.1).* Each container for packing liferafts—

(1) Must include a telltale made with a seal-and-wire, or equivalent, method for indicating whether the liferaft has been tampered with or used since packing;

(2) Must be designed so that the liferaft breaks free of the container when inflation is initiated, without the need to manually open or remove any closing arrangement;

(3) Must have an interior surface smooth and free from splinters, barbs, or rough projections;

(4) Must be of rigid construction where the liferaft is intended for float-free launching or for exposed stowage on deck;

(5) If rigid, must be designed to facilitate securing the inflatable liferaft to a vessel to permit quick release for manual launching;

(6) If constructed of fibrous-glass-reinforced plastic, must be provided with a means to prevent abrasion of the liferaft fabric, such as by using a gel-coated interior finish of the container, enclosing the liferaft in an envelope of plastic film, or equivalent means; and

(7) Except as provided in paragraph (o)(4) of this section, may be of fabric construction. Each container of fabric construction must be made of coated cloth, include carrying handles and drain holes, and be adaptable to stowage and expeditious removal from lockers and deck-mounted enclosures adjacent to liferaft-launching stations. The weight of a liferaft in a fabric container including its container and equipment may not exceed 100 kg (220 lb).

§ 160.151–17 Additional requirements for design and performance of SOLAS A and SOLAS B inflatable liferafts.

To satisfy the requirements of the indicated regulations of SOLAS, each SOLAS A and SOLAS B inflatable liferaft must be manufactured in accordance with §§ 160.151–7 and 160.151–15, and must comply with the following additional requirements:

(a) *Stability (Regulation III/39.5.1).* (1) Each liferaft with a capacity of more than 8 persons must have a waterplane of circular or elliptical shape. A hexagonal, octagonal, or similar outline approximating a circular or elliptical shape is acceptable.

(2) Each liferaft manufactured under this subpart must have water-containing stability appendages on its underside to resist capsizing from wind and waves. On or before July 1, 1998, these appendages must meet the following requirements:

(i) The total volume of the appendages must not be less than 220 liters (7.77 ft^3) for liferafts approved to accommodate up to 10 persons. The volume of an appendage is calculated using the bottom of the lowest opening in an appendage as the height of the appendage, and by deducting the volume of any objects inside the appendage. No opening designed to close as water is forced out of an appendage is an opening for the purpose of this calculation.

(ii) The total volume of the appendages for liferafts approved to accommodate more than 10 persons must be not less than $20 \times N$ liters ($0.706 \times N$ ft^3), where N = the number of persons for which the liferaft is approved.

(iii) The appendages must be securely attached and evenly distributed around the periphery of the exterior bottom of the liferaft. They may be omitted at the locations of inflation cylinders.

(iv) The appendages must consist of at least two separate parts so that damage to one part will permit at least half of the required total volume to remain intact.

(v) Openings in or between the appendages must be provided to limit the formation of air pockets under the inflatable liferaft.

(vi) The appendages must be designed to deploy underwater when the liferaft inflates, and to fill to at least 60 percent of their capacity within 25 seconds of deployment. If weights are used for this purpose, they must be of corrosion-resistant material.

(vii) The primary color of the appendages must be vivid reddish orange (color number 34 of NBS Special Publication 440), or a fluorescent color of a similar hue.

(b) *Boarding ramp (Regulation III/39.4.1).* The boarding ramp must have sufficient size and buoyancy to support one person weighing 100 kg (220 lb), sitting or kneeling and not holding onto any other part of the liferaft.

(c) *Marking (Regulation III/39.8).* On or before July 1, 1998, means must be provided for identifying the liferaft with the name and port of registry of the ship to which it is to be fitted, so that the identification can be changed without opening the liferaft container.

§ 160.151–21 Equipment required for SOLAS A and SOLAS B inflatable liferafts.

To obtain Coast Guard approval, the equipment in each SOLAS A and SOLAS B inflatable liferaft must meet the following specific requirements when complying with the indicated regulations of SOLAS:

(a) *Heaving line (Regulation III/38.5.1.1).* The buoyant heaving line described by Regulation III/38.5.1.1 must have a breaking strength of not less than 1.1 kN (250 lb), and must be attached to the inflatable liferaft near the entrance furthest from the painter attachment.

(b) *Jackknife (Regulation III/38.5.1.2).* Each folding knife carried as permitted by Regulation III/38.5.1.2 must be a jackknife approved by the Commandant under approval series 160.043.

(c) *Bailer (Regulation III/38.5.1.3).* Each bailer described by Regulation III/38.5.1.3 must have a volume of at least 2 L (125 in^3).

(d) *Sponge (Regulation III/38.5.1.4).* Each sponge described by Regulation III/38.5.1.4 must have a volume of at least 750 cm^3 (48 in^3) when saturated with water.

(e) *Sea anchors (Regulation III/38.5.1.5).* Sea anchors without the swivels described by Regulation III/38.5.1.5 may be used if, during the towing test, a sea anchor of their design does not rotate when streamed. The sea anchors need not have the tripping lines described by Regulation III/38.5.1.5 if, during the towing test, a sea anchor of their design can be hauled in by one person.

(f) *Paddles (Regulation III/38.5.1.6).*The paddles must be at least 1.2 m (4 ft) long and must be of the same size and type as used to pass the maneuverability test in paragraph 1/5.10 of IMO Resolution A.689(17).

(g) *Tin-opener (Regulation III/38.5.1.7).* Each sharp part of a tin-opener described by Regulation III/38.5.1.7 must have a guard.

(h) *First-aid kit (Regulation III/38.5.1.8).* Each first-aid kit described by Regulation III/38.5.1.8 must be approved by the Commandant under approval series 160.054.

(i) *Whistle (Regulation III/38.5.1.9).* The whistle described by Regulation III/38.5.1.9 must be a ball-type or multi-tone whistle of corrosion-resistant construction.

(j) *Rocket parachute flare (Regulation III/38.5.1.10).* Each rocket parachute flare described by Regulation III/38.5.1.10 must be approved by the Commandant under approval series 160.136.

(k) *Hand flare (Regulation III/38.5.1.11).* Each hand flare described by Regulation III/38.5.1.11 must be approved by the Commandant under approval series 160.121.

(l) *Buoyant smoke signal (Regulation III/38.5.1.12).* Each buoyant smoke signal described by Regulation III/38.5.1.12 must be of the floating type approved by the Commandant under approval series 160.122.

(m) *Electric torch (Regulation III/38.5.1.13).* The waterproof electric torch

described by Regulation III/38.5.1.13 must be a Type I or Type III flashlight constructed and marked in accordance with ASTM F1014. Three-cell-size flashlights bearing Coast Guard approval numbers in the 161.008 series may continue to be used as long as they are serviceable.

(n) *Radar reflector (Regulation III/38.5.1.14).* The radar reflector may be omitted if the outside of the container of the inflatable liferaft includes a notice near the ''SOLAS A'' or ''SOLAS B'' marking indicating that no radar reflector is included.

(o) *Signalling mirror (Regulation III/38.5.1.15).* Each signalling mirror described by Regulation III/38.5.1.15 must be approved by the Commandant under approval series 160.020.

(p) *Lifesaving signals (Regulation III/38.5.1.16).* If not provided on a waterproof card or sealed in a transparent waterproof container as described in Regulation III/38.5.1.16, the table of lifesaving signals may be provided as part of the instruction manual.

(q) *Fishing tackle (Regulation III/38.5.1.17).* The fishing tackle must be in a kit approved by the Commandant under approval series 160.061.

(r) *Food rations (Regulation III/38.5.1.18.)* The food rations must be approved by the Commandant under approval series 160.046.

(s) *Drinking water (Regulation III/38.5.1.19).* The fresh water required by Regulation III/38.5.1.19 must be ''emergency drinking water'' approved by the Commandant under approval series 160.026. The desalting apparatus described in Regulation III/38.5.1.19 must be approved by the Commandant under approval series 160.058. After July 1, 1998, 1.0 liter/person of the required water may be replaced by an approved manually powered reverse osmosis desalinator capable of producing an equal amount of water in two days.

(t) *Drinking cup (Regulation III/38.5.1.20).* The drinking cup described in Regulation III/38.5.1.20 must be graduated in ounces or milliliters or both.

(u) *Anti-seasickness medicine (Regulation III/38.5.1.21).* The anti-seasickness medicine required by Regulation III/38.5.1.21 must include instructions for use and be marked with an expiration date.

(v) *Survival instructions (Regulation III/38.5.1.22).* The instructions required by Regulation III/38.5.1.22 on how to survive in a liferaft must—

(1) Be waterproof;

(2) Whatever other language or languages they may be in, be in English;

(3) Meet the guidelines in IMO Resolution A.657(16); and

(4) Be suspended in a clear film envelope from one of the arch tubes of the canopy.

(w) *Instructions for immediate action (Regulation III/38.5.1.23).* The instructions for immediate action must—

(1) Be waterproof;

(2) Whatever other language or languages they may be in, be in English;

(3) Meet the guidelines in IMO Resolution A.657(16);

(4) Explain both the noise accompanying the operation of any provided pressure-relief valves, and the need to render them inoperable after they complete venting; and

(5) Be suspended from the inside canopy, so they are immediately visible by survivors on entering the inflatable liferaft. They may be contained in the same envelope with the instructions on how to survive if the instructions for immediate action are visible through both faces of the envelope.

(x) *Thermal protective aid (Regulation III/38.5.1.24).*

Each thermal protective aid described by Regulation III/38.5.1.24 must be approved by the Commandant under approval series 160.174.

(y) *Repair outfit (Regulation III/39.10.1.1).* The repair outfit required by Regulation III/39.10.1.1 must include—

(1) Six or more sealing clamps or serrated conical plugs, or a combination of the two;

(2) Five or more tube patches at least 50 mm (2 in) in diameter;

(3) A roughing tool, if necessary to apply the patches; and

(4) If the patches are not self-adhesive, a container of cement compatible with the liferaft fabric and the patches, marked with instructions for use and an expiration date.

(z) *Pump or bellows (Regulation III/39.10.1.2).* The pump or bellows required by Regulation III/39.10.1.2 must be manually operable and arranged to be capable of inflating any part of the inflatable structure of the liferaft.

(aa) *Plugs for pressure-relief valves.* Plugs for rendering pressure-relief valves inoperable must be provided in any liferaft fitted with such valves, unless the valves are of a type that can be rendered inoperable without separate plugs. If provided, plugs for pressure-relief valves must be usable with hands gloved in an immersion suit, and must either float or be secured to the liferaft by a lanyard.

§ 160.151–25 Additional equipment for inflatable liferafts.

The manufacturer may specify additional equipment to be carried in inflatable liferafts if the equipment is identified in the manufacturer's approved drawings and if the packing and inspection of the equipment is covered in the servicing manual. Any such additional equipment for which performance or approval standards are prescribed in this part or in 47 CFR part 80 must comply with those standards.

§ 160.151–27 Approval inspections and tests for inflatable liferafts.

(a) Except as provided in paragraph (b) of this section, to satisfy the testing requirements of: IMO Resolution A.689(17), part 1, paragraphs 5.1 through 5.15 inclusive; paragraph 5.16 for a davit-launched inflatable liferaft; and paragraph 5.17, a prototype inflatable liferaft of each design submitted for Coast Guard approval must meet the additional specific requirements and tests specified in paragraphs (c) and (d) of this section.

(b) The Commandant may waive certain tests for a liferaft identical in construction to a liferaft that has successfully completed the tests, if the liferafts differ only in size and are of essentially the same design.

(c) Tests must be conducted in accordance with the indicated paragraphs of IMO Resolution A.689(17), except:

(1) *Jump test (Paragraph 1/5.2).* One-half of the jumps must be with the canopy erect, and the remainder with the canopy furled or deflated. If a ''suitable and equivalent mass'' is used, it must be equipped with the shoes described in paragraph 1/5.2.1 of Resolution A.689(17), and arranged so the shoes strike the liferaft first.

(2) *Mooring-out test (Paragraph* 1/5.5). Initial inflation may be with compressed air.

(3) *Loading and seating test (Paragraph 1/5.7).* For a liferaft not intended for use with a launching or embarkation appliance, the persons used to determine seating capacity shall wear insulated buoyant immersion suits rather than lifejackets.

(4) *Boarding test (Paragraph 1/5.8).* This test must be performed using each boarding ramp or boarding ladder which is installed on the liferaft.

(5) *Canopy-closure test (Paragraph* 1/5.12). This test is required only for SOLAS A and SOLAS B inflatable liferafts. For a davit-launched liferaft, any opening near the lifting eye should be sealed during the test to prevent the ingress of water. The water accumulated

within the liferaft at the end of the test must not exceed 4 liters (1 gallon).

(6) *Detailed inspection (Paragraph 1/5.14).* The independent laboratory's inspection of the prototype liferaft under § 160.151–13(a) satisfies the requirements of paragraph 1/5.14.

(7) *Davit-launched liferafts—strength test (Paragraph 1/5.16.1).* The calculation of combined strength of the lifting components must be based on the lesser of—

(i) The lowest breaking strength obtained for each item; or

(ii) The component manufacturer's ultimate strength rating.

(d) The boarding ramp on each liferaft equipped with one must be demonstrated capable of supporting one person weighing 100 kg (220 lb), sitting or kneeling and not holding onto any other part of the liferaft.

§ 160.151–29 Additional approval tests for SOLAS A and SOLAS B inflatable liferafts.

To verify compliance with the requirements of Regulation III/39.5.1, on or before July 1, 1998, the following test must be conducted for SOLAS A and SOLAS B inflatable liferafts in addition to those required by § 160.151–27 and IMO Resolution A.689(17):

(a) *Test of filling time for stability appendages.* A representative sample of each type and size of stability appendage to be fitted to a liferaft must be tested as follows:

(1) The appendage must be attached to a testing jig similar in material and construction to the appendage's intended location on a liferaft. The method of attachment must be the same as used on a liferaft. The appendage and jig must be attached to a scale capable of recording peak readings, and suspended over a pool of calm water. The dry weight must be recorded.

(2) The appendage and jig must then be quickly lowered into the water until the appendage is completely submerged. When the appendage has been in the water for 25 seconds, it must be smoothly lifted completely out of the water, and the peak weight after the appendage is removed from the water recorded.

(3) The difference in weights measured according to paragraphs (a)(1) and (2) of this section must be at least 60 percent of the appendage's volume, calculated in accordance with § 160.151–17(a)(2)(i).

(b) [Reserved]

§ 160.151–31 Production inspections and tests of inflatable liferafts.

(a) Production inspections and tests of inflatable liferafts must be carried out in accordance with the procedures for independent laboratory inspection in part 159, subpart 159.007, of this chapter and with those of this section.

(b) Each liferaft approved by the Coast Guard must be identified with unique lot and serial numbers as follows:

(1) Each lot must consist of not more than 50 liferafts of the same design and carrying capacity.

(2) A new lot must begin whenever the liferafts undergo changes of design, material, production method, or source of supply for any essential component.

(3) The manufacturer may use a running-lot system, whereby the fabrication of the individual liferafts of a lot occurs over an extended interval under an irregular schedule. Each running lot must comprise not more than 10 liferafts of the same design and carrying capacity. Each running-lot system must be in accordance with a procedure proposed by the manufacturer and approved by the Commandant.

(4) Unless a lot is a running lot, each lot must consist of liferafts produced under a process of continuous production.

(c) Among the records required to be retained by the manufacturer under § 159.007–13 of this chapter, are affidavits or invoices from the suppliers identifying all essential materials used in the production of approved liferafts, together with the lot numbers of the liferafts constructed with those materials.

(d) Each approved liferaft must pass each of the inspections and tests described in IMO Resolution A.689(17), part 2, paragraphs 5.1.3 through 5.1.6 inclusive, and prescribed by paragraphs (e) through (g) of this section. For a davit-launched liferaft, these tests must be preceded by the test described in IMO Resolution A.689(17), part 2, paragraph 5.2.

(e) The test described in IMO Resolution A.689(17), Paragraph 2/5.1.5, must be conducted under the following conditions:

(1) The test must last 1 hour, with a maximum allowable pressure drop of 5 percent after compensation for changes in ambient temperature and barometric pressure.

(2) For each degree Celsius of rise in temperature, 0.385 kPa must be subtracted from the final pressure reading (0.031 psig per degree Fahrenheit). For each degree Celsius of drop in temperature, 0.385 kPa must be added to the final pressure reading (again, 0.031 psig per degree Fahrenheit).

(3) For each mm of mercury of rise in barometric pressure, 0.133 kPa must be added to the final temperature-corrected pressure reading (0.049 psig per 0.1 inch of mercury). For each mm of mercury of drop in barometric pressure, 0.133 kPa must be subtracted from the final temperature-corrected pressure reading (again, 0.049 psig per 0.1 inch of mercury). Corrections for changes in ambient barometric pressure are necessary only if a measuring instrument open to the atmosphere, such as a manometer, is used.

(f) One liferaft from each lot of fewer than 30 liferafts, and two from each lot of 30 to 50 liferafts, must pass the test described in IMO Resolution A.689(17), part 2, paragraphs 5.1.1 and 5.1.2. If any liferaft fails this test—

(1) The reason for the failure must be determined;

(2) Each liferaft in the lot must be examined for the defect and repaired if reparable, or scrapped if irreparable; and

(3) The lot test must be repeated, including random selection of the liferaft or liferafts to be tested. If any liferafts from the lot have left the place of manufacture, they must be recalled for examination, repair, and testing as necessary; or else the required actions must take place at an approved servicing facility.

(g) On or before May 11, 1998, the manufacturer shall arrange for inspections by an accepted independent laboratory at least once in each calendar quarter in which production of liferafts approved by the Coast Guard takes place. The time and date of each inspection must be selected by the independent laboratory, to occur when completed liferafts are in the manufacturing facility and others are under construction. The manufacturer shall ensure that the inspector from the independent laboratory—

(1) Conducts the inspection and witnesses the tests required by paragraph (f) of this section, and further conducts a visual inspection to verify that the liferafts are being made in accordance with the approved plans and the requirements of this subpart;

(2) Examines the records of production inspections and tests for liferafts produced since the last inspection by an independent laboratory to verify that each required inspection and test has been carried out satisfactorily;

(3) Conducts a design audit on at least one liferaft approved by the Coast Guard each year. If possible, different models of liferafts must be examined in the design audit from year to year. To retain Coast Guard approval, the manufacturer shall demonstrate to the inspector during each design audit that—

(i) Each part used in the liferaft matches the part called for by the approved plans;

(ii) Each part and subassembly are of the materials and components indicated on the approved plans or their bills of materials; and

(iii) Each critical dimension is correct as shown either by measurement or by proper fit and function in the next-higher assembly.

(h) Until such time as the manufacturer has arranged for inspections by an accepted independent laboratory in accordance with paragraph (g) of this section, the manufacturer shall notify the cognizant OCMI whenever final production inspections and tests are to be performed so that the OCMI may, at his option, assign a marine inspector to the factory to witness the applicable tests and satisfy himself that the quality assurance program of the manufacturer is satisfactory.

§ 160.151–33 Marking and labeling.

(a) Whatever other languages they may be in, markings required on each inflatable liferaft and its container must be in English.

(b) The markings required on the liferaft container under Regulation III/39.7.3 of SOLAS must be on a plate or label sufficiently durable to withstand continuous exposure to environmental conditions at sea for the life of the liferaft. In addition, the container must be marked with the—

(1) Manufacturer's model identification; and

(2) U.S. Coast Guard approval number.

(c) In addition to the markings required on the inflatable liferaft under Regulation III/39.8 of SOLAS, the liferaft must be marked with the—

(1) Manufacturer's model identification;

(2) Lot number; and

(3) U.S. Coast Guard approval number.

§ 160.151–35 Servicing.

(a) *Inspection and repair.* Inflatable liferafts carried under the regulations in this chapter, and in chapter I of title 33 CFR, must be inspected periodically by a servicing facility approved by the Coast Guard, repaired as necessary, and repacked. Requirements for periodic inspection and repair of liferafts approved by the Coast Guard appear in §§ 160.151–37 through 160.151–57.

(b) *Manufacturer's requirements.* To retain Coast Guard approval of liferafts, the manufacturer must:

(1) Prepare a servicing manual or manuals complying with § 160.151–37 to cover each model and size of liferaft that the manufacturer produces. The manual or manuals must be submitted to the Commandant for approval.

(2) At least once each year, issue a list of revisions to the manual or manuals, and issue a list of bulletins affecting the manual or manuals, that are in effect.

(3) Make available to each servicing facility approved by the Coast Guard the manual or manuals, the revisions, the bulletins, the plans, and any unique parts and tools that may be necessary to service the liferaft. The plans may be either the manufacturing drawings, or special plans prepared especially for use by servicing technicians. They may be incorporated into the manual or manuals.

(4) Have a training program complying with § 160.151–39 for the certification of servicing technicians.

(5) Notify the OCMI for the zone in which the servicing facility is located whenever the manufacturer becomes aware of servicing at approved facilities that is not in accordance with the requirements of this subpart, or aware of falsification by an approved facility of records required by this subpart.

(c) A manufacturer of liferafts not approved by the Coast Guard may establish servicing facilities approved by the Coast Guard for such liferafts in the United States if the manufacturer meets the requirements of paragraph (b) of this section.

§ 160.151–37 Servicing manual.

(a) The servicing manual must provide instructions on performing the following tasks:

(1) Removing the inflatable liferaft from the container for testing without damaging the liferaft or its contents.

(2) Examining the liferaft and its container for damage and wear including deteriorated structural joints and seams.

(3) Determining the need for repairs.

(4) Performing each repair which can be made by a servicing facility.

(5) Identifying repairs that the manufacturer must perform.

(6) Determining when liferaft equipment must be replaced.

(7) Conducting tests required by § 160.151–57.

(8) Repacking the liferaft.

(9) Changing the maximum height of stowage of the liferaft by changing the length of the painter.

(10) Special equipment limitations or packing instructions, if any, necessary to qualify the liferaft for a particular height of stowage.

(11) Changing the service of the liferaft by changing the contents of the equipment pack.

(12) Proper marking of the liferaft container, including approval number, persons' capacity, maximum height of stowage, service (equipment pack), and expiration date of servicing.

(13) A list of parts for—

(i) Survival equipment;

(ii) Compressed-gas cylinders;

(iii) Inflation valves;

(iv) Relief valves; and

(v) Repair equipment.

(14) The necessary pressures for each size of approved liferaft for conducting the ''Necessary Additional Pressure'' test required by § 160.151–57(k).

(b) Each revision to a servicing manual, and each bulletin, that authorizes the modification of a liferaft, or that affects the compliance of a liferaft with any requirement under this subpart, must be submitted to and approved by the Commandant. Other revisions and bulletins need not be approved, but a copy of each must be submitted to the Commandant when issued.

(c) Each manual provided under this section must bear the original signature of a representative of the manufacturer attesting that it is a true copy of the manual approved by the Commandant.

§ 160.151–39 Training of servicing technicians.

(a) The training program for certification of servicing technicians must include—

(1) Training and practice in packing an inflatable liferaft, repairing buoyancy tubes, repairing inflation-system valves, and other inspections and operations described in the approved servicing manual;

(2) An evaluation at the end of the training to determine whether each trainee has successfully completed the training; and

(3) Issuance of a certificate of competence to each technician who successfully completes the training.

(b) The manufacturer shall maintain refresher training for recertification of previously trained servicing technicians. This training must include—

(1) Checking the performance of the technicians in the inspections and operations described in the manual;

(2) Retraining of the technicians in inspections and operations for which they are deficient;

(3) Training and practice in new inspections and operations;

(4) An evaluation at the end of the training to determine whether or not each trainee has successfully completed the training; and

(5) Issuance of a certificate of competence to each technician who successfully completes the training.

(c) Each time the manufacturer holds a course for servicing technicians who will perform servicing on liferafts approved by the Coast Guard, the manufacturer shall notify the cognizant OCMI sufficiently in advance to allow, at the option of the OCMI, for a Coast Guard inspector or inspectors to travel to the site where the training is to occur.

§ 160.151–41 Approval of servicing facilities.

(a) To obtain and maintain Coast Guard approval as an ''approved servicing facility'' for a particular manufacturer's inflatable liferafts, a facility must meet the requirements, and follow the procedures, of this section.

(b) The owner or operator of a servicing facility desiring Coast Guard approval shall apply to the cognizant OCMI. The application must include—

(1) The name and address of the facility;

(2) The name(s) of its competent servicing technician(s);

(3) Identification of the manufacturer(s) of the liferafts the facility will service; and

(4) Any limits or special conditions that should apply to the approval of the facility.

(c) The owner or operator of the servicing facility shall arrange for an inspection with the OCMI to whom the owner or operator applied under paragraph (b) of this section. A currently trained servicing technician shall successfully demonstrate the complete service to each make and type of liferaft for which approval as a servicing facility is sought, in the presence of a Coast Guard inspector or of a third-party inspector accepted by the OCMI, or such technician shall present evidence of having performed such service at the time of initial or refresher training. The service must include:

(1) Removing the liferaft from the container for testing without damaging the liferaft or its contents;

(2) Examining the liferaft and its container for damage and wear;

(3) Determining the need for repairs;

(4) Determining whether equipment must be replaced;

(5) Conducting the tests required by § 160.151–57;

(6) Repacking the liferaft;

(7) Inflating the fully packed liferaft using its inflation mechanism; and

(8) Repairing a leak in a main buoyancy chamber, and subjecting the repaired chamber to the Necessary Additional Pressure test described in § 160.151–57(k). This repair may be done on a liferaft that actually needs it, on one condemned, or on an inflatable chamber fabricated of liferaft material specifically for this purpose. (An otherwise serviceable liferaft should not be damaged for this purpose.)

(d) Whenever servicing of liferafts takes place, each servicing facility must allow Coast Guard inspectors or third-party inspectors accepted by the OCMI access to the place where the servicing occurs.

(e) Each servicing facility must employ at least one servicing technician who has successfully completed the manufacturer's training described in § 160.151–39 (a) or (b), including training in the servicing of davit-launched liferafts if the facility will service these. The training must have been completed within the preceding—

(1) 12 months for the facility to obtain its approval to service the liferafts of a particular manufacturer; or

(2) 36 months for the facility to retain approval to service the liferafts of a particular manufacturer.

§ 160.151–43 Conditions at servicing facilities.

(a) Each facility must maintain a room to service inflatable liferafts that—

(1) Is clean;

(2) Is fully enclosed;

(3) Has enough space to service the number of liferafts likely to be present for service at one time;

(4) Has a ceiling high enough to hold and allow overturning of a fully inflated liferaft of the largest size to be serviced, or is furnished with an equally efficient means to facilitate the inspection of bottom seams;

(5) Has a smooth floor that will not damage a liferaft, can be easily cleaned, and is kept clean and free from oil, grease, and abrasive material;

(6) Is well lit but free from direct sunlight;

(7) Is arranged to maintain an even temperature and low humidity in each area where liferafts are pressure tested, including by mechanical air-conditioning equipment in climates where it is necessary;

(8) Is arranged so that stored liferafts are not subjected to excessive loads and, if stacked one directly on top of another, does not have them stacked more than two liferafts high;

(9) Is efficiently ventilated but free of drafts; and

(10) Is a designated no-smoking area.

(b) In addition to the room required by paragraph (a) of this section, each facility must maintain areas or rooms for storage of liferafts awaiting servicing, repair, or delivery; for repair and painting of reinforced plastic containers; for storage of pyrotechnics and other materials, such as spare parts and required equipment; and for administrative purposes.

§ 160.151–45 Equipment required for servicing facilities.

Each servicing facility approved by the Coast Guard must maintain equipment to carry out the operations described in the manufacturer's servicing manual approved in accordance with § 160.151–35(b)(1), including—

(a) A set of plans, as specified in § 160.151–35(b)(3), for each inflatable liferaft to be serviced;

(b) A current copy of this subpart;

(c) A current copy of the manual approved in accordance with § 160.151–35(b)(1), including all revisions and bulletins in effect as indicated on the annual list issued in accordance with § 160.151–35(b)(2);

(d) Hot presses (if applicable);

(e) Safety-type glue pots or equivalents;

(f) Abrasive devices;

(g) A source of clean, dry, pressurized air; hoses; and attachments for inflating liferafts;

(h) A source of vacuum; hoses; and attachments for deflating liferafts;

(i) Mercury manometer, water manometer, or other pressure-measurement device or pressure gauge of equivalent accuracy and sensitivity;

(j) Thermometer;

(k) Barometer, aneroid or mercury;

(l) Calibrated torque-wrench for assembling the inflation system;

(m) Accurate weighing scale;

(n) Repair materials and equipment, and spare parts as specified in the applicable manual, except that items of limited ''shelf life'' need not be stocked if they are readily available;

(o) A complete stock of the survival equipment required to be stowed in the liferafts, except for items of equipment that are readily available;

(p) A means for load-testing davit-launched liferafts, unless the facility services only non-davit-launched liferafts;

(q) A supply of parts for all inflation components and valves specified in the applicable manual; and

(r) A tool board that clearly indicates where each small tool is stored, or has an equivalent means to make sure that no tools are left in the liferaft when repacked.

§ 160.151–47 Requirements for owners or operators of servicing facilities.

To maintain Coast Guard approval, the owner or operator of each servicing facility approved by the Coast Guard must—

(a) Ensure that servicing technicians have received sufficient information and training to follow instructions for changes and for new techniques related

to the inflatable liferafts serviced by the facility, and have available at least one copy of each manufacturer's approved servicing manual, revision, and bulletin;

(b) Calibrate each pressure gauge, mechanically-operated barometer, and weighing scale at intervals of not more than 1 year, or in accordance with the equipment manufacturer's requirements;

(c) Ensure that each liferaft serviced under the facility's Coast Guard approval is serviced by or under the direct supervision of a servicing technician who has completed the requirements of either § 160.151–39(a) or (b);

(d) Ensure that each liferaft serviced under the facility's Coast Guard approval is serviced in accordance with the approved manual;

(e) Specify which makes of liferafts the facility is approved to service when representing that the facility is approved by the Coast Guard; and

(f) Ensure that the facility does not service any make of liferaft for an inspected vessel of the U.S. or any other U.S.-flag vessel required to carry approved liferafts, unless the facility is approved by the Coast Guard to service that make of liferafts.

§ 160.151–49 Approval of servicing facilities at remote sites.

A servicing facility may be approved for servicing liferafts at a remote site, provided that appropriate arrangements have been made to ensure that each such site meets the requirements of §§ 160.151–41(e), 160.151–43, and 160.151–45. The facility must have a portable assortment of test equipment, spare parts, and replacement survival equipment to accompany the technician doing the servicing. However, if repair of liferafts will not be attempted at a remote site, equipment needed for repair does not need to be available at that site. A facility must be specifically authorized in its letter of approval to conduct servicing at a remote site.

§ 160.151–51 Notice of approval.

If the cognizant OCMI determines that the servicing facility meets the applicable requirements of §§ 160.151–39 through 160.151–47, the OCMI notifies the facility that it is approved and notifies the Commandant. The Commandant issues an approval letter to the servicing facility with copies to the OCMI and to the manufacturer(s) whose liferafts the facility is approved to service. The letter will specify any limits on the approval, and will assign the facility's approval code for use on the inspection sticker required by § 160.151–57(m)(3). The Commandant will maintain a current list of approved facilities.

§ 160.151–53 Notice to OCMI of servicing.

(a) Before servicing an inflatable liferaft under the servicing facility's Coast Guard approval, the owner or operator of the facility must tell the cognizant OCMI for each liferaft to be serviced—

(1) The make and size of the liferaft;

(2) The age of the liferaft; and

(3) Whether the liferaft is due for a five-year inflation test.

(b) The OCMI will inform the servicing facility whether the servicing of the liferaft must be witnessed by an inspector.

(c) If the OCMI requires the servicing of the liferaft to be witnessed by an inspector—

(1) The servicing facility must arrange a schedule with the OCMI that will allow a Coast Guard inspector to travel to the site where the servicing is to occur;

(2) The owner or operator of the servicing facility, by permission of the OCMI, may arrange for the servicing to be witnessed instead by a third-party inspector accepted by the OCMI if a Coast Guard marine inspector is not available in a timely manner; and

(3) The servicing facility must not begin servicing the liferaft until the inspector arrives at the site.

(d) No deviation from servicing-manual procedures may occur without the prior approval of the OCMI. To request the approval of a deviation, the owner or operator of the servicing facility shall notify the OCMI of the proposed deviation from the procedures, and must explain to the OCMI the need for the deviation.

§ 160.151–55 Withdrawal of approval.

(a) The OCMI may withdraw the approval of the servicing facility, or may suspend its approval pending correction of deficiencies, if the Coast Guard inspector or accepted third-party inspector finds that—

(1) The facility does not meet the requirements of §§ 160.151–41 through 160.151–47, or

(2) The servicing is not performed in accordance with § 160.151–57.

(b) A withdrawal of approval may be appealed in accordance with part 1, subpart 1.03, of this chapter.

(c) The OCMI may remove a suspension pending correction of deficiencies if the servicing facility demonstrates that the deficiencies have been corrected.

§ 160.151–57 Servicing procedure.

(a) Each inflatable liferaft serviced by a servicing facility approved by the Coast Guard must be inspected and tested in accordance with paragraphs (b) through (r) of this section, and the manufacturer's servicing manual approved in accordance with § 160.151–35(b)(1).

(b) The following procedures must be carried out at each servicing:

(1) The working-pressure leakage test described in IMO Resolution A.689(17), paragraph 2/5.1.5, must be conducted.

(2) Inflation hoses must be pressurized and checked for damage and leakage as part of the working-pressure leakage test, or in a separate test.

(3) An inflatable floor must be inflated until it is firm, and let stand for one hour. The inflatable floor must still be firm at the end of the hour.

(4) The seams connecting the floor to the buoyancy tube must be checked for slippage, rupture, and lifting of edges.

(5) Each item of survival equipment must be examined, and—

(i) Replaced if its expiration date has passed; and

(ii) Otherwise, repaired or replaced if it is damaged or unserviceable.

(6) Each battery must be replaced with a fresh one if—

(i) Its expiration date has passed;

(ii) It has no expiration date; or

(iii) It is to return to service in an item of survival equipment, but its measured voltage is less than its rated voltage.

(7) Each power cell for the top and inside canopy lights must be inspected and tested as prescribed in the servicing manual unless it is a battery serviced in accordance with paragraph (b)(6) of this section. Each cell that is tested and found satisfactory may be reinstalled. Each cell that is outdated, is not tested, or fails the test must be replaced.

(8) If the liferaft is equipped with an Emergency Position-Indicating Radio Beacon (EPIRB) or a Search and Rescue Transponder (SART), the EPIRB or SART must be inspected and tested in accordance with the manufacturer's instructions. An EPIRB must be tested using the integrated test circuit and output indicator to determine whether it is operative. Each EPIRB or SART not operative must be repaired or replaced.

(9) The manual inflation-pump must be tested for proper operation.

(10) Each damaged, faded, or incorrect instruction label or identification label on the liferaft or its container must be replaced.

(11) Each liferaft must be examined to ensure that it is properly marked with retroreflective material. The arrangement of the retroreflective material must meet the requirements of IMO Resolution A.658(16). Damaged or missing retroreflective material must be

replaced with Type I material approved under part 164, subpart 164.018, of this subchapter as complying with SOLAS.

(12) Each inflation cylinder must be weighed. If its weight loss exceeds five percent of the weight of the charge, it must be recharged.

(c) When an inflation cylinder is recharged for any reason, the following inflation-head components must be renewed:

(1) The poppet-pin assembly, if any.

(2) Each plastic or elastomeric seal, and each other part that deteriorates with age.

(d) Each recharged inflation cylinder must stand for at least two weeks and be checked for leakage by weighing before being installed in a liferaft. An alternative mechanical or chemical test for fast detection of leakage may be used if the servicing manual approved by the Commandant in accordance with § 160.151–35(b)(1) provides for it.

(e) Each inflation cylinder that requires a hydrostatic test under 49 CFR 173.34 must be tested and marked in accordance with that section.

(f) At every second servicing of a davit-launched liferaft, the launching-load test in paragraph 2/5.2 of IMO Resolution A.689(17) must be conducted.

(g) At every fifth annual servicing, before the conduct of the tests and inspections required in paragraphs (b) through of this section, each liferaft must be removed from its container and, while still folded, inflated by the operation of its gas-inflation system.

(h) Each liferaft showing minor leaks during the gas inflation test conducted in accordance with paragraph (g) of this section, may be repaired.

(i) Each liferaft ten or more years past its date of manufacture must be condemned if it leaks extensively, or shows fabric damage other than minor porosity, during the gas inflation test conducted in accordance with paragraph (g) of this section.

(j) After the gas inflation test conducted in accordance with paragraph (g) of this section, the liferaft may be evacuated and refilled with air for the tests in paragraphs (b) through (f) of this section.

(k) At each annual servicing of a liferaft ten or more years past its date of manufacture during which the gas-inflation test in paragraph (g) of this section is not conducted, a ''Necessary Additional Pressure'' (NAP) test must be conducted. Before the tests and inspections required in paragraphs (b) through (f) of this section are conducted, the NAP test must be completed, using the following procedure:

(1) Plug or otherwise disable the pressure-relief valves.

(2) Gradually raise the pressure to the lesser of 2 times the design working pressure, or that specified in the manufacturer's servicing manual as sufficient to impose a tensile load on the tube fabric of 20 percent of its minimum required tensile strength.

(3) After 5 minutes, there should be no seam slippage, cracking, other defects, or pressure drop greater than 5 percent. If cracking in the buoyancy tubes is audible, accompanied by pressure loss, condemn the liferaft. If it is not, reduce the pressure in all buoyancy chambers simultaneously by enabling the pressure-relief valves.

(l) At each annual servicing of a liferaft 10 or more years past its date of manufacture, the integrity of the seams connecting the floor to the buoyancy tube must be checked by the following procedure, or an equivalent procedure specified in the manufacturer's approved servicing manual:

(1) With the buoyancy tube supported a sufficient distance above the floor of the servicing facility to maintain clearance during the test, a person weighing not less than 75 kg (165 lb) shall walk or crawl around the entire perimeter of the floor of the liferaft.

(2) The seams connecting the floor to the buoyancy tube must then be inspected for slippage, rupture, and lifting of edges.

(m) The servicing facility must complete the following for each liferaft that passes these inspections and tests:

(1) Permanently mark the liferaft on its outside canopy, or on a servicing-record panel on an interior portion of one of its buoyancy tubes near an entrance, with—

(i) The date of the servicing;

(ii) The identification and location of the servicing facility; and

(iii) If applicable, an indication that the special fifth-year servicing was performed.

(2) On or before July 1, 1998, permanently and legibly mark on the identification device provided in accordance with § 160.151–17(c), or on the outside canopy of the liferaft, the name, if known, of the vessel on which the raft will be installed or the name, if known, of the vessel owner.

(3) On or before November 10, 1997, affix an inspection sticker to the liferaft container or valise. The sticker must be of a type that will remain legible for at least 2 years when exposed to a marine environment, and that cannot be removed without being destroyed. The sticker must be about 100 mm x 150 mm (4 by 6 inches), with the last digit of the year of expiration superimposed over a background color that corresponds to the colors specified for the validation stickers for recreational-boat numbers in 33 CFR 174.15(c), and be marked with the Coast Guard identifying insignia in accordance with the requirements of 33 CFR 23.12. The sticker must also contain the following:

(i) The name of the manufacturer of the liferaft.

(ii) The year and month of expiration determined in accordance with paragraph (n) of this section.

(iii) Identification of the servicing facility, printed on the sticker or indicated on the sticker by punch using an approval code issued by the Commandant.

(n) The expiration date of the servicing sticker is 12 months after the date the liferaft was repacked, except that:

(1) For a new liferaft, the expiration date may be not more than two years after the date the liferaft was first packed, if—

(i) Dated survival equipment in the liferaft will not expire before the sticker expiration date; and

(ii) The liferaft will not be installed on a vessel certificated under SOLAS.

(2) For a liferaft stored indoors, under controlled temperatures (between 0 °C (32 °F) and 45 °C (113 °F)), for not more than 6 months from the date it was serviced or first packed, the expiration date may be extended up to the length of time the liferaft remained in storage.

(3) For a liferaft stored indoors, under controlled temperatures (between 0 °C (32 °F) and 45 °C (113 °F)), for not more than 12 months from the date it was serviced or first packed, the expiration date may be extended up to the length of time the liferaft remained in storage, if the liferaft is opened, inspected, and repacked in a servicing facility approved in accordance with §§ 160.151–49 and 160.151–51. When the liferaft is opened—

(i) The condition of the liferaft must be visually checked and found to be satisfactory;

(ii) The inflation cylinders must be checked and weighed in accordance with paragraph (b)(12) of this section;

(iii) All survival equipment whose expiration date has passed must be replaced; and

(iv) All undated batteries must be replaced.

(o) The servicing facility must remove and destroy the markings of Coast Guard approval on each liferaft condemned in the course of any servicing test or inspection.

(p) The servicing facility must issue a certificate to the liferaft owner or

owner's agent for each liferaft it services. The certificate must include—

(1) The name of the manufacturer of the liferaft;

(2) The serial number of the liferaft;

(3) The date of servicing and repacking;

(4) A record of the fifth-year gas-inflation test required in paragraph (g) of this section, whenever that test is performed;

(5) A record of the hydrostatic test of each inflation cylinder required in paragraph (e) of this section, whenever that test is performed;

(6) A record of any deviation from the procedures of the manufacturer's servicing manual authorized by the OCMI in accordance with § 160.151–53(d);

(7) The identification of the servicing facility, including its name, address, and the approval code assigned by the Commandant in accordance with § 160.151–51;

(8) The name, if known, of the vessel or vessel owner receiving the liferaft; and

(9) The date the liferaft is returned to the owner or owner's agent.

(q) The servicing facility must keep a record of each liferaft approved by the Coast Guard that it services for at least five years, and must make those records available to the Coast Guard upon request. Those records must include—

(1) The serial number of the liferaft;

(2) The date of servicing and repacking;

(3) The identification of any Coast Guard or third-party inspector present;

(4) The name, if known, of the vessel or vessel owner receiving the liferaft; and

(5) The date the liferaft is returned to the owner or owner's agent.

(r) The servicing facility must prepare and transmit to the OCMI, at least annually, statistics showing the nature and extent of damage to and defects found in liferafts during servicing and repair. The facility must notify the OCMI immediately of any critical defects it finds that may affect other liferafts.

§ 160.151–59 Operating instructions and information for the ship's training manual.

(a) The liferaft manufacturer shall make operating instructions and information for the ship's training manual available in English to purchasers of inflatable liferafts approved by the Coast Guard, to enable vessel operators to meet regulations III/18.2, 19.3, 51, and 52 of SOLAS.

(b) The instructions and information required by paragraph (a) of this section may be combined with similar material for hydrostatic releases or launching equipment, and must explain—

(1) Release of the inflatable liferaft from its stowage position;

(2) Launching of the liferaft;

(3) Survival procedures, including instructions for use of survival equipment aboard; and

(4) Shipboard installations of the liferaft.

(c) The operating instructions required by paragraphs (a) and (b) of this section must also be made available in the form of an instruction placard. The placard must be not greater than 36 cm (14 in.) by 51 cm (20 in.), made of durable material and suitable for display near installations of liferafts on vessels, providing simple procedures and illustrations for launching, inflating, and boarding the liferaft.

§ 160.151–61 Maintenance instructions.

(a) The liferaft manufacturer shall make maintenance instructions available in English to purchasers of inflatable liferafts approved by the Coast Guard, to enable vessel operators to meet regulations III/19.3 and III/52 of SOLAS.

(b) The maintenance instructions required by paragraph (a) of this section must include—

(1) A checklist for use in monthly, external, visual inspections of the packed liferaft;

(2) An explanation of the requirements for periodic servicing of the liferaft by an approved servicing facility; and

(3) A log for maintaining records of inspections and maintenance.

PART 199—LIFESAVING SYSTEMS FOR CERTAIN INSPECTED VESSELS

11. The authority citation for part 199 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; 46 CFR 1.46.

12. In § 199.190, revise paragraphs (g)(3) introductory text and (g)(3)(i) to read as follows:

§ 199.190 Operational readiness, maintenance, and inspection of lifesaving equipment

* * * * *

(g) Servicing of inflatable lifesaving appliances, inflated rescue boats, and marine evacuation systems. * * *

(3) Each inflatable liferaft and inflatable buoyant apparatus must be serviced—

(i) In accordance with servicing procedures meeting the requirements of part 160, subpart 160.151 of this chapter; and

* * * * *

Dated: May 2, 1997.

Joseph Angelo,

Acting Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 97–11897 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–14–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 90–66, RM–7139, 7368 and 7369]

Radio Broadcasting Services; Lincoln, Osage Beach, Steelville and Warsaw, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule; petition for reconsideration.

SUMMARY: This document dismisses in part the petition for reconsideration in this proceeding filed by Twenty One Sound Communications, Inc. of our *Memorandum Opinion and Order,* 61 FR 29311 (June 10, 1996) as repetitious under Section 1.429 of the Commission's Rules. In all other respects, this document denies Twenty One Sound's reconsideration petition and affirms the dismissal of its counterproposal. With this action, this proceeding is terminated.

EFFECTIVE DATE: May 9, 1997.

FOR FURTHER INFORMATION CONTACT: Arthur D. Scrutchins, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Memorandum Opinion and Order, MM Docket No. 90–66, adopted April 23, 1997 and released May 2, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, N.W., Suite 140, Washington, D.C. 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Douglas W. Webbink,

Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–12170 Filed 5–8–97; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 62, No. 90
Friday, May 9, 1997

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.

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1603

Thrift Savings Plan Vesting

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Proposed rule with request for comments.

SUMMARY: The Executive Director of the Federal Retirement Thrift Investment Board (Board) is publishing a proposed rule with request for comments concerning vesting in amounts contributed to the Thrift Savings Plan (TSP) by or on behalf of an employee. This proposed rule would conform the Board's vesting regulations to the Federal Employees' Retirement System Technical Corrections Act of 1988, update the terms used in these regulations to match those used throughout 5 CFR chapter VI, and clarify the language of several provisions of the interim regulations.

DATES: Comments must be received on or before June 9, 1997.

ADDRESSES: Comments may be sent to Patrick J. Forrest, Federal Retirement Thrift Investment Board, 1250 H Street, NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Patrick J. Forrest, (202) 942–1661.

SUPPLEMENTARY INFORMATION: The Board administers the TSP, which was established by the Federal Employees' Retirement System Act of 1986 (FERSA), Pub. L. 99–335, 100 Stat. 514, codified, as amended, largely at 5 U.S.C. 8401–8479 (1994). The TSP is a tax-deferred retirement savings plan for Federal employees that is similar to cash or deferred arrangements established under section 401(k) of the Internal Revenue Code. The vesting provisions of FERSA are found at 5 U.S.C. 8432(g) and 8432b.

On August 12, 1987, the Board published in the **Federal Register** (52 FR 29635) an interim rule with request for comments. The interim rule established 5 CFR part 1603 to implement the vesting provisions of FERSA. On January 7, 1991, the Board published in the **Federal Register** (56 FR 600) an amendment to the interim rule. The amendment to the interim rule revised the definition of ''separation from government service'' from a separation of more than three days to a separation of more than 30 days. On May 9, 1995, the Board published in the **Federal Register** (60 FR 24535) an interim rule with request for comment. The interim rule implemented section 4 of the Uniformed Services Employment and Reemployment Rights Act (USSERA), Pub. L. 103–353, 108 Stat. 3149, 3170–73. Section 4 of USSERA added section 8432b to title 5 of the United States Code, providing that certain military service will count for TSP vesting purposes. The Board received no comments on any of the preceding **Federal Register** publications.

Section 1603.2(b) of this proposed rule provides that a TSP participant's first conversion contributions (which are defined in a new definition at proposed section 1603.1) are immediately vested. Under FERSA, first conversion contributions have always been excepted from the years-in-service vesting requirements. 5 U.S.C. 8432(g). However, previous Board regulations addressed this issue only by implication; an explicit treatment of the first conversion contributions issue could help avoid confusion.

Section 1603.2(d) conforms the TSP vesting regulations to section 115 of the Federal Employees' Retirement System, Technical Corrections Act (FERSTC), Pub. L. 100–238, 101 Stat. 1744, 1751 (1988) (codified at 5 U.S.C. 8432(g)), which provides that a participant's agency automatic (1%) contributions are not forfeited if the participant dies before completing the number of years in service that are normally required before such contributions are vested. Because the effective date of FERSTC was January 8, 1988, proposed section 1603.2(d) explains that the agency automatic (1%) contributions of participants who died before January 8, 1988, were subject to the years-in-service vesting requirements. The Board implemented the change required by section 115 of FERSTC on January 8, 1988.

Proposed sections 1603.3 (a) and (b), and the proposed new definitions of ''separation date'' and ''separation from Government service'' at section 1603.1, together explain that a participant does not separate from Government service for TSP vesting purposes unless he or she has a break in service of more than 30 calendar days. They also explain that a participant must have fulfilled the years-of-service requirement at the time of separation to avoid the forfeiture of agency automatic (1%) contributions and attributable earnings. Proposed sections 1603.3 (a) and (b) and the new definitions do not create new rules; they rewrite and reorganize the Board's regulations to make the current rules which govern the computation of years-of-service easier to understand.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the criteria of the Paperwork Reduction Act of 1980.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, section 201, Pub. L. 104–4, 109 Stat. 48, 64, the effect of these regulations on State, local, and tribal governments and on the private sector has been assessed. These regulations will not compel the expenditure in any one year of $100 million or more by any State, local, and tribal governments in the aggregate or by the private sector. Therefore, a statement under section 202, 109 Stat. 48, 64–65, is not required.

Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), the Board submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the publication of this rule in today's **Federal Register.** This interim rule is not a major rule as defined at 5 U.S.C. 804(2).

List of Subjects in 5 CFR Part 1603

Employee benefits plans, Government employees, Pensions, Retirement.

Federal Retirement Thrift Investment Board.

Roger W. Mehle,

Executive Director.

For the reasons set out in the preamble, 5 CFR Part 1603 is proposed to be amended as follows:

PART 1603—VESTING

1. The authority citation for part 1603 continues to read as follows:

Authority: 5 U.S.C. 8432(g), 8432b(h)(1), 8474 (b)(5) and (c)(1).

2. Section 1603.1 is revised to read as follows:

1603.1 Definitions.

Terms used in this part shall have the following meaning:

Agency automatic (1%) contributions means any contributions made under 5 U.S.C. 8432(c)(1);

CSRS means the Civil Service Retirement System established by 5 U.S.C. chapter 83, subchapter III, and any equivalent Federal Government retirement plan;

CSRS employee means any employee, Member, or participant covered by CSRS, including employees authorized to contribute to the Thrift Savings Plan under 5 U.S.C. 8351, or 5 U.S.C. 8440a to 8440d;

FERS means the Federal Employees' Retirement System established by 5 U.S.C. chapter 84, and any equivalent Federal Government retirement plan;

FERS employee means an employee, Member, or participant covered by FERS;

First conversion contributions refers to the retroactive agency contributions, including interest on these contributions, made under 5 U.S.C. 8432(c)(3)(C) to the TSP accounts of employees who were automatically converted to the Federal Employees' Retirement System on January 1, 1987;

Individual account means the total of all sums contributed to the Thrift Savings Plan by or on behalf of a CSRS employee or FERS employee, plus earnings allocated to the employee's account under 5 CFR part 1645;

Separation date means the effective date of an employee's separation from Government service;

Separation from Government service has the same meaning as provided in 5 CFR 1650.3;

Service means:

(1) Any non-military service that is creditable under either 5 U.S.C. chapter 83, subchapter III, or 5 U.S.C. 8411, provided however, that such service is to be determined without regard to any time limitations, any deposit or redeposit requirements contained in those statutory provisions after performing the service involved, or any requirement that the individual give written notice of that individual's desire to become subject to the retirement system established by 5 U.S.C. chapters 83 or 84; or

(2) Any military service creditable under the provisions of 5 U.S.C. 8432b(h)(1) and the regulations issued at 5 CFR part 1620, subpart H;

Vested means those amounts in an individual account which are nonforfeitable; and

Year of service means one full calendar year of service.

3. Section 1603.2 is amended by revising the section heading and adding a new paragraph (d) and by revising paragraphs (b) and (c) to read as follows:

1603.2 Basic vesting rules.

* * * * *

(b) Except as provided in paragraph (c) of this section, all amounts in a FERS employee's individual account (including all first conversion contributions) are immediately vested.

(c) Except as provided in paragraph (d) of this section, upon separation from Government service without meeting the applicable service requirements of § 1603.3, a FERS employee's agency automatic (1%) contributions and attributable earnings will be forfeited.

(d) If a FERS employee dies (or died) after January 7, 1988, without meeting the applicable service requirements set forth in § 1603.3, the agency automatic (1%) contributions and attributable earnings in his or her individual account are deemed vested and shall not be forfeited. If a FERS employee died on or before January 7, 1988, without meeting those service requirements, his or her agency automatic (1%) contributions and attributable earnings are forfeited to the Thrift Savings Plan.

4. Section 1603.3 is amended by revising paragraph (a) and the introductory text of paragraph (b) to read as follows:

1603.3 Service requirements.

(a) Except as provided under paragraph (b) of this section, FERS employees will be vested in their agency automatic (1%) contributions and attributable earnings upon separating from Government only if, as of their separation date, they have completed three years of service.

(b) FERS employees will be vested in their agency automatic (1%) contributions and attributable earnings upon separating from Government service if, as of their separation date, they have completed two years of service and they are serving in one of the following positions:

* * * * *

[FR Doc. 97–12167 Filed 5–8–97; 8:45 am]

BILLING CODE 6760–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1640

Periodic Participant Statements

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Proposed rule.

SUMMARY: The Executive Director of the Federal Retirement Thrift Investment Board (Board) proposes to amend the Board's interim regulations concerning periodic information to be furnished to participants in the Thrift Savings Plan (TSP). The regulations implement various provisions of the Federal Employees' Retirement System Act of 1986 (FERSA), as amended. The proposed rule would clarify the types of periodic information provided to participants in the TSP, conform definitions in the interim regulations to those found in the Board's other regulations, and otherwise make the proposed regulations easier to read.

DATES: Comments must be received on or before June 9, 1997.

ADDRESSES: Comments may be sent to Merritt A. Willing, Federal Retirement Thrift Investment Board, 1250 H Street, N.W., Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT: Merritt A. Willing on (202) 942–1661.

SUPPLEMENTARY INFORMATION: The Board administers the Thrift Savings Plan (TSP), a defined contribution plan for Federal employees established by the Federal Employees' Retirement System Act of 1986 (FERSA), Pub. L. 99–335, 100 Stat. 514 (codified, as amended, largely at 5 U.S.C. 8401–8479). The TSP is a tax-deferred retirement savings plan for Federal employees that is similar to cash or deferred arrangements established under section 401(k) of the Internal Revenue Code. The requirement that periodic statements be provided to participants by the TSP is found at 5 U.S.C. 8439(c). On June 1, 1987, the Board published an interim rule with request for comments in the **Federal Register** (52 FR 20371) which implemented the periodic statement provision of FERSA. The Board has received comments from employees and

agencies suggesting that the Board issue periodic statements more than twice a year. The Board considered these comments but decided not to issue statements more often than is required by statute because of the administrative cost associated with additional statements, which is an expense borne by all TSP participants.

Section 1640.1 contains definitions of words or terms used throughout the regulation. Some of the definitions contained in the interim regulations would be amended by the proposed rule to conform them to the Board's other regulations issued at 5 CFR chapter VI.

Section 1640.2 requires the Board to provide information to each TSP participant at least once every six months, no later than 30 days before the last month of an open season.

Sections 1640.3 and 1640.4 set forth the type of information that will be furnished to a participant regarding the status of his or her individual account during the reporting period.

Section 1640.5 describes the information to be furnished to participants relating to investments in the three investment funds described in 5 U.S.C. 8438. Two types of information are provided: (1) a description of the investment fund, and (2) a five-year history of the performance of that type of investment.

Section 1640.6 provides that individual account statements will be mailed to TSP participants by the Board's record keeper. Information regarding the TSP investments may either be mailed to TSP participants or included with other informational material that is distributed in a way reasonably designed to reach TSP participants.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities. They will affect only internal Government procedures related to the TSP.

Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the criteria of the Paperwork Reduction Act of 1980.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, section 201, Pub. L. 104–4, 109 Stat. 48, 64, the effect of these regulations on State, local, and tribal governments and on the private sector has been assessed. This regulation will not compel the expenditure in any one year of $100 million or more by any State, local, and tribal governments in the aggregate or by the private sector. Therefore, a statement under section 202, 109 Stat. 48, 64–65, is not required.

Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), the Board submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States before the publication of this rule in today's **Federal Register**. This rule is not a major rule as defined in section 804(2).

List of Subjects in 5 CFR Part 1640

Employee Benefit Plans, Government employees, Pensions, Reporting and recordkeeping requirements, Retirement.

Federal Retirement Thrift Investment Board.

Roger W. Mehle,

Executive Director.

For the reasons set forth in the preamble, part 1640 of chapter VI of title 5 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1640—PERIODIC PARTICIPANT STATEMENTS

1. The authority citation for part 1640 continues to read as follows:

Authority: 5 U.S.C. 8439(c)(1) and (c)(2), 5 U.S.C. 8474 (b)(5) and (c)(1).

2. Section 1640.1 is amended by removing the definitions of ''Employee contribution,'' ''Employer basic contribution,'' ''Employer matching contribution,'' ''Source,'' ''Thrift Savings Fund,'' ''Thrift Savings Plan or Plan,'' and ''Thrift Savings Plan Service Office,'' by revising the definitions of ''C Fund,'' ''Executive Director,'' ''F Fund,'' ''G Fund,'' ''Individual account,'' ''Investment fund,'' ''Open season,'' and ''Participant,'' and by adding, in alphabetical order, three new definitions to read as follows:

§ 1640.1 Definitions.

* * * * *

C Fund means the Common Stock Index Investment Fund established under 5 U.S.C. 8438(b)(1)(C);

Executive Director means the Executive Director of the Board described in 5 U.S.C. 8474;

F Fund means the Fixed Income Investment Fund established under 5 U.S.C. 8438(b)(1)(B);

G Fund means the Government Securities Investment Fund established under 5 U.S.C. 8438(b)(1)(A);

Individual account means the account established for a participant in the Thrift Savings Plan under 5 U.S.C. 8439(a);

Investment fund means either the G Fund, the F Fund, or the C Fund, or any other Thrift Savings Plan investment fund created after [the effective date of the final rule];

Open season means the period during which participants may choose to begin making contributions to the Thrift Savings Plan, to change or discontinue the amount they are currently contributing to the Thrift Savings Plan (without losing the right to recommence contributions the next open season), or to allocate prospective contributions to the Thrift Savings Plan among the investment funds;

Participant means any person with an individual account in the Thrift Savings Plan, or who would have an account in the Thrift Savings Plan but for an employing agency error;

Record keeper means the entity that is engaged by the Board to perform record keeping services for the Thrift Savings Plan. As of [the effective date of the final rule], the record keeper is the National Finance Center, Office of the Chief Financial Officer, United States Department of Agriculture, located in New Orleans, Louisiana.

Source of contributions means either agency automatic (1%) contributions under 5 U.S.C 8432(c)(1) or 8432(c)(3), agency matching contributions under 5 U.S.C. 8432(c)(2), or employee contributions under 5 U.S.C. 8351, or 8440(a) through 8440d;

Thrift Savings Plan means the Federal Retirement Thrift Savings Plan established by the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99–335, 100 Stat. 514, which has been codified, as amended, largely at 5 U.S.C. 8401–8479.

3. Section 1640.2 is revised to read as follows:

§ 1640.2 Duty to provide information.

The Executive Director will provide the information prescribed in §§ 1640.3 and 1640.5 at least once every six months, and not later than thirty (30) days before the last month of an open season.

4. Section 1640.3 is amended by revising the introductory text and paragraphs (c)(2), (d) and (e) to read as follows:

§ 1640.3 Statement of individual account.

The Executive Director will furnish each participant with the following information concerning that participant's individual account:

* * * * *

(c) * * *

(2) The amounts of contributions and earnings in the C Fund, the F Fund, and the G Fund, by source of contribution;

(d) All transactions made in accordance with § 1640.4 and affecting the individual account which occurred during the period covered by the statement;

(e) Any other information that the Executive Director determines should be in the statement.

5. Section 1640.4 is revised to read as follows:

§ 1640.4 Account transactions.

(a) Where relevant, the following transactions will be reported in each individual account statement:

(1) Contributions;

(2) Earnings posted;

(3) Withdrawals;

(4) Forfeitures;

(5) Loan Activity;

(6) Transfers among investment funds;

(7) Adjustments to prior transactions; and

(8) Any other transaction that the Executive Director deems will affect the status of the individual account.

(b) Where relevant, the statement will contain the following information concerning each transaction identified in paragraph (a) of this section:

(1) Type of transaction;

(2) Pay date of the pay period in which the transaction was reflected in the participant's salary payment;

(3) Investment funds affected;

(4) Date the transaction was processed;

(5) Source of the contribution;

(6) Amount of the transaction; and

(7) Any other information the Executive Director deems relevant.

6. Section 1640.5 is revised to read as follows:

§ 1640.5 Investment fund information.

For each open season, the Executive Director will furnish each participant with a statement concerning each of the investment funds. This statement will contain the following information concerning each investment fund:

(a) A summary description of the type of investments to be made by the fund, written in a manner that will allow the participant to make an informed decision; and

(b) The performance history of the type of investments to be made by the fund, covering the five-year period preceding the date of the evaluation.

7. Section 1640.6 is revised to read as follows:

§ 1640.6 Method of providing information.

(a) *Individual account statement.* The information concerning each participant's individual account described in §§ 1640.3 and 1640.4 will be sent to the participant at the participant's last known address, by first class mail. It is the participant's responsibility to provide his or her current address to his or her agency or, in the case of a separated employee, to the record keeper.

(b) *Investment information.* The investment information described in § 1640.5 will be furnished to each participant either:

(1) By mailing the information to the participant by the method described in paragraph (a) of this section; or

(2) By including that information in material published by the Board and distributed in a manner reasonably designed to reach the participant. This includes distributing the material through the participant's agency or, in the case of a separated employee, through the record keeper.

[FR Doc. 97–12169 Filed 5–8–97; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 97–011–1]

Importation of Coffee

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the regulations for importing coffee by removing unnecessary text, updating references to officials of the Animal and Plant Health Inspection Service, and clarifying the requirements for moving samples of unroasted coffee through Hawaii and Puerto Rico to other destinations and the prohibitions on importing coffee berries or fruits. These nonsubstantive changes would make the regulations easier to read and understand, thereby facilitating compliance.

DATES: Consideration will be given only to comments received on or before July 8, 1997.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 97–011–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 97–011–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Mr. James Petit de Mange, Staff Officer, Import-Export Team, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236; phone (301) 734–6799; fax (301) 734–5786; or e-mail: jpdmange@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations contained in 7 CFR 319.73 through 319.73–4, ''Subpart—Coffee'' (referred to below as the coffee regulations), restrict the importation of coffee from foreign countries and localities. The coffee regulations are intended to prevent the introduction of coffee berry borers *Hypothenemus hampei* (Ferrari) and a rust disease caused by the fungus *Hemileia vastatrix* (Berkeley and Broome) into Hawaii and Puerto Rico, where coffee is commercially grown.

Section 319.73–2 of the coffee regulations prohibits the importation into Hawaii and Puerto Rico of unroasted coffee, coffee berries or fruits, coffee plants and leaves, and empty sacks previously used for unroasted coffee. Section 319.73–3 of the coffee regulations allows samples of unroasted coffee to transit Hawaii or Puerto Rico in the mail or as cargo, provided the samples are packaged so as to prevent the escape of any plant pests that may be present in the samples.

We propose to amend the coffee regulations to remove unnecessary text, update references to officials of the Animal and Plant Health Inspection Service (APHIS), and make other nonsubstantive changes to clarify the transit provisions. In addition, we propose to amend the import provisions to make it clear that coffee fruits or berries are prohibited importation into all parts of the United States because they present a significant risk of introducing the Mediterranean fruit fly, which attacks a wide range of host material grown throughout the United States. The regulations at 7 CFR 319.37–2(a), ''Subpart—Nursery Stock, Plants, Roots, Bulbs, Seeds, and Other Plant Products,'' prohibit the importation into the United States of seeds of all kinds when in pulp from all countries of the world except Canada. This prohibition covers coffee fruits or berries. However, the coffee regulations only prohibit

importations into Hawaii and Puerto Rico. The prohibition on importing coffee fruits or berries into other parts of the United States may not be clear to the public because it is not stated in the coffee regulations. Therefore, we propose to state in § 319.73–2 that coffee fruits or berries are prohibited importation into all parts of the United States in accordance with 7 CFR 319.37–2(a). These changes would clarify the regulations and make them easier to understand, thereby facilitating compliance.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This proposed rule would update and clarify the regulations for importing coffee into the United States and for moving samples of unroasted coffee through Hawaii and Puerto Rico in transit to other destinations. This proposed rule would make no substantive changes in import or transit requirements. Therefore, it should have no economic impact on any United States entities, whether large or small.

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

List of Subjects in 7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery Stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly 7 CFR part 319 would be revised to read as follows:

PART 319—FOREIGN QUARANTINE NOTICES

Subpart—Coffee

Sec.

319.73–1 Definitions.
319.73–2 Products prohibited importation.
319.73–3 Conditions for transit movement of certain products through Puerto Rico or Hawaii.
319.73–4 Costs.

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167, 450, 2803, and 2809; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.2(c).

§ 319.73–1 Definitions.

Administrator. The Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any employee of the United States Department of Agriculture delegated to act in his or her stead.

Inspector. Any individual authorized by the Administrator to enforce this subpart.

Sample. Unroasted coffee not for commercial resale. Intended use includes, but is not limited to, evaluation, testing, or market analysis.

United States. The States, District of Columbia, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands of the United States.

Unroasted coffee. The raw or unroasted seeds or beans of coffee.

§ 319.73–2 Products prohibited importation.

(a) To prevent the spread of the coffee berry borer *Hypothenemus hampei* (Ferrari) and the fungus *Hemileia vastatrix* (Berkely and Broome), which causes an injurious rust disease, the following articles are prohibited importation into Hawaii and Puerto Rico, except as provided in § 319.73–3 of this subpart:

(1) Unroasted coffee;

(2) Coffee plants and leaves; and

(3) Empty sacks previously used for unroasted coffee.

(b) Due to the risk of Mediterranean fruit fly, coffee berries or fruits with pulp are prohibited importation into all parts of the United States by § 319.37–2(a) of this part.

§ 319.73–3 Conditions for transit movement of certain products through Puerto Rico or Hawaii.

(a) *Mail.* Samples of unroasted coffee that are transiting Hawaii or Puerto Rico en route to other destinations and that are packaged to prevent the escape of any plant pests may proceed without action by an inspector. Packaging that would prevent the escape of plant pests includes, but is not limited to, sealed cartons, air tight containers, or vacuum packaging. Samples of unroasted coffee received by mail but not packaged in this manner are subject to inspection and safeguard by an inspector. These samples must be returned to origin or forwarded to a destination outside Hawaii or Puerto Rico in a time specified by an inspector and in packaging that will prevent the escape of any plant pests. If this action is not possible, the samples must be destroyed.

(b) *Cargo.* Samples of unroasted coffee that are transiting Hawaii or Puerto Rico as cargo and that remain on the carrier may proceed to a destination outside Hawaii or Puerto Rico without action by an inspector. Samples may be transshipped in Puerto Rico or Hawaii only after an inspector determines that they are packaged to prevent the escape of any plant pests. Samples that are not packaged in this manner must be rewrapped or packaged in a manner prescribed by an inspector to prevent the escape of plant pests before the transshipment will be allowed.

(c) Other mail, cargo, and baggage shipments of articles covered by § 319.73–2 arriving in Puerto Rico or Hawaii may not be unloaded or transshipped in Puerto Rico or Hawaii and are subject to inspection and other applicable requirements of the Plant Safeguard Regulations (part 352 of this chapter).

§ 319.73–4 Costs.

All costs of inspection, packing materials, handling, cleaning, safeguarding, treating, or other disposal of products or articles under this subpart will be borne by the owner or a responsible representative of the commodity. The services of an inspector during regularly assigned hours of duty and at the usual places of duty will be furnished without cost to the importer.

Done in Washington, DC, this 5th day of May 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–12083 Filed 5–8–97; 8:45 am]

BILLING CODE 3410–34–P

FEDERAL HOUSING FINANCE BOARD

12 CFR Chapter IX

[No. 97–N–4]

Mission Achievement by the Federal Home Loan Banks

AGENCY: Federal Housing Finance Board.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: On April 9, 1997, the Federal Housing Finance Board (Finance Board) published an advance notice of proposed rulemaking requesting public comment on ways in which the Federal Home Loan Banks (Banks) can further achieve their statutory mission to support housing finance and community investment and ways in which the Finance Board, as regulator of the Banks, can measure and ensure that the Banks achieve their mission (62 FR 17108, April 9, 1997). Comments originally were requested by May 9, 1997. In recognition of the broad scope of issues on which comments have been requested, and in order to receive comprehensive and creative comments on all aspects of these issues, the Finance Board has decided to extend the comment period for 30 days for all commenters.

DATES: Comments must be received on or before June 9, 1997.

ADDRESSES: Comments should be mailed to: Elaine Baker, Secretary to the Board, Federal Housing Finance Board, 1777 F Street, NW, Washington, DC 20006. Comments will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: Jonathan Curtis, Senior Financial Analyst, Office of Policy, (202) 408–2866, or Brandon B. Straus, Senior Attorney-Advisor, (202) 408–2589, Office of General Counsel, Federal Housing Finance Board, 1777 F Street, NW, Washington, DC 20006.

Dated: May 5, 1997.

By the Board of Directors of the Federal Housing Finance Board.

Bruce A. Morrison,

Chairman.

[FR Doc. 97–12245 Filed 5–8–97; 8:45 am]

BILLING CODE 6725–01–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–CE–54–AD]

RIN 2120–AA64

Airworthiness Directives; Twin Commander Aircraft Corporation 500, 680, 690, and 695 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 96–12–08 on Twin Commander Aircraft Corporation (Twin Commander) 500, 680, 690, and 695 series airplanes that do not have a nose landing gear drag link bolt with the manufacturer's serial number, manufacture date, and the last three digits of the drawing number, 055, on the bolt head, which currently requires replacing the nose landing gear (NLG) drag link bolt with one that has been manufactured with the proper heat-treatment. The proposed action would retain these requirements, would require additional models and serial numbers be added to the applicability section, and would require certain Models 690D and 695A airplanes to replace bolt part number (P/N) ED10055 with bolt P/N 750076–1. The addition of airplane models and serial numbers, as well as changing the part number of the bolt to be replaced on some models prompted the proposed action. The actions specified by the proposed AD are intended to prevent the NLG from collapsing which could result in loss of control of the airplane during landing operations.

DATES: Comments must be received on or before July 17, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–CE–54–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Twin Commander Aircraft Corporation, 19010 59th Dr. NE., Arlington, Washington, 98223–7832; telephone (360) 435–9797; facsimile (360) 435–1112. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Jeffrey Morfitt, Aerospace Engineer, FAA, Seattle Aircraft Certification Office, 1601 Lind Ave. SW., Renton, Washington, 98055–4056; telephone (206) 227–2595; facsimile (206) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 96–CE–54–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–CE–54–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

Airworthiness Directive (AD) 96–12–08, Amendment 39–9650, (61 FR 28738, dated June 6, 1996), currently requires replacing the NLG drag link bolt with an approved heat-treated bolt on Twin Commander 500, 680, 690, and 695 series airplanes. This bolt has the manufacturer's serial number, manufacture date, and the last three digits of the drawing number, 055, on the bolt head.

Actions Since Issuance of Previous Rule

Since the issuance of AD 96–12–08, the manufacturer has notified the FAA that Twin Commander Model 680V was inadvertently left out of the applicability section, several serial numbers on the other applicable airplane models were not listed, and the part number of the bolt to be used on Models 690D and 695A was not correct. The AD should have required installing Twin Commander bolt part number (P/N) 750076–1, instead of P/N ED10055 on these two airplane Models.

Relevant Service Information

Twin Commander has revised their original Service Bulletin No. 224, Revision A, dated April 24, 1996 to reflect the changes in applicability and part numbers with a new revised Twin Commander Service Bulletin (SB) No. 224, Revision C, dated July 25, 1996. Twin Commander SB No. 224, Revision B also added serial numbers that were not included in the first revision. All three revisions retain the same action which specifies procedures for inspecting the nose landing gear drag link bolt for a specific part number, and replacing any bolt that does not have the correct part number stamped on the top of the bolt head.

The FAA's Determination

After examining the circumstances and reviewing all available information related to the incidents described above, the FAA has determined that AD action should be taken to prevent the NLG from collapsing which could result in loss of control of the airplane during landing operations.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Twin Commander 500, 680, 690, and 695 series airplanes of the same type design, the proposed AD would supersede AD 96–12–08 with a new AD that would require:

- Replacing the NLG drag link bolt with an approved heat-treated bolt that has the manufacturer's serial number, manufacture date, and the last three digits of the drawing number on the bolt head,
- including Model 680V in the applicability of the affected airplanes,
- including additional serial numbers of the already affected models, and
- changing the bolt part number (P/N) to be installed on Models 690D and 695A from P/N ED10055 to P/N 750076–1.

Cost Impact

The FAA estimates that 54 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately one workhour per airplane to accomplish the proposed action, and that the average labor rate is approximately $60 an hour. The manufacturer is providing parts and one hour labor free of charge. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be zero.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Airworthiness Directive (AD) 96–12–08, Amendment 39–9650, and by adding a new AD to read as follows:

Twin Commander Aircraft Corporation: Docket No. 96–CE–54–AD; Supersedes AD 96–12–08, Amendment 39–9650.

Applicability: The following Model and serial number airplanes, certificated in any category:

Models	Serial numbers
500S	3185, 3228, 3230, 3262, and 3291
500U	1765
680F	1195
681	6027
680V	1677
690	11035, 11053, 11068, and 11074
690A	11111, 11134, 11146, 11153, 11173, 11177, 11205, 11215, 11237, 11249, 11271, 11273, and 11282
690B	11360, 11382, 11409, 11424, 11451, 11455, 11463, 11491, 11513, 11521, 11535, 11536, 11539, and 11566
690C	11638, 11643, 11676, 11689, and 11719
690D	15041
695	95010, 95033, 95044, and 95066
695A	69010, 69041, 69056, and 69061

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 75 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished. Compliance with Twin Commander Service Bulletin (SB) 224, Revision A, dated April 24, 1996, or Revision C, dated July 25, 1996, fulfills the applicable requirements of this AD, and is considered ''unless already accomplished.''

To prevent the nose landing gear (NLG) from collapsing which could result in loss of control of the airplane during landing operations, accomplish the following:

(a) For all airplane Models, except for Models 690D and 695A, replace the NLG drag link bolt, part number (P/N) ED 10055, with a new bolt in accordance with the INSTRUCTIONS section of Twin Commander Service Bulletin (SB) 224, Revision C, dated July 25, 1996.

(b) For airplane Models 690D and 695A, replace the NLG drag link bolt (P/N ED

10055), with a new bolt (P/N 750076–1) in accordance with Twin Commander SB 224, Revision C, dated July 25, 1996.

(c) The new replacement bolt must be marked with the manufacturer's serial number, the date of manufacture, and the last three digits of the drawing number, 055, on the bolt head for all but Models 690D and 695A. Models 690D and 695A bolts must be marked with the manufacturer's serial number, the date of manufacture, and the last three digits of the drawing number, 76–1, on the bolt head.

Note 2: Although not required by this AD, FAA highly recommends that the removed bolt (P/N ED 10055) be returned to Twin Commander for Rockwell Hardness testing.

(d) As of the effective date of this AD, no person shall install an NLG drag link bolt that does not have the manufacturer's serial number, manufacture date, and the last three digits of the drawing numbers as specified in paragraph (c) of this AD.

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

(f) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Seattle Aircraft Certification Office, 1601 Lind Ave. SW., Renton, Washington, 98055–4056. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Seattle Aircraft Certification Office. Alternative methods of compliance approved in accordance with AD 96–12–08 are not considered approved as alternative methods of compliance for this AD.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from Seattle Aircraft Certification Office.

(g) All persons affected by this directive may obtain copies of the document referred to herein upon request to Twin Commander Aircraft Corporation, 19010 59th Dr. NE., Arlington, Washington, 98223–7832; telephone (360) 435–9797; facsimile (360) 435–1112; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(h) This amendment supersedes AD 96–12–08, Amendment 39–9650.

Issued in Kansas City, Missouri, on April 30, 1997.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–11878 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–256–AD]

RIN 2120–AA64

Airworthiness Directives; Lockheed Model L–1011–385 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Lockheed Model L–1011–385 series airplanes. This proposal would require repetitive external visual inspections and internal borescope inspections to detect discrepancies of the elevator assembly; and repair/modification of any discrepancy. This proposal is prompted by a report of fretting at the diagonal truss to web joint of the elevator and cracking in the cap fillet radius adjacent to the joint, apparently due to loose fasteners as a result of local vibration. The actions specified by the proposed AD are intended to detect and correct such fretting and cracking, which could result in reduced structural integrity of the elevator and consequent flutter instability if coupled with other structural failures.

DATES: Comments must be received by June 20, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–256–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Lockheed Aeronautical Systems Support Company (LASSC), Field Support Department, Dept. 693, Zone 0755, 2251 Lake Park Drive, Smyrna, Georgia 30080. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, Campus Building, 1701 Columbia Avenue, Suite 2–160, College Park, Georgia.

FOR FURTHER INFORMATION CONTACT: Thomas Peters, Aerospace Engineer, Systems and Flight Test Branch, ACE–116A, FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, Campus Building, 1701 Columbia Avenue, Suite 2–160, College Park, Georgia 30337–2748; telephone (404) 305–7367; fax (404) 305–7348.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–256–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–256–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received a report of fretting at the diagonal truss to web joint of the elevator and cracking in the cap fillet radius adjacent to the joint on a Lockheed Model L–1011–385 series airplane. The thickness of the truss was worn in half (i.e., worn from 0.040 to 0.020 inches). The apparent cause of the fretting and cracking has been attributed to loose fasteners that attach the diagonal trusses with the elevator ribs, as a result of local vibration. Such fretting and cracking, if not detected and corrected, could result in reduced

structural integrity of the elevator and consequent flutter instability if coupled with other structural failures.

Explanation of Relevant Service Information

The FAA has reviewed and approved Lockheed Service Bulletin 093–55–031, dated April 26, 1996, which describes procedures for repetitive external visual inspections and internal borescope inspections to detect discrepancies (i.e., loose/missing fasteners or rivets, sponginess, sheared rivets, fretting, damage, and cracking) of the elevator assembly; and repair/modification, if necessary.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require repetitive external visual inspections and internal borescope inspections to detect discrepancies (i.e., loose/missing fasteners or rivets, sponginess, sheared rivets, fretting, damage, and cracking) of the elevator assembly; and repair/modification of any discrepancy. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Cost Impact

There are approximately 235 Lockheed Model L–1011–385 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 117 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 20 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $140,400, or $1,200 per airplane.

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

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Lockheed: Docket 96–NM–256–AD.

Applicability: All Model L–1011–385 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct fretting at the diagonal truss to web joint of the elevator, and cracking in the cap fillet radius adjacent to the joint, which could result in reduced structural integrity of the elevator and consequent flutter instability if coupled with other structural failures, accomplish the following:

(a) Within 12 months after the effective date of this AD, perform an external visual inspection and internal borescope inspection to detect discrepancies (i.e., loose/missing fasteners or rivets, sponginess, sheared rivets, fretting, damage, and cracking) of the elevator assembly, in accordance with Part I of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–55–031, dated April 26, 1996. Repeat the inspections thereafter at intervals not to exceed 18 months.

(b) If any discrepancy is detected during any inspection required by this AD, prior to further flight, accomplish the repair/modification in accordance with Part II of the Accomplishment Instructions of the service bulletin. Repeat the inspections required by paragraph (a) of this AD thereafter at intervals not to exceed 18 months.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

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

Issued in Renton, Washington, on May 5, 1997.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–12252 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–212–AD]

RIN 2120–AA64

Airworthiness Directives; Saab Model SAAB SF340A, SAAB 340B, and SAAB 2000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness

directive (AD) that is applicable to certain Saab Model SAAB SF340A, SAAB 340B, and SAAB 2000 series airplanes. This proposal would require repetitive operational tests of the pitch trim system of the elevator trim-tab of the flight control unit to ensure that the system operates correctly, and repair, if necessary. This proposal is prompted by a report of uncommanded movement of the right-hand elevator trim-tab to a maximum deflection position, which was apparently due to a failure in the aircraft harness and a fault in the pitch trim synchronizer. The actions specified by the proposed AD are intended to prevent such uncommanded movement of the elevator trim-tab, which could lead to structural overload of the horizontal stabilizers at speeds above 180 knots, and resultant reduced controllability of the airplane.

DATES: Comments must be received by June 20, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–212–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from SAAB Aircraft AB, SAAB Aircraft Product Support, S–581.88, Linköping, Sweden. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Ruth Harder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1721; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–212–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–212–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Luftfartsverket (LFV), which is the airworthiness authority for Sweden, notified the FAA that an unsafe condition may exist on certain Saab Model SAAB SF340A, SAAB 340B, and SAAB 2000 series airplanes. The LFV advises of a report of uncommanded movement of the right-hand elevator trim-tab to a position of maximum deflection on a Model SAAB 340 series airplane. Uncommanded movement of the right-hand elevator trim-tab may be caused by a combination of factors, such as a failure of the aircraft harness and a fault in the pitch trim synchronizer. Such uncommanded movement could result in the elevator trim-tab moving to a maximum deflection position and a split occurring in the elevator position. Uncommanded movement of the right-hand elevator trim-tab due to failure of the aircraft harness and a fault in the pitch trim synchronizer, if not prevented, could lead to a structural overload of the horizontal stabilizers at speeds above 180 knots, and result in reduced controllability of the airplane.

Similar Models Subject to the Unsafe Condition

This problem also could occur on certain Model SAAB 2000 series airplanes that have mechanically controlled elevator control systems, because the pitch trim system is the same.

Explanation of Relevant Service Information

Saab has issued Service Bulletin 340–27–079 (for certain Model SAAB SF340A and SAAB 340B series airplanes); and Service Bulletin 2000–27–018 (for certain Model SAAB 2000 series airplanes); both dated December 22, 1995. These service bulletins describe procedures for repetitive operational tests of the pitch trim system that moves the elevator trim-tab of the flight control unit to ensure that the system operates correctly. Accomplishment of these operational tests will ensure that the standby trim switch operates correctly when commanded to the maximum up position, and continues to operate correctly when the reset button is pushed. A similar operational test ensures that the standby trim switch also operates correctly in the maximum down position.

The LFV classified the two service bulletins as mandatory and issued Swedish airworthiness directive (SAD) 1–083, Revision 1, dated January 2, 1996, in order to assure the continued airworthiness of these airplanes in Sweden.

FAA's Conclusions

These airplane models are manufactured in Sweden and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LFV has kept the FAA informed of the situation described above. The FAA has examined the findings of the LFV, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require repetitive operational tests of the pitch trim system that moves the elevator trim-tab of the flight control unit to ensure that the system operates correctly, and repair, if necessary. The repair would be required to be accomplished in accordance with a method approved by the FAA. Other actions would be required to be accomplished in accordance with the

two service bulletins described previously.

Interim Action

This is considered to be interim action until final action is identified, at which time the FAA may consider further rulemaking.

Cost Impact

The FAA estimates that 235 Model SAAB SF340A and SAAB 340B series airplanes of U.S. registry would be affected by this proposed AD. Currently, there are no Model SAAB 2000 series airplanes of U.S. registry that would be affected by this proposed AD. It would take approximately 1 work hour per airplane to accomplish the proposed actions, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $14,100, or $60 per airplane, per operational test.

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

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Saab Aircraft AB: Docket 96–NM–212–AD.

Applicability: Model SAAB SF340A series airplanes, serial numbers −004 through −159 inclusive; Model SAAB 340B series airplanes, serial numbers −160 and subsequent; and Model SAAB 2000 series airplanes, serial numbers −005 and −007 through −009 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent uncommanded movement of the right-hand elevator trim-tab to a maximum deflection position, which could lead to structural overload of the horizontal stabilizers at speeds above 180 knots, and resultant reduced controllability of the airplane, accomplish the following:

(a) Within 150 hours time-in-service after the effective date of this AD, perform an operational test of the pitch trim system that moves the elevator trim-tab of the flight control unit to ensure that the system operates correctly, in accordance with Saab Service Bulletin 340–27–079 (for Model SAAB SF340A and SF340B series airplanes); and 2000–27–018 (for Model SAAB 2000 series airplanes); both dated December 22, 1995; as applicable.

(1) If no discrepancy is found, repeat the operational test of the pitch trim system thereafter at intervals not to exceed 150 hours time-in-service.

(2) If any discrepancy is found, prior to further flight, repair the system in accordance with a method approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate.

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

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

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

Issued in Renton, Washington, on May 5, 1997.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–12251 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AAL–4]

Proposed Revision of Class E Airspace; Kodiak, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action revises Class E airspace at Kodiak, AK. The creation of the CHINI fix on the front course of the localizer to runway (RWY) 25 at Kodiak, AK, has made this action necessary. Holding is established at CHINI from 1,600 feet MSL through 6,000 feet MSL. The protected airspace needed for the CHINI holding pattern at these altitudes will extend beyond the currently established Class E airspace. The area would be depicted on aeronautical charts for pilot reference. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Kodiak, AK.

DATES: Comments must be received on or before June 13, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, System Management Branch, AAL–530, Docket No. 97–AAL–4, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

The official docket may be examined in the Office of the Assistant Chief

Counsel for the Alaskan Region at the same address.

An informal docket may also be examined during normal business hours in the Office of the Manager, System Management Branch, Air Traffic Division, at the address shown above and on the Internet at Alaskan Region's homepage at www.mmac.jccbi.gov/aal/at.

FOR FURTHER INFORMATION CONTACT: Robert van Haastert, System Management Branch, AAL–538, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number: (907) 271–5863; email: Robert.van.Haastert@faa.dot.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AAL–4.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the System Management Branch, Air Traffic Division, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the System Management Branch, AAL–530, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise Class E airspace for instrument approach procedures at Kodiak, AK. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 of FAA Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1 (61 FR 48403; September 13, 1996). The Class E airspace designation listed in this document would be published subsequently in the Order.

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

List of Subjects in 14 CFR part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Kodiak, AK [Revised]

Kodiak Airport, AK
(lat. 57° 45′ 00″ N, long. 152° 29′ 38″ W)
Kodiak VORTAC
(lat. 57° 46′ 30″ N, long. 152° 20′ 23″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Kodiak Airport and within 5 miles south and 9 miles north of the 070° radial of the Kodiak VORTAC extending to 17 miles northeast of the VORTAC and within 8 miles north and 4 miles south of the Kodiak Localizer front course extending from the airport to 20.3 miles east of the airport and within 14 miles of the Kodiak VORTAC extending from the 358° radial clockwise to the 107° radial; and that airspace extending upward from 1,200 feet above the surface within 27 miles of the Kodiak VORTAC extending clockwise from the 023° radial to the 088° radial and within 8 miles north and 5 miles south of the Kodiak Localizer front course extending from the airport to 32 miles east of the airport.

* * * * *

Issued in Anchorage, AK, on April 30, 1997.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 97–12238 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–13–P

DELAWARE RIVER BASIN COMMISSION

18 CFR Part 430

Protected Area Permits for New Withdrawals; Proposed Amendments to the Commission's Ground Water Protected Area Regulations for Southeastern Pennsylvania; Public Hearing

AGENCY: Delaware River Basin Commission.

ACTION: Notice of proposed rulemaking and public hearing.

SUMMARY: Notice is hereby given that the Delaware River Basin Commission will hold a public hearing to receive comments on proposed amendments to its Ground Water Protected Area Regulations for Southeastern Pennsylvania with respect to the establishment of numerical ground water withdrawal limits for subbasins in the protected area. The proposed limits, based upon hydrologic budget analyses, would initially be specified for the 14 subbasins in the Neshaminy Creek Basin. Limits for the remaining 52 subbasins within the protected area would be developed upon completion of additional hydrologic budget analyses, scheduled to be completed late in 1997.

DATES: The public hearing will be held on Tuesday, June 24, 1997 beginning at 3:00 p.m. and continuing until 5:00 p.m., as long as there are people present wishing to testify. The hearing will resume at 7:00 p.m. and continue until 9:00 p.m., as long as there are people present wishing to testify.

The deadline for inclusion of written comments in the hearing record will be announced at the hearing. Persons wishing to testify at the hearing are requested to register with the Secretary in advance of the hearing.

ADDRESSES: Written comments should be submitted to Susan M. Weisman, Delaware River Basin Commission, P.O. Box 7360, West Trenton, New Jersey 08628. The public hearing will be held in the Goddard Conference Room of the Commission's offices at 25 State Police Drive, West Trenton, New Jersey.

FOR FURTHER INFORMATION CONTACT: Copies of the Commission's Ground Water Protected Area Regulations for Southeastern Pennsylvania may be obtained by contacting Susan M. Weisman, Commission Secretary, telephone (609) 883–9500 ext. 203.

SUPPLEMENTARY INFORMATION:

Background and Rationale

The Commission's Ground Water Protected Area Regulations for Southeastern Pennsylvania were adopted in 1980 to prevent depletion of ground water, protect the interests and rights of lawful users of the same water source, and balance and reconcile alternative and conflicting uses of limited water resources in the area. Lowered water tables resulting from withdrawals in excess of recharge rates have led to reduction of flows in some perennial streams in the region and have dried up some stream reaches which previously flowed all year. Such reductions in base flow interfere with instream and downstream water uses, adversely affect fisheries and aquatic life, and threaten to reduce the capacity of streams in the region to assimilate pollutants.

Since then, the ground water protected area regulations have been implemented and all interference issues have been addressed, with many sources limited to more reliable quantities. In addition, other alternative supplies have been made available in much of the protected area. While it is clear that ground water withdrawals have impacted the low flow of perennial streams, it has been difficult to address the impact on streamflow on a project by project basis. With this in mind, the Commission and its Ground Water Advisory Committee evaluated a variety of approaches and determined that additional information was needed. In 1996, the U.S. Geological Survey completed work on a computer program to more accurately compare water withdrawals and ground water base flow in the Neshaminy Creek Basin. Over the past year, the Commission's Ground Water Advisory Committee met on several occasions to review the study products and discuss possible management strategies to address the problems identified by the study. Commission staff has presented the study results and options to some 15 county planning entities, state and federal agencies and watershed, civic and professional organizations. Finally, the Commission held public briefings on the proposed amendments to the regulations on April 8, 1997 in Doylestown, Pennsylvania and on April 10, 1997 in West Chester, Pennsylvania.

The proposed amendments to the Ground Water Protected Area Regulations would establish a two-tiered system of withdrawal limits. The first tier would serve as a warning that a subbasin is ''potentially stressed.'' In potentially stressed subbasins, applicants for new or expanded ground water withdrawals would be required to implement one or more programs to mitigate adverse impacts of additional ground water withdrawals. Acceptable programs would include: conjunctive use of ground water and surface water; expanded water conservation; programs to control ground water infiltration; and artificial recharge and spray irrigation. The second tier would serve as the maximum withdrawal limit. The Commission would seek to prevent ground water withdrawals from exceeding the maximum withdrawal limit.

The proposed regulations would also provide incentives for holders of existing DRBC dockets and protected area permits to implement the above-cited conjunctive use and conservation programs to mitigate the adverse impacts of their ground water withdrawals. If docket or permit holders successfully implement one or both programs, the Commission would extend the docket or permit duration for up to ten years.

The proposed regulations would also specify administrative criteria for issuing and review of dockets and permits as well as protocol for updating and revising withdrawal limits to provide additional protection for streams designated by the Commonwealth of Pennsylvania as ''high quality'' or ''exceptional value'', or to correspond with any integrated resources plans adopted by municipalities for subbasins. This regulation would become effective upon adoption by the Commission.

The ground water study which provided the basis for the proposed withdrawal limits for the 14 subbasins in the Neshaminy Creek Basin was prepared by the U.S. Geological Survey in cooperation with the Commission and is entitled ''Water-Use Analysis Program for the Neshaminy Creek Basin, Bucks and Montgomery Counties, Pennsylvania.'' Limited quantities of this report and its accompanying map series entitled ''Maps of Difference Between Ground-Water Contributions to Base Flow for the Various Recurrence Intervals and Ground Water Withdrawals in the Neshaminy Creek Basin, Pennsylvania'' were printed and may be reviewed at the Commission's offices at 25 State Police Drive, West Trenton, New Jersey. Please contact Judith L. Strong, Commission Librarian at (609) 883–9500 ext. 263 to make an appointment. Review copies are also available at the offices of the Bucks County Planning Commission (215) 345–3400; Bucks County Library Center (215) 348–9082; Montgomery County Planning Commission (Drew Shaw) (610) 278–3733; the Chester County Library (Sue Wilson) (610) 363–0884; and Lehigh Valley Planning Commission (610) 264–4544.

The subject of the hearing will be as follows:

Amendment to the Commission's Ground Water Protected Area Regulations for Southeastern Pennsylvania Relating to the Establishment of Numerical Ground Water Withdrawal Limits for Subbasins in the Protected Area

For the reasons set forth in the preamble, part 430 is proposed to be amended as follows:

PART 430—GROUND WATER PROTECTION AREA: PENNSYLVANIA

1. The authority citation for part 430 continues to read as follows:

Authority: Pub. L. 87–328 (75 Stat. 688).

2. Section 430.13 is amended by adding new paragraphs (h) through (m), to read as follows:

§ 430.13 protected area permits for new withdrawals.

(h) Dockets and protected area permits may be issued for a duration of up to ten years and shall specify the maximum total withdrawals that must not be exceeded during any consecutive 30-day period. Such maximum total withdrawals shall be based on demands projected to occur during the duration of the docket or protected area permit.

(i) Ground water withdrawal limits shall be defined for subbasins in accordance with the provisions of paragraph (i) (1) or (2) of this section. The limits for specific subbasins are set forth in paragraph (i)(3) of this section.

(1) Hydrologic budget analyses shall be conducted for all subbasins in the Southeastern Pennsylvania Ground Water Protected Area. The analyses shall determine the 1-year-in-25 average annual baseflow rate. The 1-year-in-25 average annual baseflow rate shall serve as the maximum withdrawal limit for net annual ground water withdrawals for subbasins. If net annual ground water withdrawals exceed 75 percent of this rate for a subbasin, such a subbasin shall be deemed ''potentially stressed.'' The Commission shall maintain a current list of net annual ground water withdrawals for all subbasins. ''Net'' annual ground water withdrawals include total ground water withdrawals less total water returned to the ground water system of the same subbasin.

(2) Upon application by the appropriate governmental body or bodies, the withdrawal limits criteria set forth in paragraph (i)(1) of this section may be revised by the Commission to provide additional protection for any subbasin identified in paragraph (i)(3) of this section with streams or stream segments designated by the Commonwealth of Pennsylvania as either ''high quality'' or ''exceptional value'' or to correspond with more stringent requirements in integrated resource plans adopted and implemented by all municipalities within a subbasin identified in paragraph (i)(3) of this section. Integrated resource plans shall set forth the hydrologic basis for more stringent withdrawal limits and consider ground water availability, potential impacts of withdrawals on flow frequency, and existing and future water needs in the subbasin. Integrated resource plans shall be adopted and implemented by all municipalities within a subbasin and incorporated into each municipality's Comprehensive Plan, which is required by the Pennsylvania Municipalities Planning Code.

(3) The potentially stressed levels and withdrawal limits for all delineated basins and subbasins are set forth below:

NESHAMINY CREEK BASIN

Subbasin	Potentially stressed (mgy)	Withdrawal limit (mgy)
West Branch Neshaminy	1054	1405
Pine Run	589	785
North Branch Neshaminy	845	1126
Main Stem Doylestown	713	950
Main Stem Warwick	927	1236
Little Neshaminy Warrington	505	673
Park Creek	584	779
Little Neshaminy Warminster	1008	1344
Mill Creek	1175	1567
Main Stem Northampton	593	791
Newtown Creek	298	397
Core Creek	497	662
Ironworks Creek	326	434
Main Stem Lower Neshaminy	2876	3835

Subject to public notice and hearing, this section may be updated or revised based upon completion of hydrologic budget analyses for the remaining 52 subbasins within the Protected Area or in accordance with paragraph (i)(2) of this section.

(j) Upon its determination that a subbasin is potentially stressed, the Commission shall notify all ground water users in the subbasin withdrawing 10,000 gallons per day or more during any 30-day period of its determination. If any such users have not obtained a docket or protected area permit from the Commission, they shall be required to apply to the Commission within 60 days of notification.

(k) In potentially stressed subbasins, dockets and protected area permit applications for new or expanded ground water withdrawals must include one or more programs to mitigate the adverse impacts of the new or expanded ground water withdrawal. The eligible programs are noted below. If the remainder of the application and the program(s) submitted are acceptable, the withdrawal may be approved by the Commission for an initial three-year period. The applicant shall implement the program(s) immediately upon Commission approval. If after the three-year period the program(s) is deemed successful by the Commission, the docket or permit duration may be extended for up to 10 years. The project sponsor shall be required to continue the program(s) for the duration of the docket or permit.

(1) A conjunctive use program that demonstrates the applicant's capability to obtain at least 15 percent of its average annual system usage from a reliable surface water supply. An acceptable program shall include either reservoir storage or an interconnection with a surface water supplier and an agreement or contract to purchase water from the supplier for the duration of the docket or permit.

(2) A water conservation program that exceeds the requirements of § 430.15. For existing water utilities, the program shall reduce average annual per capita water usage by at least five percent. All conservation programs shall include water conservation pricing, either inclining block rates, seasonal rates, or excess-use surcharges, and plumbing

fixture rebate or retrofit components. For self-supplied users, the program shall include water efficient technologies such as recycling, reuse, xeriscaping, drip or micro irrigation, or other innovative technology approved by the Commission.

(3) A program to monitor and control ground water infiltration to the receiving sewer system. The program must quantify ground water infiltration to the system and document reductions in infiltration. The program should include such measures as leakage surveys of sewer mains, metering of sewer flows in mains and interceptors, analysis of sewer system flows to quantify infiltration, and remedial measures such as repair of leaks and joints, main lining, and main replacement.

(4) An artificial recharge or spray irrigation program that demonstrates a return of at least 60 percent of the total new or expanded annual withdrawal to the same ground water basin and aquifer system from which it is withdrawn. The program shall not impair ground water quality.

(l) The durations of all existing dockets and protected area permits may be extended by the Commission for an additional five years if the docket or permit holder successfully implements either option (k)(1) or (k)(2) of this section. If the docket or permit holder successfully implements both options, the docket or permit may be extended for an additional ten years. The Executive Director shall notify all docket and permit holders potentially affected by this resolution of their right to file an application to determine their eligibility for extension.

(m) It is the policy of the Commission to prevent, to the extent reasonably possible, net annual ground water withdrawals from exceeding the maximum withdrawal limit. An application for a proposed new or expanded ground water withdrawal that would result in net annual ground water withdrawals exceeding the maximum withdrawal limit established in paragraph (i)(3) of this section shall set forth the applicant's proposal for complying with the Commission's policy, with such supporting documentation as may be required by the Executive Director. Notification of the application shall be given to all affected existing water users who may also submit comments or recommendations for consideration by the Commission on the pending application. In taking action upon the application, the Commission shall give consideration to the submissions from the applicant and affected water users. If the Commission determines that it is in the public interest to do so, it may reduce the total of proposed and existing ground water withdrawals within a subbasin to a level at or below the withdrawal limit. Unless otherwise determined by the Commission, docket and permit holders shall share equitably in such reductions.

Dated: May 2, 1997.

Susan M. Weisman,

Secretary.

[FR Doc. 97–12069 Filed 5–8–97; 8:45 am]

BILLING CODE 6360–01–P

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 207

RIN 1510–AA59

Electronic Benefits Transfer; Selection and Designation of Financial Institutions as Financial Agents

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of the Treasury, Financial Management Service (Service), proposes to adopt a new regulation dealing with the Direct Federal electronic benefits transfer (EBT) program. The Direct Federal EBT program provides access to Federal program benefit payments through electronic funds transfer (EFT) to individuals who do not have an account at a financial institution. The proposed Part 207 describes how the Service will implement EBT through the selection and designation of financial institutions as Financial Agents of the Treasury, and specifies the duties of such Financial Agents.

DATES: Comments must be received no later than July 8, 1997.

ADDRESSES: Comments may be mailed to the Director, Card Technology Division, Financial Management Service, U.S. Department of the Treasury, Room 526, Liberty Center, 401 14th Street, S.W., Washington, D.C. 20227. A copy of the proposed rule is available at the Service's home page at: http://www.fms.treas.gov. Comments on the proposed rule will be available for inspection in a reading room in the Department of the Treasury.

FOR FURTHER INFORMATION CONTACT: John P. Galligan, Director, Card Technology Division, (202) 874–6550, or Anne Wallace, Senior Attorney (202) 874–6681.

SUPPLEMENTARY INFORMATION:

Background

The Department of the Treasury's Financial Management Service (Service) is the Federal Government's financial manager. Its mission includes providing leadership and assistance to Federal agencies in cash management, payment policy and financial systems, and collecting and disbursing public money. The Service issues over 850 million payments each year, totaling in excess of $1 trillion.

The Service disburses payments under a variety of Federal programs, including Social Security Old Age, Survivors, and Disability Insurance, Supplemental Security Income, Black Lung, Railroad Retirement Board Retirement and Annuity, Department of Veterans Affairs Compensation and Pension, Civil Service Retirement and Disability, and Office of Personnel Management wage and salary payments. These payments are referred to as Direct Federal payments.

The Service disburses public monies in one of two ways: Treasury check and EFT. Slightly more than half of the 850 million payments made annually, representing payments to more than 30 million individuals, are made by Direct Deposit. Direct Deposit is a safe, reliable, and economical EFT payment mechanism in which funds are sent through the automated clearing house (ACH) into an account established by the recipient at a financial institution.

To utilize Direct Deposit under Treasury's regulations, a Direct Federal payment recipient must have an account with a financial institution and must designate that account as the location to which payments are to be sent by means of Direct Deposit. 31 CFR 210.4(a). However, an estimated 20–30 million Americans, including 10 million recipients of the Direct Federal payments mentioned above, do not have a bank account. These individuals are referred to as ''unbanked recipients'' in this proposal. Without an account at a financial institution, these recipients cannot receive their Direct Federal benefits via Direct Deposit. In order to afford unbanked recipients with a safe, reliable, and economical means of accessing their benefits, Treasury, together with other agencies in the Executive Branch, has been developing EBT for Direct Federal payments.

EBT is any delivery system which disburses government benefits through EFT and replaces paper benefit distribution with EFT and electronic access in the form of a plastic card. EBT may utilize a debit card or a stored value card, usable at point of sale (POS)

terminals and automated teller machines (ATMs). A debit card is a plastic card with a magnetic stripe that permits access to an account at a financial institution. A stored value card is a plastic card in which a computer chip is embedded. The computer chip retains a record of the card's value.

A majority of the States have implemented or are developing EBT systems. The benefits distributed in State EBT programs include those which are partly or fully funded by the Federal Government and administered by the State, such as Aid to Families with Dependent Children (AFDC), Food Stamps, and Women, Infants, and Children, and those that are fully funded and administered by the State, such as general assistance and unemployment compensation. For example, a number of States have replaced paper Food Stamp coupons with plastic cards that Food Stamp recipients use when purchasing food at participating certified grocery stores.

Treasury also has tested EBT in the delivery of Direct Federal payments. In 1989, Treasury designated the First National Bank of Maryland as its Financial Agent in the SecureCard pilot in Baltimore, Maryland. This one-year pilot was conducted with approximately 300 Supplemental Security Income recipients. In 1992, Treasury designated Citibank, N.A. as its Financial Agent in the Direct Payment Card pilot in Texas. The Direct Payment Card is an EBT program which provides unbanked recipients with access to Direct Federal payments. At the present time, there are approximately 21,000 active users of the Direct Payment Card throughout the State of Texas. In January, 1996, Treasury designated Citibank F.S.B. as its Financial Agent for EBT in the Southern Alliance of States (SAS). The SAS includes the states of Alabama, Arkansas, Florida, Georgia, Kentucky, Missouri, North Carolina and Tennessee.

In his National Performance Review Report, ''On An Implementation Plan For Nationwide EBT,'' Vice President Gore encouraged Federal agencies, in partnership with State and local governments, to develop a nationwide integrated EBT system utilizing the commercial infrastructure and combined access to Direct Federal payments and State-administered benefits for an individual recipient on a single card.

Recent legislation has provided additional urgency to the development of an electronic delivery system for the unbanked. Chapter 10 of Pub. L. 104–134, which was signed by the President on April 25, 1996, is the Debt Collection Improvement Act (DCIA). Section 31001(x) of the DCIA amends 31 U.S.C. 3332 to require Federal agencies to convert Federal payments, other than payments under the Internal Revenue Code, from checks to EFT in two phases. Phase one affects newly-eligible recipients of Federal payments. During phase one, which began on July 26, 1996, a recipient of a Federal payment who becomes eligible to receive the payment on or after July 26, 1996, must receive it by EFT unless the recipient certifies in writing that the recipient does not have an account at a financial institution or authorized payment agent. Phase two involves the conversion from checks to EFT of all Federal payments, except payments under the Internal Revenue Code. The DCIA provides that, subject to the Secretary's authority to grant waivers, after January 1, 1999, all Federal payments must be made by EFT.

Section 3332(i) authorizes Treasury to issue regulations to implement the mandatory EFT requirements. On July 26, 1996, the Service issued an interim rule to implement the provisions of the DCIA that took effect on that date and to seek public comment on issues relating to implementation of the requirements that take effect in January 1999. 61 FR 39254. The Service also described the steps it intends to take to implement the DCIA. The Service noted that it plans to engage in extensive educational and marketing efforts to promote Direct Deposit and Direct Deposit Too. Direct Deposit Too is a collaborative marketing initiative between the Federal Government and the financial services industry under which the Federal Government will encourage the financial industry to offer simple, low-cost, electronically-accessible accounts and will help market such accounts. 61 FR 39254–5.

Treasury hopes that many unbanked recipients of Direct Federal payments will become ''banked'' as a result of public and private sector educational and marketing efforts. However, it is likely that a certain percentage of Direct Federal recipients will remain unbanked by the January 1999 deadline. Therefore, by that time, Treasury must have in place payment systems, such as EBT, which will permit the electronic delivery of funds to the unbanked. Treasury believes that, by establishing a legal framework, the adoption of Part 207 will facilitate implementation of the Direct Federal EBT program.

Part 207

The Service has adopted regulations dealing with Direct Deposit which are codified at 31 CFR Part 210. Although Direct Deposit and EBT are similar in that both involve the movement of funds by EFT through the ACH, there are significant distinctions between them. For this reason, the Service believes it is desirable to adopt a regulation that deals specifically with EBT.

There are three principal distinctions between Direct Deposit and EBT. First, Direct Deposit is an EFT system for recipients who already have an account at a financial institution; EBT is an EFT system for unbanked recipients of Direct Federal benefit payments. In the Direct Federal EBT program, a financial institution designated by Treasury as its Financial Agent for EBT establishes an account in the name of the recipient for the purpose of receiving and providing adequate access to Direct Federal payments by EFT. The establishment of this account can be viewed as changing the recipient's status from ''unbanked'' to ''banked.'' However, it is important to note that, in EBT, all of the attributes of the account are determined by Treasury, none by the recipient, and the recipient has no ability to change the attributes of the account.

The second distinction relates to the nature of the disbursement process and the relationship between Treasury and the financial institution that receives the funds. Both Direct Deposit and EBT involve the disbursement of public funds. In Direct Deposit, Treasury disburses public funds by originating an ACH credit to the financial institution that holds the recipient's account. By definition, however, EBT is a payment system for the unbanked. Therefore, the mere origination of an ACH credit will not accomplish the program objective of placing funds representing the benefit payment into the hands of the recipient. Thus, in EBT, disbursement is a multi-step process that includes, in addition to the origination of an ACH credit, the establishment of an account for the unbanked recipient by Treasury's Financial Agent and the provision of access to that account by the Financial Agent.

As discussed below, under Federal law, the authority to disburse public money is limited to specific persons and entities. Financial institutions that have been designated by the Secretary as financial agents of the Government are among the entities authorized by Federal law to carry out the disbursement function. The designation of a financial institution as a financial agent creates a principal-agent relationship between Treasury and the financial agent. As in any agency relationship, as agents of the United States, financial agents act upon the instructions of the principal, the

Treasury, and answer only to the principal. Under proposed Part 207, the Financial Agent acts as agent of the United States, not as agent of the unbanked recipient, in establishing the account and providing services. For example, under proposed § 207.3(a)(1), the Financial Agent opens an account for the unbanked recipient at Treasury's direction and may close the account only at Treasury's direction. The Financial Agent for EBT is accountable only to Treasury, and Treasury will hold the Financial Agent responsible for the performance of these duties.

In contrast, under Treasury's Direct Deposit regulations, a financial institution does not become a financial agent by virtue of its receipt of a payment by Direct Deposit. 31 CFR 210.7(g). This is because, in Direct Deposit, the financial institution is selected by and acts as agent of its depositor, the recipient, and not as an agent of the Government. The depositor has complete freedom to choose the financial institution at which the account will be maintained and to change institutions at will.

The third distinction between Direct Deposit and EBT relates to the discretion possessed by the financial institution in providing access to the recipient's funds. In Direct Deposit, the recipient's financial institution provides access to funds in the recipient's account in accordance with the deposit contract between the financial institution and its depositor. Treasury is not a party to the deposit contract. Thus, the financial institution provides its depositor with whatever means of access, including checks, as agreed to by the parties. And, of course, Treasury has no responsibility for the nature or quality of services provided.

In the Direct Federal EBT program, the Financial Agent provides unbanked recipients with access to their benefit payments in the manner and on the terms specified in Part 207 and the agreement between Treasury and the Financial Agent. Specifically, under proposed § 207.3(a)(4), the Financial Agent is required to issue to each unbanked recipient a debit card bearing the Treasury's registered service mark for EBT, the Benefit Security Card®. The service mark identifies the debit card, and the cardholder-recipient, with the Direct Federal EBT program. The recipient is able to use this card at ATMs and POS terminals on terms and conditions specified by Treasury. No checks are issued to the recipient.

The statutory basis for the designation of financial institutions as financial agents and the relationship between Treasury, the Financial Agent for EBT, and the unbanked recipient are discussed in more detail below.

Section-by-Section Analysis

Section 207.1—Scope

Proposed § 207.1 provides that Part 207 governs Direct Federal EBT. The Direct Federal EBT program differs in several important respects from Direct Deposit, which is subject to regulations found at 31 CFR Part 210. The Service believes it is desirable to adopt a regulation that reflects the unique character of Direct Federal EBT.

Section 207.2—Definitions

The Service is the registered owner of the Benefit Security Card® mark; the Patent and Trademark Office issued Registration number 1,946,344 to the Service on January 9, 1996. Treasury intends to use the Benefit Security Card® mark to identify the Direct Federal EBT program. Proposed § 207.3(a)(4) directs the Financial Agent for EBT to use this service mark on all EBT cards.

The Service proposes to define the term ''Direct Federal electronic benefits transfer (EBT)'' as a program for providing the unbanked with electronic access to their Direct Federal benefit payments through the disbursement by a financial institution acting as Financial Agent of the United States. The proposed definition makes it clear that EBT is for the unbanked, unlike Direct Deposit where a recipient must have a preexisting account relationship with a financial institution. The proposed definition also makes clear that EBT involves the disbursement of public funds. See the discussion below of the proposed definition of ''disburse.''

The Service proposes to define the term ''Direct Federal payment'' as including payments under any Federally funded entitlement, pension, annuity, wage or salary program not administered by a State government. This category includes Social Security Old Age, Survivors, and Disability Insurance, Supplemental Security Income, Black Lung, Railroad Retirement Board Retirement and Annuity, Department of Veterans Affairs Compensation and Pension, Civil Service Retirement and Disability, and Office of Personnel Management wage and salary payments.

Proposed § 207.2 defines the term ''disburse'' in the context of EBT as the performance of a series of functions by a financial institution that has been designated as a Financial Agent of the United States. These functions are: The establishment of an account in the name of an unbanked recipient; the maintenance of the account; the crediting of Direct Federal payments to the account; and the provision of access to the account on terms specified by the Service.

Two elements of this definition are significant: the multiple functions which, taken together, comprise the act of disbursement; and the identity of the party performing disbursement. First, it should be noted that the broad definition of ''disburse'' in proposed § 207.2 reflects the Service's determination that all these functions must be performed in order to accomplish Treasury's goal of providing unbanked recipients with electronic access to their benefit payments. By contrast, the term ''disburse'' is used in a narrower sense in 31 CFR Part 206, where the Service's regulation deals with the management of Federal agency receipts and collections. There, ''disburse'' is defined in 31 CFR 206.2 as the initiation of an electronic funds transfer because, in the context of agency cash management where all the parties have accounts at financial institutions, the only function that needs to be performed in order to deliver public money by EFT to the intended recipient is the initiation of an electronic funds transfer.

Federal law authorizes the Secretary of the Treasury to disburse public money for the executive branch and specifies the individuals and entities to whom the Secretary can delegate the performance of this task. Section 3321 of Title 31 provides, in relevant part:

> (a) Except as provided in this section or another law, only officers and employees of the Department of the Treasury designated by the Secretary of the Treasury as disbursing officials may disburse public money available for expenditure by an executive agency.
>
> (b) For economy and efficiency, the Secretary may delegate the authority to disburse public money to officers and employees of other executive agencies.

Thus, the authority to disburse public funds is limited to designated officers and employees of Treasury, designated officers and employees of another executive agency under a delegation of authority from Treasury, or other entities to the extent they are authorized under some other specific statutory provision. One such provision is 31 U.S.C. 3327, which provides, in pertinent part:

> When the Secretary decides it is convenient to a public creditor and in the public interest, the Secretary may designate a depositary to issue a check or other draft on public money held by the depositary to pay an obligation of the Government.

Other Federal laws specifically authorize ''depositaries'' of public money, that is, banks or other financial institutions, to disburse public money as ''financial agents'' of the Government. For example, 12 U.S.C. 90 authorizes the Secretary of the Treasury to designate national banks as financial agents. That section provides, in relevant part:

> All national banking associations, designated for that purpose by the Secretary * * * shall be depositaries of public money, under such regulations as may be prescribed by the Secretary; and they may also be employed as financial agents of the Government; and they shall perform all such reasonable duties, as depositaries of public money and financial agents * * * as may be required from time to time.

Federal law also authorizes the Secretary to designate other types of financial institutions as financial agents. See, 12 U.S.C. 265, 266, 391, 1452(d), 1767, 1789a, 2013, 2122, and 31 U.S.C. 3122 and 3303.

Recent legislation clarified the Secretary's authority to use financial institutions designated as financial agents for EBT. Section 665, Omnibus Consolidated Appropriations Act, 1997, Pub. L. 104–208, amends 12 U.S.C. 90 by adding the following sentence to the end of that provision:

> Notwithstanding the Federal Property and Administrative Services Act of 1949, as amended, the Secretary may select [national banking] associations as financial agents in accordance with any process the Secretary deems appropriate and their reasonable duties may include the provision of [EBT] services (including State-administered benefits with the consent of the States), as defined by the Secretary.

Corresponding amendments were made to the ten other provisions of Federal law that authorize the designation of financial institutions as financial agents.

Relying upon this authority, the Service proposes to use financial institutions designated as financial agents of the Government to perform the disbursement of public funds that is central to the Direct Federal EBT program. The Service wishes to emphasize that proposed definition would not preclude a financial agent from working with one or more non-financial institutions in providing Direct Federal EBT services.

The proposed definition of ''eligible financial institution'' lists the eleven provisions in Federal law discussed above that authorize the designation of financial institutions as financial agents of the Government.

The Service proposes to define the term ''Financial Agent'' as a financial institution that has been designated as a Financial Agent of the United States for EBT.

Proposed § 207.2 defines ''recipient'' as a natural person entitled to receive a Direct Federal payment.

The proposed definition of the ''Service'' provides that the Financial Management Service is a bureau of the Department of the Treasury. The Service is responsible for implementation of the Direct Federal EBT program.

The Service proposes to define ''State EBT program'' as a program established under State or local law or administered by a State or local agency to provide electronic access to benefits. A number of States distribute cash benefits, such as AFDC and unemployment compensation, through the ACH. Proposed § 207.3(a)(3) authorizes the Financial Agent for EBT to credit such payments to the account established pursuant to § 207.3(a)(1). Obviously, non-cash benefits, such as Food Stamps, could not be added to the deposit account established by the Financial Agent.

The Service's proposed definition of ''State EBT program'' is based on language used by the Board of Governors of the Federal Reserve System in a recently proposed amendment to Regulation E, 12 CFR Part 205. 62 FR 3242.

The Board's proposed amendment implements legislation which exempted from the Electronic Funds Transfer Act ''needs-tested'' EBT programs, such as AFDC, established or administered under State or local law. However, the Service's proposed definition is not limited to needs-tested programs. Therefore, under this proposal, the Financial Agent could credit to the account established under § 207.3(a)(1) needs-tested cash payments, such as AFDC, or cash payments which are not needs-tested, such as unemployment compensation.

The proposed definition of ''unbanked recipient'' describes the class of persons eligible to participate in the Direct Federal EBT program as comprising those recipients who do not have an account at a financial institution. This definition reflects the distinction between Direct Deposit and the Direct Federal EBT program. The Service's Direct Deposit regulation provides that, in order to receive a benefit payment by Direct Deposit, the recipient ''shall designate the desired financial institution and account identification at that financial institution.'' 31 CFR 210.4(a). Obviously, a recipient who does not have an account at a financial institution cannot satisfy this requirement. The Direct Federal EBT program is designed to meet the needs of such recipients.

Section 207.3—Duties of the Financial Agent

Proposed § 207.3(a) describes the duties of a Financial Agent for EBT. The proposal contemplates the performance by the Financial Agent of a broad range of duties; as noted above, non-financial institutions can partner with the Financial Agent. In addition, it should be noted that Treasury possesses the inherent authority to perform, as principal, many of the duties described in this section. The regulation should not be interpreted as precluding Treasury from performing certain functions directly, should it determine that doing so is in the best interests of the Government.

Proposed § 207.3(a)(1) requires the Financial Agent to establish an account in the name of each unbanked recipient. The operational or accounting convention used by the Financial Agent is irrelevant; the account may be a master or subaccount, provided the deposit account records of the Financial Agent make clear the unbanked recipient's ownership rights in the account. In addition, the proposal provides that, since the Financial Agent acts as agent of Treasury in establishing the account, the account may be closed only at the direction of the Service.

Proposed § 207.3(a)(2) provides that the Financial Agent must comply with Regulation E, 12 CFR Part 205. The Financial Agent would be required to comply with Regulation E regardless of the requirement imposed by § 207.3(a)(2); the Service includes this requirement in Part 207 merely to emphasize that unbanked recipients participating in the Direct Federal EBT program will receive full Regulation E protection.

Proposed § 207.3(a)(3) requires the Financial Agent to credit to the account established pursuant to § 207.3(a)(1) Direct Federal payments received through the ACH. In addition, as discussed above, the Service is proposing to permit the Financial Agent to credit cash payments made to the recipient under a State EBT program to such account. No other deposits, whether over the counter or by EFT, may be made to the account.

Proposed § 207.3(a)(4) would require the Financial Agent to issue to each unbanked recipient a debit card bearing the Service's registered service mark, Benefit Security Card®. The recipient may use this card to access his or her account at ATMs and POS terminals.

Under proposed § 207.3(a)(5), the Financial Agent is required to provide service to cardholders on such terms and conditions as the Service specifies. The customer service duties of the Financial Agent will be described in detail in the Invitation for Expression of Interest (IEI) or in the Financial Agency Agreement between the Service and the Financial Agent.

Proposed § 207.3(a)(6) is a catch-all provision that would require the Financial Agent to perform any duties not specifically enumerated in this Part which the Service determines are necessary or appropriate in connection with the Direct Federal EBT program.

Proposed § 207.3(b) provides that, in carrying out its duties, the Financial Agent acts as agent of the United States and not as agent of the unbanked recipient.

Rulemaking Analysis

Treasury has determined that this proposed regulation is not a significant regulatory action as defined in Executive Order 12866. It is hereby certified that this rule will not have a significant economic impact on a substantial number of small business entities. The proposed rule does not require any actions on the part of small entities. Accordingly, a Regulatory Flexibility Act analysis is not required.

List of Subjects in 31 CFR Part 207

Automated clearing house, Banks, Banking, Electronic funds transfer, Federal Reserve System, Financial institutions, Government payments.

For the reasons set out in the preamble, the Service proposes to add Part 207 to title 31, chap. II, as follows:

PART 207—ELECTRONIC BENEFITS TRANSFER; DESIGNATION OF FINANCIAL INSTITUTIONS AS FINANCIAL AGENTS

Sec.
207.1 Scope.
207.2 Definitions.
207.3 Duties of the financial agent.

Authority: 12 U.S.C. 90, 265, 266, 391, 1452(d), 1767, 1789a, 2013, 2122; 31 U.S.C. 321, 3122, 3303, 3321, 3327, 3332, 3335 and 3336.

§ 207.1 Scope.

This part governs Direct Federal electronic benefits transfer (EBT), which involves the disbursement by electronic funds transfer of Direct Federal payments to unbanked recipients through the selection and designation of financial institutions as Financial Agents of the United States, and describes the duties of such Financial Agents.

§ 207.2 Definitions.

For purposes of this part:

Benefit Security Card® means the Service's registered service mark for Direct Federal EBT.

Direct Federal electronic benefits transfer (EBT) means a program for providing electronic access to Direct Federal payments to unbanked recipients through disbursement by a financial institution acting as Financial Agent of the United States.

Direct Federal payment means a payment under any entitlement, pension, annuity, or wage or salary program.

Disburse means, in the context of Direct Federal EBT, the performance of the following duties by a Financial Agent acting as agent of the United States: the establishment at a financial institution of an account in the name of an unbanked recipient; the maintenance of such account; the receiving of Direct Federal payments through the ACH and crediting of Direct Federal payments to the account; and the provision of access to such account on the terms specified by the Service and in accordance with this part.

Eligible financial institution means an institution eligible for designation as a Depositary and Financial Agent under any one of the following provisions of Federal law: 12 U.S.C. 90, 265, 266, 391, 1452(d), 1767, 1789a, 2013, 2122; and 31 U.S.C. 3122 and 3303.

Financial agent means an eligible financial institution that has been designated as a Depository and Financial Agent of the United States for EBT pursuant to this part.

Recipient means a natural person entitled to receive a Direct Federal payment.

Service means the Financial Management Service, a bureau of the United States Treasury.

State EBT program means a program established under State or local law or administered by a State or local agency for providing electronic access to needs-tested or other benefits.

Unbanked recipient means a recipient who does not have an account at a financial institution.

§ 207.3 Duties of the financial agent.

(a) The financial agent shall:

(1) Establish an account in the name of each unbanked recipient. Such account must be eligible for Federal deposit insurance and may be closed only at the direction of the Service.

(2) Comply with Regulation E, 12 CFR part 205.

(3) Credit to such account Direct Federal payments received through the automated clearing house. The Financial Agent also may credit to the account payments under a State EBT program.

(4) Issue to each unbanked recipient a debit card bearing the Benefit Security Card® service mark which will permit the recipient to access the account established pursuant to paragraph (a)(1) of this section at automated teller machines and point of sale terminals.

(5) Provide service to Benefit Security Card® holders on such terms as the Service specifies; and,

(6) Perform such other duties as the Service may specify.

(b) In performing the duties described in subsection (a), the financial agent shall act solely as the agent of the United States, not as agent of the unbanked recipient, and shall be accountable only to the Treasury.

Russell D. Morris,

Commissioner.

[FR Doc. 97–11928 Filed 5–8–97; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 167

[CGD 97–004]
RIN 2115–AF42

Traffic Separation Scheme in the Approaches to Delaware Bay

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the traffic separation scheme (TSS) in the approaches to Delaware Bay by shifting the Eastern approach lanes southward; establishing a two-way route for use by tug and tow traffic; and reconfiguring the precautionary area to exclude shoal areas too shallow for deep draft vessels. Navigation safety, economic, and environmental considerations necessitate action to separate large inbound vessels from tug and barge traffic transiting easterly and northerly along traditional New Jersey coastal routes. The proposed reconfiguration will reduce frequent near misses and the probability of an incident which could result in a major chemical or petroleum oil spill.

DATES: Comments must be received on or before August 7, 1997.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council (G–LRA/3406) (CGD 97–004), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001, or may be delivered to

room 3406 at the same address between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1477.

The Executive Secretary maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room 3406, U.S. Coast Guard Headquarters, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Margie G. Hegy, Project Manager, Office of Vessel Traffic Management at (202) 267–0415.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD 97–004) and the specific section of this proposal to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Marine Safety Council at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The 1978 amendments to the Posts and Waterways Safety Act (PWSA), 33 U.S.C. 1223(c), require that a port access route study be conducted prior to establishing or adjusting a traffic separation scheme (TSS). A TSS is an internationally recognized routing measure intended to minimize the risk of collision by separating vessels into opposing streams of traffic through the establishment of traffic lanes. To be internationally recognized, a TSS must be approved by the International Maritime Organization (IMO). IMO approves a TSS only if the proposed routing system complies with IMO principles and guidelines on ships routing. Rule 10 of the International Regulations for Preventing Collisions at Sea, 1972 (COLREG 1972), prescribes the conduct of vessels within or near a TSS adopted by IMO.

The Coast Guard conducted a study of the TSS in the Approaches to Delaware Bay which was announced in the **Federal Register** on March 22, 1994 (59 FR 14126). The notice of study results for the Approaches to Delaware Bay was published in the **Federal Register** on September 22, 1995 (60 FR 49237).

The existing TSS, adopted by the Inter-Governmental Maritime Consultative Organization (as the IMO was formerly known) on October 28, 1969, is published in the IMO publication *Ships' Routing* (B–IX/6–1). A change to the southeastern approach lanes was implemented on March 15, 1976. The TSS off Delaware Bay consists of an Eastern approach, a South-eastern approach, and a precautionary area. The Eastern approach consists of a westbound traffic lane and an eastbound traffic lane divided by a separation zone. The Southeastern approach consists of a northwesterly traffic lane and a southeasterly traffic lane divided by a separation zone. The precautionary area consists of an eight mile radius centered upon Harbor of Refuge light.

The study showed that navigation safety, economic, and environmental considerations necessitate establishment of a TSS to better separate large inbound vessels from tug and barge traffic transiting easterly and northerly along their traditional New Jersey coastal route. In the current configuration near misses occur much too frequently. The probability of a major chemical or petroleum oil spill is much too great to ignore. Therefore, the Coast Guard is proposing to adjust the Eastern Approach TSS, establish a Two-Way Traffic Route for tug and barge traffic entering and departing Delaware Bay, and reconfigure the precautionary area. The proposed changes have already been adopted by IMO, and barring any changes resulting from this rulemaking, will be implemented in June 1997.

Discussion of Proposed Rules

The proposed Eastern approach would still consist of a traffic lane for westbound traffic and a traffic lane for eastbound traffic divided by a separation zone, but the west end of the northern boundary of the TSS would be rotated clockwise to the position of Delaware Bay North Approach Lighted Bell Buoy 2 (LLNR 1475).

The Southeastern approach would remain unchanged, but would be added to the CFR. It consists of a north-westbound traffic lane and a south-eastbound traffic lane divided by a separation zone.

The proposed Two-Way Traffic Route would start north of the Eastern approach and would follow the general contour of the New Jersey coast heading southwesterly, then west before turning back to the northwest. This route would better separate tug and tow traffic from large inbound traffic in the Eastern approach. This route would not be for the exclusive use of tug and tow traffic, but would be available for use by all vessels with a draft that enables them to operate safely.

Reconfiguring the Precautionary area, as proposed, would remove areas that cannot be used by deep draft vessels due to the naturally available water depths and more accurately reflects to the international mariner where caution should be exercised.

Regulatory Evaluation

This proposal is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary since this proposal is an adjustment of an existing TSS which will provide a much higher degree of safety.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposal, if adopted, will have a significant economic impact on a substantial number of small entities. ''Small entities'' may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000.

The adjustment of the existing TSS provides an increased level of safety for mariners using the TSS thereby decreasing any adverse economic effect on the region due to a potential collision. Because it expects the impact of this proposal to be minimal, the Coast

Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposal contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this proposal under the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

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

List of Subjects in 33 CFR Part 167

Navigation (water), Traffic separation schemes, Vessels.

In consideration of the foregoing, the Coast Guard proposes to amend 33 CFR part 167 as set forth below.

PART 167—OFFSHORE TRAFFIC SEPARATION SCHEMES

1. The authority citation for part 167 continues to read as follows:

Authority: 33 U.S.C. 1223; 49 CFR 1.46.

2. Section 167.5 is amended to add paragraph (f) to read as follows:

§ 167.5 Definitions.

* * * * *

(f) Two-way route means a route within defined limits inside which two way traffic is established, aimed at providing safe passage of ships through waters where navigation is difficult or dangerous.

3. Sections 167.170 through 167.174 are added to read as follows:

§ 167.170 Off Delaware Bay Approach Traffic Separation Scheme and Precautionary Area.

The Off Delaware Bay Traffic Separation Scheme consists of four parts: An Eastern approach, a South-eastern approach, a Two-Way Traffic Route, and a precautionary area. The specific areas of the Off Delaware Bay Traffic Separation Scheme and Precautionary Area are described in § 166.171, § 167.172, § 167.173, and § 167.174 of this chapter.

§ 167.171 Eastern approach.

(a) A separation zone is established bounded by a line connecting the following points:

Latitude	Longitude
38°46′18″ N	74°35′27″ W
38°46′20″ N	74°55′45″ W
38°47′27″ N	74°55′24″ W
38°47′21″ N	74°34′30″ W

(b) A traffic lane for westbound traffic is established between the northern side of the separation zone and a line connecting the following points:

Latitude	Longitude
38°46′19″ N	74°55′18″ W
38°49′40″ N	74°36′45″ W

(c) A traffic lane for eastbound traffic is established between the south side of the separation zone and a line connecting the following points:

Latitude	Longitude
38°45′27″ N	74°56′12″ W
38°44′27″ N	74°34′21″ W

§ 167.172 Southeastern approach.

(a) A separation zone is established bounded by a line connecting the following points:

Latitude	Longitude
38°27′00″ N	74°42′17″ W
38°43′24″ N	74°57′59″ W
38°44′12″ N	74°57′11″ W
38°27′36″ N	74°41′17″ W

(b) A traffic lane for north-westbound traffic is established between the northeastern side of the separation zone and a line connecting the following points:

Latitude	Longitude
38°28′48″ N	74°39′17″ W
38°45′06″ N	74°56′35″ W

(c) A traffic lane for south-eastbound traffic is established between the southwestern side of the separation zone and a line connecting the following points:

Latitude	Longitude
38°42′48″ N	74°58′53″ W
38°27′00″ N	74°45′23″ W

§ 167.173 Two-Way Traffic Route.

The Two-Way Traffic Route is recommended for use predominantly by tug and tow traffic transiting to and from the North East in order to separate such traffic from large, inbound vessel traffic.

(a) The Two-Way Traffic Route is bounded on the west and south by a line connecting the following points:

Latitude	Longitude
38°50′45″ N	75°03′24″ W
38°47′30″ N	75°01′48″ W
38°48′19″ N	74°55′18″ W
38°50′12″ N	74°49′44″ W
39°00′00″ N	74°40′14″ W

(b) The Two-Way Traffic Route is bounded on the east and north by a line connecting the following points:

Latitude	Longitude
39°00′00″ N	74°41′00″ W
38°50′29″ N	74°50′18″ W
38°48′48″ N	74°55′15″ W
38°48′20″ N	74°59′18″ W
38°49′06″ N	75°01′39″ W
38°51′16″ N	75°02′50″ W

§ 167.174 Precautionary area.

The Precautionary area is defined as follows: from 38°42′48″ N, 74°58′54″ W; thence northerly by an arc of eight nautical miles centered at 38°48′54″ N, 75°05′36″ W to 38°47′27″ N, 74°55′18″ W; thence westerly to 38°47′30″ N, 75°01′48″ W; thence northerly to 38°50′45″ N, 75°03′24″ W; thence northeasterly to 38°51′16″ N, 75°02′50″ W; thence northerly to 38°54′48″ N, 75°01′36″ W; thence westerly by an arc of 6.7 nautical miles centered at 38°48′54″ N, 75°05′36″ W to 38°55′32″ N, 75°05′52″ W; thence southwesterly to 38°54′00″ N, 75°08′00″ W; thence southerly to 38°42′48″ N, 74°58′54″ W. Datum: NAD 83.

Dated: February 25, 1997.

G.N. Naccara,

Acting Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 97–12254 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–14–M

POSTAL RATE COMMISSION

39 CFR Part 3001

[Docket No. RM97–2; Order No. 1174]

Amendment to Rules Concerning Evidence Based on Market Research

AGENCY: Postal Rate Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission proposes to amend its rules of practice by clarifying foundational requirements for market research evidence. The amendment entails three substantive revisions. One requires a survey sponsor to provide additional supporting information about technical aspects of the market research. Another provides for participants using statistical techniques to limit the possibility of disclosing the identity of a survey respondent and data uniquely associated with that respondent. The third clarifies the level of access to data files and computer programs that is to be provided, including the stage at which rights to replication of survey results attach. These revisions will clarify rule 31(k)(2)'s applicability to market research, thereby reducing the need for case-by-case determinations and minimizing the potential for delay in issuing Commission recommendations. The amendment also makes minor editorial improvements in rule 31(k).

DATES: Comments responding to this notice of proposed rulemaking must be submitted on or before June 9, 1997.

ADDRESS: Comments and correspondence should be sent to Margaret P. Crenshaw, Secretary of the Commission, 1333 H Street NW, Suite 300, Washington, DC 20268–0001 (telephone: 202/789–6840).

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, Legal Advisor, Postal Rate Commission, 1333 H Street NW., Suite 300, Washington, DC, 20268–0001, (telephone: 202/789–6820).

SUPPLEMENTARY INFORMATION: Rule 31(k) outlines foundational requirements for studies and analyses offered as evidence to be relied upon in Commission proceedings. *See* 39 CFR 3001.31(k). Submissions within the rule's purview are subject either to the terms of rule 31(k)(1) or to similar provisions tailored to specific types of statistical studies and computer analyses. *See generally* rule 31(k)(2) and (k)(3) (39 CFR 3001.31(k)(2) and (k)(3)). These requirements call for a description of the study plan, relevant assumptions, data collection techniques, the facts and judgments upon which conclusions are based, alternative courses of action considered, and certain other supporting information and data. This material must be filed along with the related study or be produced upon request.

Rule 31(k) generally reflects settled evidentiary principles, but persistent questions have arisen in recent proceedings about the impact of certain market research practices on the interpretation of paragraphs (k)(2) and (3). The debate has centered primarily on three major—and often interrelated—concerns. One is the interest survey sponsors assert in providing survey participants with reasonable assurances that their participation in the survey and the sensitive commercial data or information provided in their responses will not be disclosed. Another is reviewers' interests in replicating survey results and, in certain instances, in using a preferred method to accomplish that end. A third issue is the impact of computer-assisted data collection (CADC) techniques on compliance with rule 31(k)'s requirement that ''input data'' be provided. *See* PRC Op. MC93–1, paras. 117–122; *see also* PRC Op. MC95–1, Appendix C. CADC techniques, in particular, have altered some participants' expectations about how—and whether—rule 31(k)'s data disclosure requirements apply to certain market research efforts.

The Commission has resolved conflicts on a case-by-case basis, but finds that revising the rule to provide participants with additional guidance on how market research submissions should be supported is warranted. PRC Op. MC95–1, Appendix C at 1–2. Having had an opportunity to review pertinent issues and concerns outside the constraints imposed by motion practice, the Commission has made preliminary determinations about the manner in which rule 31(k) should be revised.

Postponement of Comprehensive Revisions

While developing an amendment to address problematic aspects of market research submissions, the Commission also considered proposing a comprehensive reorganization of rule 31(k). Structurally, a comprehensive review would permit redundant or overlapping requirements to be modified or eliminated, thereby simplifying a rule that has been the subject of several amendments. In addition, consideration could be given to whether the numerous provisions now covered in paragraph (k) should continue to be located within rule 31, which is an umbrella evidentiary provision, or whether they should form an independent provision.

Substantively, a broader focus would provide an opportunity to address the advisability of maintaining certain formal distinctions within the rule, such as a special set of requirements for computer-based studies. Computer-specific provisions were added to the rule (in subparagraph (3)) in the early 1980s, when the use of computers to prepare or develop evidence was in its infancy and several related evidentiary issues were unsettled. Since then, computer use has become routine not only for submissions covered by rule 31(k)(3), but in the preparation of nearly every filing in Commission proceedings. Thus, the rule's underlying orientation may warrant reconsideration. At a minimum, revisions to subparagraph (3) and conforming changes in other provisions may need to be made. *See generally* Docket No. RM81–1, Notice of Proposed Rulemaking (NPRM) at 5. Similarly, the need for distinctions between studies that involve statistics and those that do not could be reviewed. Moreover, a broader approach might allow issues related to the emergence of electronic data bases, from which a number of different studies and analyses can be developed, to be explored.

The Commission's interest in updating and reorganizing the rule is tempered with a concern that wholesale revision might unduly delay addressing the questions that have surfaced about market research. Based on this consideration and an assessment that other aspects of the rule appear to be working reasonably well, the Commission has decided to propose only limited changes now. Accordingly, the proposed amendment has been drafted to conform, as closely as possible, to the existing approach and to cause minimal disruption to the current numbering system. Structurally, this is accomplished primarily by distinguishing market research from other sample surveys, with the requirements specific to market research designated as rule 31(k)(2)(i). Existing rule 31(k)(2)(i), now entitled ''Sample surveys,'' is renamed ''Other sample surveys'' and redesignated as rule 31(k)(2)(ii). Conforming numbering changes are also made to other subparagraphs of the rule. Substantively, the Commission notes that this amendment is not inconsistent with its recent statement, in PRC Op. MC96–3, that the existing rules on sample surveys require certain quantitative disclosures. *See generally* PRC Op. MC96–3 at 37–38. Given its general position on the scope of the existing sample survey requirements, the Commission is not proposing to make them more explicit at this time.

Expanded Foundational Requirements for Market Research-Based Submissions

Rule 31(k) now provides, in subparagraph (2)(i)(*a*), that a proponent of a sample survey is to provide a clear description of the survey design, including the definition of the universe

under study, the sampling frame and units, and the validity and confidence limits that can be placed on major estimates. The rule also provides, in subparagraph (2)(i)(*b*), that the survey sponsor provide an explanation of the methods of selecting the sample and the characteristics measured or counted.

These provisions generally provide a straightforward and serviceable base for evaluating sample surveys. However, given the growing importance of market research in Commission proceedings, it appears advantageous to be more specific about the detail sponsors should provide at the time the market research (or the submission it supports) is filed. This also is consistent with the Commission's view, previously expressed in connection with survey replication, that providing descriptions of technical procedures can provide reviewers with the ability to make an assessment, from the description itself, of the appropriateness of various standard procedures. *See* PRC Op. MC95–1, Appendix C at 7.

The Commission therefore proposes to specify, in § 3001.31(k)(2)(i)(*a*)(*1*), that the foundational requirements include details of the sampling, observational, and data preparation designs, with definitions of the target population, sampling frame, units of analysis and survey variables. These requirements also include an explanation of the methodology for the production and analysis of the major estimates and the associated sampling errors. Proposed § 3001.31(k)(2)(i)(*a*)(*2*) requires that the proponent not only provide measures of sampling error, but also present coverage, response and editing rates.

In addition to these changes, which are primarily adaptations of existing requirements for sample surveys, the Commission is also proposing four new foundational requirements. Proposed subparagraph (*a*)(*3*) requires a discussion of data comparability over time and with other data sources, and the effects of benchmarking and revisions. ''Benchmarking,'' in this context, refers to establishing an acceptable standard by which to evaluate estimates. Subparagraph (*a*)(*4*) requires an assessment of the effects of editing and imputation and other potential sources of error on the quality of the survey estimates. Subparagraph (*a*)(*5*) requires identification of applicable statistical models when model-based procedures are employed. Finally, subparagraph (*a*)(*6*) requires an explanation of all statistical tests performed and an appropriate set of summary statistics summarizing the results of each test.

Confidentiality

Confidentiality issues have dominated recent motion practice, and they have been a concern for some time. In Docket No. RM81–1, for example, the American Bankers Association (ABA) filed comments noting that compliance with a requirement of producing actual input data upon request could pose difficulties because of confidentiality promises. In evaluating ABA's position, the Commission noted that the provision in question was not a new element of the proposal under consideration, but had been in effect for several years without creating serious difficulties. The Commission concluded, at that time, that it preferred to continue its practice of addressing special needs for confidentiality as they arose, rather than alter the general rule to meet exceptional cases. Docket No. RM81–1, Final (Rulemaking) Notice at 11. In PRC Op. MC95–1, however, the Commission clearly signaled its interest in ending this practice by stating that it intended to institute a rulemaking and explore whether a widely-applicable standard or policy statement on the confidentiality of market research data and information could be developed.

The Commission has made a preliminary determination that the continuing motion practice on this topic confirms the need for a revision to its existing practice, and that statistical disclosure limitation (SDL) methods provide a workable, objective standard. SDL methods are techniques that limit the risk of disclosure of individual information when statistics are disseminated in tabular or microdata formats. These practices are not new, but have been developed and implemented by various federal agencies over the past 25 years. *See generally* Jabine, Thomas B., ''Statistical Disclosure Limitation Practices of United States Statistical Agencies,'' Journal of Official Statistics, Vol. 9, No. 2 (1993) at 427–454.

In conjunction with this rulemaking, the Commission is establishing, for participants' convenience, Library Reference PRC–LR–1, containing Statistical Policy Working Paper 22, ''Report on Statistical Disclosure Limitation Methodology'' (May 1994), (hereafter, Working Paper). The report was prepared by the Subcommittee on Disclosure Limitation Methodology of the Federal Committee on Statistical Methodology, which is associated with the Statistical Policy Office of the Office of Information and Regulatory Affairs of the Office of Management and Budget. The preface indicates that the report includes a tutorial, guidelines, various recommendations, and an annotated bibliography. The Commission notes that the report specifically indicates that legal questions are beyond its scope. Working Paper at 2. An excerpt on survey research from the ''Reference Manual on Scientific Evidence,'' published by the Federal Judicial Center in 1994, is also included in the library reference.

The specific provision the Commission proposes adding, in new rule 31(k)(2)(i)(*b*) is: ''Protection against disclosure of sensitive data should be provided through the application of appropriate statistical disclosure limitation (SDL) practices when data are produced for secondary analysis.'' The rule indicates that SDL practices include the following: Removal of respondent identifiers from microdata files; cell concentration and suppression rules; and data masking through aggregation, random noise injection, and simulation of artificial records.

In the sense used in the rule, a *microdata file* consists of individual records, each containing values of variables for a single person, business establishment or other unit. Id. at 3. There are no identifiers on the file, and the data may be disguised in some way to ensure that the individual data items cannot be uniquely associated with a particular respondent. Id. at 6. *Cell concentration* means that a specific number of cases in a given cell of a data table cannot account for a percentage of the cell total equal to or exceeding a prescribed threshold; that is, the (n,p) cell concentration rule is violated if n or fewer respondents account for at least p percent of the total cell value. If this rule is violated, the cell is *suppressed* or collapsed with other cells to reduce the risk of disclosure. *Data masking* entails distorting data prior to its release or limiting the amount of data released. It can involve random error (noise) to the data entries, multiplying the data by random values from known distributions, or *data swapping.* The latter refers to the practice of interchanging the values for survey items of sample cases having similar characteristics or values for auxiliary variables.

The proposed rule also provides that statistical disclosure is defined as the identification of the respondent or the linking of a respondent to sensitive data in a survey record or data file. The revised rule also affirmatively states that under certain conditions, the post-SDL data shall be the starting point for an evaluation on the merits.

The Commission recognizes that its endorsement of SDL techniques as a means of limiting disclosure

presupposes certain expertise on the part of both survey sponsors and survey reviewers. However, the complexity of the surveys that have been at the center of recent motion practice indicate that the sponsor (in most cases, the Postal Service) would have access to the resources needed to meet the rule's standard. To the extent that survey reviewers might need assistance in understanding the discovery implications of the SDL techniques, technical conferences or other forms of assistance can be made available.

Reviewers' Access to Data, Including Replication of Survey Results

As with confidentiality, replication of survey results also has been an issue over the course of several proceedings. In Docket No. RM81–1, for example, the Postal Service questioned whether the word ''replicate'' in the proposed rule imposed too broad a standard. The Commission concluded that it did not, emphasizing that the fact that this term was not explicitly used in the final rule reflected a technical drafting decision, rather than a substantive change in position. The Commission said: ''We think it is clear—even without express use of this term—that the final rule allows a participant, upon proper request, to obtain materials that would allow replication of the results of computer-generated presentations.'' Final (Rulemaking) Notice at 13.

By Docket No. MC95–1 the question of what ''materials'' should be made available had come to the fore, and the Commission noted that newer market research techniques complicated the issue. It cautioned:

> (P)articipants' insistence on the ability to trace a numerical result from CADC market research to the primary data source by replicating various data adjustments may often be very impractical, and sometimes simply impossible. The task of verifying a specific numerical result could, in itself, entail running a rather extensive set of complex computer programs associated with the survey's data collection, editing, coding, estimation and analysis procedures.

PRC Op. MC95–1, Appendix C at 6. In a related comment, the Commission noted that it viewed the overall objective of the rule as ''* * * placing reviewers in a position to determine whether the data are sufficiently accurate to satisfy the (evidentiary) standards the Commission must apply.'' Id.

The Commission also noted that one difficulty in resolving disputes is that several key terms in rule 31(k) are not defined. The Commission suggested that consideration should be given to whether inclusion of a set of definitions or guidelines for interpretation might be useful. At this time, the Commission has decided against including definitions of the proposed SDL techniques in the rule, but is clarifying the meaning of ''input file.'' In addressing participants'' uncertainty over the meaning of this term, the Commission has noted previously that an ''input file'' can be *any* data set that is entered into a statistical program or package designed for a specific purpose, and that it is therefore

> * * * unlikely that the ''raw data'' and the ''input data'' for adjustment and estimation programs would be coincidental in a moderate-to-large survey research effort. This is because the raw data are usually modified to some extent—even if no more than recoded—before they are entered in a database.

PRC Op. MC95–1, Appendix C at 4. To address this situation, the Commission proposes a new provision—in rule 31(k)(2)(i)(*b*)—providing that access ''shall be sufficient to permit the replication of electronic data processing after production of the edited data file.'' The term ''edited data file'' is defined in the rule as raw data after appropriate coding, editing for consistency checks and application of SDL methodology.''

Availability of Opportunity To Request Waiver

Assuming adoption of the proposed amendment, the Commission expects participants to exercise all reasonable efforts to comply with its terms, including the use of SDL methods. To the extent a participant believes it cannot do so, but nevertheless seeks evidentiary status for affected submissions, a separate rule of practice—rule 22—provides an opportunity to seek waiver, in whole or in part, by filing a timely motion. *See* 39 CFR 3001.22. Waiver is conditioned on a showing that the interests of other participants will not be unduly prejudiced, and that it is consistent with the public interest and the Commission's discharge of its responsibilities. Given these conditions, the Commission expects that a participant seeking relief from application of the new requirements would propose, at a minimum, alternative means of satisfying the interests sought to be protected by rule 31(k).

Limited Editorial Improvements

The Commission is also proposing limited editorial improvements in § 3001.31(k)(3) at this time. One entails the proposed deletion of a citation to outdated software documentation standards. These standards were current when the related text was added to rule 31(k) in the early 1980s, but are now seriously outdated and, in some instances, out of print. The Commission has considered, but rejected, replacing these references with more current standards, on the assumption that participants no longer need to be provided with examples of documentation. Thus, the proposed amendment eliminates the footnote citation associated with the word ''standards'' in the main text of rule 31(k)(3)(i)(*e*) and deletes the related footnote in its entirety. The Commission also considered replacing the reference to ''magnetic tape'' in rule 31(k)(3)(i)(*i*) with a more generic term or phrase, but instead decided to change it to ''a compact disc.'' The Commission invites comments on retaining the reference in the same provision to a time-sharing service.

Comments

To assist commenters in preparing a response to this proposal, the Commission reiterates its conscious decision to keep the focus of this rulemaking comparatively limited. Thus, this proposal addresses the existing sample survey provisions only in the sense of their application to market research. Within this framework, commenters are invited to submit comments addressing pertinent issues. In particular, the Commission welcomes attention to the following matters:

- Whether participants anticipate difficulties in employing SDL methods and, if so, what these might be;
- Whether participants are aware of any supplementary methods or approaches that could or should be included in the rule;
- Whether the general availability of an opportunity to request waiver under rule 22 is sufficient, or whether waiver should be further conditioned or restricted through express language in rule 31(k)(3);
- Whether the definitions in this Notice of Proposed Rulemaking provide participants with sufficient information on SDL techniques;
- Whether the Commission's assumption that a reference to specific software standards is no longer needed is correct, or whether the standards should be updated; and
- Whether other minor editorial revisions in rule 31(k) are necessary or desirable at this time, and can be incorporated with minimal disruption.

List of Subjects in 39 CFR Part 3001

Administrative practice and procedures, Postal Service.

For the reasons set forth in the preamble, 39 CFR Part 3001 is amended as follows:

PART 3001—RULES OF PRACTICE AND PROCEDURE

1. The authority citation for 39 CFR part 3001 continues to read as follows:

Authority: 39 U.S.C 404(b), 3603, 3622–24, 3661, 3662.

2. 39 CFR 3001.31(k) is amended as follows:

3. Redesignate paragraph (k)(2)(i) through (iii) as (k)(2)(ii) through (iv).

4. Amend redesignated paragraph (k)(2)(ii) by changing the title from *Sample surveys* to *Other sample surveys.*

5. Add paragraph (k)(2)(i) to read as follows:

§ 3001.31 Evidence

* * * * *

(k) *Introduction and reliance upon studies and analyses*—(1) * * *

(2) * * *

(i) *Market research.* (*a*) The following data and information shall be provided: (*1*) A clear and detailed description of the sampling, observational, and data preparation designs, including definitions of the target population, sampling frame, units of analysis, and survey variables;

(*2*) an explanation of methodology for the production and analysis of the major survey estimates and associated sampling errors;

(*3*) a presentation of response, coverage and editing rates;

(*4*) a discussion of data comparability over time and with other data sources, and the effects of benchmarking and revisions;

(*5*) an assessment of the effects of editing and imputation and other potential sources of error on the quality of the survey estimates;

(*6*) identification of applicable statistical models, when model-based procedures are employed;

(*7*) an explanation of all statistical tests performed and an appropriate set of summary statistics summarizing the results of each test.

(*b*) Upon request, access to data files and computer programs shall be provided. Access shall be sufficient to permit replication of results after development of the edited data file. For purposes of this subparagraph, the phrase ''edited data file'' refers to raw data after appropriate coding, editing for consistency checks and application of statistical disclosure limitation methods (SDL) methods.

(*c*) *Protection against disclosure of confidential commercial data.* (*1*) If the recipient of a request for data pursuant to this paragraph asserts that compliance with the request would conflict with a confidentiality agreement, the recipient shall be expected to employ SDL methods to protect against the disclosure of confidential commercial data. The SDL method(s) selected shall not interfere with other reasonable or expected uses of the data.

(*2*) For purposes of this subparagraph, SDL methods include the removal of respondent identifiers from microdata files; cell concentration and suppression rules; and data masking through aggregation, ''random noise'' injection, and simulation of artificial records. Statistical disclosure means the identification of the respondent or the linking of a respondent to sensitive data in a tabular presentation, survey record or data file.

(*3*) If the results or conclusions reached after application of the SDL method(s) differ materially from those reached prior to such application, the post-SDL data shall be deemed controlling for purposes of the sponsoring party's evidentiary presentation and related legal argument.

6. Revising paragraph (k)(3)(i)(*e*) to read as follows:

* * * * *

(k) * * *

(3) * * *

(i) * * *

(*e*) For all source codes, documentation sufficiently comprehensive and detailed to satisfy generally accepted software documentation standards appropriate to the type of program and its intended use in the proceeding.

7. Revise the first sentence of the concluding text after paragraph (k)(3)(i)(*i*) to read as follows:

* * * * *

(k) * * *

(3) * * *

(i) * * *

(*i*) * * *

Paragraphs (k)(3)(i)(*d*) and (*f*) of this section shall be provided either in the form of a compact disc or through access to a time-sharing service, at the option of the provider. * * *

Issued by the Commission on May 2, 1997.

Margaret P. Crenshaw,

Secretary.

[FR Doc. 97–12191 Filed 5–8–97; 8:45 am]

BILLING CODE 7710–FW–P

Notices

Federal Register
Vol. 62, No. 90
Friday, May 9, 1997

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. DA–97–04]

Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Agricultural Marketing Service's (AMS) intention to request an extension for and revision to a currently approved information collection for National Research, Promotion, and Consumer Information Programs for Agricultural Marketing Service.

DATES: Comments on this notice must be received on or before July 8, 1997 to be assured of consideration.

ADDITIONAL INFORMATION OR COMMENTS: Contact Eugene E. Krueger, Promotion and Research Staff, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 96456, Rm. 2734—South, Washington DC 20090, Telephone (202) 720–6909 and Fax (202) 720–0285.

SUPPLEMENTARY INFORMATION:

Title: National Research, Promotion, and Consumer Information Programs for Agricultural Marketing Service.

OMB Number: 0581–0093.

Expiration Date of Approval: Current expiration date is 10/31/97.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: National research and promotion programs are designed to strengthen the position of a commodity in the marketplace, maintain and expand existing domestic and foreign markets, and develop new uses and markets for specified agricultural commodities. These programs carry out projects relating to research, consumer information, advertising, sales promotion, producer information, market development, and product research to assist, improve, or promote the marketing, distribution, and utilization of their respective commodities. Approval of the programs is required through referendum of those who would be covered. The programs are directed by industry boards. These boards, usually composed of producer, handler, processor, and in some cases, importer and public members, are appointed by the Secretary of Agriculture to administer the programs. The funding for such programs is collected from designated industry segments, usually through deductions from sales by producers, processors, marketers, and/or importers. The appointed boards are responsible for collecting assessments from the affected persons covered under these programs.

The Secretary also approves the boards' budgets, plans, and projects. These responsibilities have been delegated to the Agricultural Marketing Service (AMS). The applicable commodity divisions within AMS have direct oversight of the respective programs.

The information collection requirements in this request are essential to carry out the intents of the various Acts authorizing such programs, thereby providing a means of administering the programs. The forms covered under this collection require the minimum information necessary to effectively carry out the requirements of the respective orders, and their use is necessary to fulfill the intents of the Acts as expressed in the orders. The information collected is used only by authorized employees of the various boards and authorized employees of USDA.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .0826125 hours per response.

Respondents: Producers, processors, handlers, and/or importers of a variety of agricultural commodities.

Estimated Number of Respondents: Total respondents are estimated to be 319,342.

Estimated Number of Responses per Respondent: Number of responses per respondent varies between programs but is estimated to average 13.90636.

Estimated Total Annual Burden on Respondents: Estimated total annual burden is 366,873 hours.

Comments are invited on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Eugene E. Krueger, Promotion and Research Staff, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 96456, Rm.2734-South, Washington D.C., 20090. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: May 5, 1997.

Richard M. McKee,

Director, Dairy Division.

[FR Doc. 97–12092 Filed 5–8–97; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Tusayan Growth Environmental Impact Statement, Kaibab National Forest, Coconino County, Arizona.

AGENCY: Forest Service, USDA.

ACTION: Revised Notice of Intent to prepare an environmental impact statement.

SUMMARY: In the March 8, 1994, edition of the **Federal Register,** page 10781, the Forest Service published a Notice of Intent (NOI) to prepare an environmental impact statement (EIS) on a proposed land exchange in the

Kaibab National Forest. This revised NOI is being published to give notice that the scope of the alternatives being considered in the EIS has broadened, and that the schedule for filing the draft and final EIS has been changed.

DATES: Comments in response to this Notice of Intent concerning the scope of the analysis should be received by June 13, 1997.

ADDRESSES: Written comments concerning this EIS should be sent to Tusayan Growth EIS, Kaibab National Forest, 800 South Sixth Street, Williams, Arizona 86046.

RESPONSIBLE OFFICIAL: Regional Forester for the Southwestern Region, Charles W. Cartwright, Jr., is the Responsible Official.

FOR FURTHER INFORMATION: Questions about the EIS should be directed to Dennis Lund, Forest Lands Staff Officer, or Tom Gillett, Forest Lands Staff Assistant, (520) 635–8200.

SUPPLEMENTARY INFORMATION: The March 1994 NOI featured the proposed land exchange as a method for providing an expanded land base in the Tusayan/Grand Canyon area to address needs related to the transportation, housing, community facilities, and visitor services.

Five alternatives are being considered in the EIS that examine different ways of accommodating area needs through the use or acquisition of National Forest System (NFS) lands. The alternatives include the ''no action'' alternative, several land exchange options in which area needs would be met through the development of NFS lands acquired through exchange, a Townsite Act alternative in which standard community facilities would be constructed on NFS lands acquired through the Townsite Act and on NFS lands under special use permit, and a transportation/federal housing alternative that accommodates imminent National Park Service needs for housing and transportation facilities. A preferred alternative will not be identified in the draft EIS.

The decision to be made is: (1) Whether or not to use NFS land for community expansion and additional visitor services and facilities, including construction of a transportation staging area for Grand Canyon National Park visitors; and (2) if NFS land is to be so used, what method or combination of methods of acquiring access to NFS land best meets the needs of the area.

The Forest Service is the lead agency in the preparation of the EIS. The National Park Service, Coconino County, and Northern Arizona Council of Governments are cooperating agencies.

Issues that have been identified through public scoping include the socio-economic impacts to outlying communities that rely heavily on tourism related to Grand Canyon National Park visitation, the availability of water for development of the NFS lands, the impact on proposed development on Grand Canyon water resources, impacts on the management and visitation to Grand Canyon National Park, impacts on the visitor experience, development plan assurances, and impacts to National Forest resources and management including fire, recreation, cultural, wildlife and threatened, endangered, and sensitive species.

Various federal, state and local regulatory permits, approvals and licenses would be required under federal and state law beyond the decision made in the EIS for the proposed development of the NFS land. These requirements could include conditional use permits, building permits, occupancy permits and resource protection permits and licenses.

Extensive public participation, or scoping (40 CFR 1501.7), has occurred during the preparation of the draft EIS. A series of nine public meetings was held initially in the spring of 1994. Numerous presentations have been made to chambers of commerce in the region, American Indian Tribe representatives and various organizations. A series of seven newsletters, each focusing on different aspects of the EIS, have been prepared and distributed as part of the public involvement process from March 1995 through November 1996.

The draft EIS is expected to be available for public review by late May or June 1997 (the earlier NOI specified a target release date of February 1995 for draft EIS and a projected release date of October 1995 for the final EIS). The comment period on the draft EIS will be 90 days from the date the Environmental Protection Agency publishes a notice of availability in the **Federal Register**.

The final EIS is expected to be completed by May or June 1998. In the final EIS, the Forest Service will respond to comments received during the comment period on the draft EIS. The Responsible Official will decide which, if any, of the alternatives will be implemented. The Responsible Official will document the decision and reasons for the decision in the Record of Decision. That decision will be subject to Forest Service appeal regulations in 36 CFR 217.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* versus *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45 day comment period so that substantive comment and objections are made available to the Forest Service in a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision under 36 CFR Part 215. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of

Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under the FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address.

Dated: April 29, 1997.

Louis Volk, Jr.,

Acting Regional Forester.

[FR Doc. 97–12071 Filed 5–8–97; 8:45 am]

BILLING CODE 3410–11–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds to the Procurement List commodities to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: June 9, 1997.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On December 6, 1996, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (61 F.R. 64666) of proposed addition to the Procurement List. Comments were received from both current contractors for the paper. One contractor's comments appeared to question the capability of the designated nonprofit agency to produce the paper. The other contractor indicated that it needed all the business it had to remain profitable and retain its employees.

The nonprofit agency was found capable based on an inspection and affirmative capability finding by the Government agency which buys the paper. The impact of the addition on the two contractors is well below the level which the Committee considers to be severe adverse impact. Accordingly, it is unlikely that either contractor's employees will lose their jobs.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and impact of the addition on the current or most recent contractors, the Committee has determined that the commodities listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities.

3. The action will result in authorizing small entities to furnish the commodities to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities proposed for addition to the Procurement List.

Accordingly, the following commodities are hereby added to the Procurement List:

Paper, Kraft Wrapping
8135–00–160–7762
8135–00–160–7776
8135–00–160–7778
8135–00–160–7758
8135–00–286–7317
8135–00–160–7771
8135–00–160–7769
8135–00–160–7768
8135–00–160–7766
8135–00–160–7759
8135–00–160–7757
8135–00–160–7753
8135–00–160–7752
8135–00–160–7764
8135–00–290–3407
8135–00–160–7772
8135–00–160–7770

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 97–12184 Filed 5–8–97; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: June 9, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46—48c) in connection with the commodities and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Dog Bones
M.R. 405 thru 411
NPA: Wiscraft Inc.—Wisconsin Enterprises for the Blind, Milwaukee, Wisconsin

Services

Grounds Maintenance
Smithsonian National Gallery of Art, 6th & Constitution Avenue, NW, Washington, DC
NPA: Melwood Horticultural Training Center, Upper Marlboro, Maryland
Janitorial/Custodial
DoD Center, Monterey, California
NPA: Hope Rehabilitation Services, Santa Clara, California

Beverly L. Milkman,

Executive Director.

[FR Doc. 97–12185 Filed 5–8–97; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the procurement list.

SUMMARY: This action adds to the Procurement List commodities and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: June 9, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On March 17 and 21, 1997, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (62 FR 12596 and 13591) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and service and impact of the additions on the current or most recent contractors, the Committee has determined that the commodities and service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and service to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities and service.

3. The action will result in authorizing small entities to furnish the commodities and service to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and service proposed for addition to the Procurement List.

Accordingly, the following commodities and service are hereby added to the Procurement List:

Commodities

Gasket
5330–00–599–4230
Helmet Assembly, Combat Vehicle Crewman
8470–00–NIB–0003
(Requirements for the U.S. Army Soldier Systems Command, Natick, Massachusetts)

Service

Customer Service Representatives
FISC SERVMART Division, Norfolk, Virginia

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 97–12186 Filed 5–8–97; 8:45 am]

BILLING CODE 6353–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Connecticut Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Connecticut Advisory Committee to the Commission will convene at 12:30 p.m. and adjourn at 4:30 p.m. on Friday, May 23, 1997, at the Catholic Charities, Conference Room, 467 Bloomfield Avenue in Bloomfield, Connecticut 06002. The purpose of the meeting is to discuss and plan details of the forthcoming civil rights leadership conference to be held late 1997.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Neil Macy, 860–242–7287, or Ki-Taek Chun, Director of the Eastern Regional Office, 202–376–7533 (TDD 202–376–8116). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 2, 1997.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 97–12198 Filed 5–8–97; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the West Virginia Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the West Virginia Advisory Committee to the Commission will convene at 12:30 p.m. and adjourn at 4:30 p.m., on Wednesday, June 12, 1997, at the Veteran's Affairs Medical Center Building 500, 3rd Floor, Room 3A–141, Route 9, Martinsburg, West Virginia 25401. The purpose of the meeting is to plan a project activity for fiscal year 1997 and receive information from invited guests on civil rights issues in West Virginia.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Gregory T. Hinton, 304–367–4244, or Ki-Taek Chun, Director of the Eastern Regional Office, 202–376–7533 (TDD 202–376–8116). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at

least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 2, 1997.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 97–12199 Filed 5–8–97; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Bureau of the Census

The American Community Survey

ACTION: Proposed Collection; Comment Request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paper work and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 8, 1997.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instruments(s) and instructions should be directed to Lawrence S. McGinn, Bureau of the Census, Room 2A, Silver Hill Executive Plaza, Washington, DC 20233–8400, (301) 763–8327.

SUPPLEMENTARY INFORMATION:

I. Abstract

The American Community Survey (ACS), implemented in November 1995, is a continuing full-scale operation of a continuous measurement system. Continuous Measurement is a reengineering of the method for collecting the housing and socio-economic data traditionally collected in the decennial census. It provides data every year instead of once in ten years. It blends the strength of small area estimation from the census with the quality and timeliness of the continuing surveys through a large monthly survey.

The data from the ACS will determine the feasibility of a continuous measurement system that provides socioeconomic data on a continual basis throughout the decade for small areas and small subpopulations.

The ACS is presently conducted in eight survey sites—Fulton County, Pennsylvania; Rockland County, New York; Brevard County, Florida; Multnomah County, Oregon, including the city of Portland; Douglas County, Nebraska; Otero County, New Mexico; Harris and Fort Bend Counties, Texas; and Franklin County, Ohio. The data collected in this survey will be within the general scope and nature of those inquiries covered in the decennial census every ten years.

The continuing research through the American Community Survey of the feasibility of a continuous measurement system in 1998 will include the present survey sites and additional sites in Richland and Kershaw Counties, South Carolina and Broward County, Florida. No changes to the forms used in the ACS or our field operations are proposed.

II. Method of Collection

In the urban areas, the Census Bureau will mail questionnaires to households selected for the ACS. In the rural sites where city-style addresses are not available, Field Representatives will deliver the questionnaires to the household. Participation of the selected households is mandatory in accordance with the provisions of Title 13. For those households not returning the questionnaire, we will collect household information by both telephone interview and personal visit.

III. Data

OMB Number: 0607–0810.

Form Number: ACS–1/1A, ACS–10/10A, ACS–12(L)/12A(L), ACS–13(L)/13A(L), ACS–14(L)/14A(L), ACS–15(L), ACS–16(L), ACS–20/20A, ACS–30/30A.

Type of Review: Regular.

Affected Public: Individuals or households.

Estimated Number of Respondents: 260,000.

Estimated Time Per Response: 30 minutes.

Estimated Total Annual Burden Hours: 130,000 hours.

Estimated Total Annual Cost: Except for a few minutes of their time, there is no cost to respondents.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collections techniques or others forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 5, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–12088 Filed 5–8–97; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

National Defense Stockpile Market Impact Committee Request for Public Comments

AGENCY: Office of Strategic Industries and Economic Security, Bureau of Export Administration, U.S. Department of Commerce.

ACTION: Notice of request for public comments on the potential market impact of proposed revisions to the current Annual Materials Plan disposal levels of certain commodities currently held in the National Defense Stockpile.

SUMMARY: This notice is to advise the public that the interagency National Defense Stockpile Market Impact Committee is seeking public comment on the potential market impact of the Department of Defense's proposed increase in disposal levels for Analgesics, Columbium (Ferro), Graphite, and Vanadium Pentoxide in the Fiscal Year (FY) 1997 and FY 1998 Annual Materials Plans.

DATES: Comments must be received by May 27, 1997.

ADDRESSES: Written comments should be sent to Richard V. Meyers, Co-Chair, Stockpile Market Impact Committee, Office of Strategic Industries and Economic Security, Room 3876, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; FAX (202) 482–5650.

FOR FURTHER INFORMATION CONTACT: Richard V. Meyers, Office of Strategic Industries and Economic Security, U.S.

Department of Commerce, (202) 482–3634; or Richard Watkins, International Commodities Division, U.S. Department of State, (202) 647–2871; co-chairs of the National Defense Stockpile Market Impact Committee.

SUPPLEMENTARY INFORMATION: Under the authority of the Strategic and Critical Materials Stock Piling Act of 1979, as amended, (50 U.S.C. 98 *et seq.*), the Department of Defense (DOD), as National Defense Stockpile Manager, maintains a stockpile of strategic and critical materials to supply the military, industrial, and essential civilian needs of the United States for national defense. Section 3314 of the Fiscal Year (FY) 1993 National Defense Authorization Act (NDAA) (50 U.S.C. 98h–1) formally established a Market Impact Committee (the Committee) to ''advise the National Defense Stockpile Manager on the projected domestic and foreign economic effects of all acquisitions and disposals of materials from the stockpile. * * *'' The Committee must also balance market impact concerns with the statutory requirement to protect the Government against avoidable loss.

The Committee is comprised of representatives from the Departments of Commerce, State, Agriculture, Defense, Energy, Interior, Treasury and the Federal Emergency Management Agency and is co-chaired by the Departments of Commerce and State. The FY 1993 NDAA directs the Committee to ''consult from time to time with representatives of producers, processors and consumers of the types of materials stored in the stockpile.''

Because of current industry demand and favorable market conditions, DOD has requested the Committee to consider proposed revisions to the Annual Materials Plan (AMP) disposal levels for Analgesics, Columbium (Ferro), Graphite, and Vanadium Pentoxide from the National Defense Stockpile in the Fiscal Year (FY) 1997 and (except Vanadium Pentoxide) FY 1998 AMPs. In order for the Committee to obtain sufficient information to prepare its recommendations to DOD, the Committee requests that interested parties provide comment on the potential market impact of the proposed revised disposals of these commodities as listed below.

Included with the AMP listing of materials below are the proposed maximum disposal quantity for each material. These quantities are not sales target disposal quantities. They are only a statement of the proposed maximum disposal quantity of each material that may be sold in a particular fiscal year. The quantity of each material that will actually be offered for sale will depend on the market for the material at the time as well as on the quantity of material approved for disposal by Congress.

Material	Units	Current FY 1997 quantity	Revised FY 1997 quantity
PROPOSED REVISIONS TO FISCAL YEAR 1997 AMP			
Analgesics	AMA Lb	2,500	64,128
Columbium (Ferro)	Lb Cb	60,000	200,000
Graphite	ST	1,220	2,660
Vanadium Pentoxide	ST V	200	400
PROPOSED REVISIONS TO FISCAL YEAR 1998 AMP			
Analgesics	AMA Lb	2,500	64,128
Columbium (Ferro)	Lb Cb	100,000	200,000
Graphite	ST	1,220	2,660

The Committee requests that interested parties provide written comments, supporting data and documentation, and any other relevant information on the potential market impact of the sale of any of the commodities in the above lists. Although comments in response to this Notice must be received by May 27, 1997 to ensure full consideration by the Committee, interested parties are encouraged to submit additional comments and supporting information at any time thereafter to keep the Committee informed as to the market impact of the sale of the commodities. Public comment is an important element of the Committee's market impact review process.

Public comments received will be made available at the Department of Commerce for public inspection and copying. Material that is national security classified or business confidential will be exempted from public disclosure. Anyone submitting business confidential information should clearly identify the business confidential portion of the submission and also provide a non-confidential submission that can be placed in the public file. Communications from agencies of the United States Government will not be made available for public inspection.

The public record concerning this notice will be maintained in the Bureau of Export Administration's Records Inspection Facility, Room 4525, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, telephone (202) 482–5653. The records in this facility may be inspected and copied in accordance with the regulations published in Part 4 of Title 15 of the Code of Federal Regulations (15 CFR 4.1 *et seq.*).

Information about the inspection and copying of records at the facility may be obtained from Ms. Margaret Cornejo, the Bureau of Export Administration's Freedom of Information Officer, at the above address and telephone number.

Dated: May 6, 1997.

William V. Skidmore,

Acting Director, Strategic Industries and Economic Security.

[FR Doc. 97–12269 Filed 5–8–97; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

Intent To Revoke Antidumping Duty Orders and Findings and To Terminate Suspended Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of intent to revoke antidumping duty orders and findings and to terminate suspended investigations.

SUMMARY: The Department of Commerce (the Department) is notifying the public of its intent to revoke the antidumping duty orders and findings and to terminate the suspended investigations listed below. Domestic interested parties who object to these revocations and terminations must submit their comments in writing no later than the last day of May 1997.

EFFECTIVE DATE: May 9, 1997.

FOR FURTHER INFORMATION CONTACT: Michael Panfeld or the analyst listed under Antidumping Proceeding at: Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, N.W., Washington, D.C. 20230.

SUPPLEMENTARY INFORMATION:

Background

The Department may revoke an antidumping duty order or finding or terminate a suspended investigation if the Secretary of Commerce concludes that it is no longer of interest to interested parties. Accordingly, as required by § 353.25(d)(4) of the Department's regulations, we are notifying the public of our intent to revoke the following antidumping duty orders and findings and to terminate the suspended investigations for which the Department has not received a request to conduct an administrative review for the most recent four consecutive annual anniversary months:

Antidumping Proceeding

Argentina
Rectangular Carbon Steel Tubing
A–357–802
54 FR 22794
May 26, 1989
Contact: Tom Killiam at (202) 482–2704

Brazil
Iron Construction Castings
A–351–503
51 FR 17220
May 9, 1986
Contact: Hermes Pinilla at (202) 482–3477

Japan
Impression Fabric
A–588–066
43 FR 22344
May 25, 1978
Contact: Lyn Johnson at (202) 482–5287

South Korea
Malleable Cast Iron Pipe Fittings, Other than Grooved
A–580–507
51 FR 18917
May 23, 1986
Contact: Thomas Schauer at (202) 482–4852

Taiwan
Malleable Cast Iron Pipe Fittings, Other Than Grooved
A–583–507
51 FR 18918
May 23, 1986
Contact: Laurel LaCivita at (202) 482–4740

If no interested party requests an administrative review in accordance with the Department's notice of opportunity to request administrative review, and no domestic interested party objects to the Department's intent to revoke or terminate pursuant to this notice, we shall conclude that the antidumping duty orders, findings, and suspended investigations are no longer of interest to interested parties and shall proceed with the revocation or termination.

Opportunity To Object

Domestic interested parties, as defined in § 353.2(k) (3), (4), (5), and (6) of the Department's regulations, may object to the Department's intent to revoke these antidumping duty orders and findings or to terminate the suspended investigations by the last day of May 1997. Any submission to the Department must contain the name and case number of the proceeding and a statement that explains how the objecting party qualifies as a domestic interested party under § 353.2(k) (3), (4), (5), and (6) of the Department's regulations.

Seven copies of such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, Washington, D.C. 20230. You must also include the pertinent certification(s) in accordance with § 353.31(g) and § 353.31(i) of the Department's regulations. In addition, the Department requests that a copy of the objection be sent to Michael F. Panfeld in Room 4203.

This notice is in accordance with 19 CFR 353.25(d)(4)(i).

Dated: May 2, 1997.

Richard W. Moreland,

Acting Deputy Assistant Secretary for AD/CVD Enforcement.

[FR Doc. 97–12205 Filed 5–8–97; 8:45 am]

BILLING CODE 3510–DS–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textile Products Produced or Manufactured in Bangladesh

May 6, 1997.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs increasing limits.

EFFECTIVE DATE: May 12, 1997.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Uruguay Round Agreements Act.

The current limits for certain categories are being increased by recrediting unused carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 61 FR 66263, published on December 17, 1996). Also see 61 FR 68241, published on December 27, 1996.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

May 6, 1997.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive

issued to you on December 20, 1996, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Bangladesh and exported during the twelve-month period which began on January 1, 1997 and extends through December 31, 1997.

Effective on May 12, 1997, you are directed to increase the limits for the following categories, as provided for under the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
237	440,629 dozen.
331	1,061,102 dozen pairs.
334	134,426 dozen.
336/636	431,924 dozen.
341	2,343,153 dozen.
342/642	386,533 dozen.
352/652	9,605,759 dozen.
641	981,144 dozen.
645/646	372,641 dozen.
847	675,291 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1996.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C.553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc.97–12173 Filed 5–8–97; 8:45 am]

BILLING CODE 3510–DR–F

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

Agency Holding the Meeting: Commodity Futures Trading Commission.

Time and Date: 10:00 a.m., Thursday, May 22, 1997.

Place: 1155 21st St., N.W., Washington, D.C., 9th Fl. Conference Room.

Status: Closed.

Matters to be Considered: Enforcement Matters.

Contact Person for More Information: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 97–12410 Filed 5–7–97; 8:45 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

Agency Holding the Meeting: Commodity Futures Trading Commission.

Time and Date: 10:00 a.m., Thursday, May 15, 1997.

Place: 1155 21st St., N.W., Washington, D.C., 9th Fl. Conference Room.

Status: Closed.

Matters to be Considered: Enforcement Matters.

Contact Person for More Information: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 97–12411 Filed 5–7–97; 3:09 pm]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Department of the Navy, DoD

Notice of Availability and Public Hearing for the Draft Environmental Impact Statement for Disposal and Reuse of Naval Air Station Cecil Field, Jacksonville, FL

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969 as implemented by the Council on Environmental Quality regulations (40 CFR 1500–1508), the Department of the Navy prepared and filed with the U. S. Environmental Protection Agency a Draft Environmental Impact Statement (DEIS) to evaluate the proposed disposal and reuse of Naval Air Station (NAS) Cecil Field, Jacksonville, Florida. A Notice of Availability (NOA) for the DEIS was published in the **Federal Register** on April 25, 1997. The April 25 NOA initiated a 45-day public comment period on the DEIS.

In accordance with the Defense Base Closure and Realignment Act (PL 101–510), as implemented by the 1993 and 1995 Base Realignment and Closure processes, the Navy has been directed to close Naval Air Station (NAS) Cecil Field, located in Duval and Clay Counties, Florida. The Navy intends to dispose of approximately 17,000 acres of land in two of the station's operational areas, the Main Station and the Yellow Water area.

The Navy intends to retain other NAS Cecil Field assets including Outlying Field (OLF) Whitehouse, the Yellow Water Family Housing Area, and the Pinecastle Target Complex.

The Navy's DEIS addresses the environmental impacts associated with the disposal and proposed redevelopment of NAS Cecil Field. The proposed redevelopment includes a mix of aviation, industrial, forestry, and recreational uses in the Duval County portion, and the portion in Clay County would be retained for conservation purposes. The DEIS also addresses the environmental impacts of four alternative reuse scenarios (ARSs), which consist of reasonable future uses of the military property to be disposed at NAS Cecil Field.

The DEIS has been distributed to various federal, state and local agencies, elected officials, and public interest groups. The DEIS has also been filed for public review at the local libraries. A limited number of single copies are available, and may be obtained by contacting the Navy representative listed at the end of this notice. The Department of the Navy will hold a public hearing for interested parties and agencies to provide comments on the DEIS on May 27, 1997, beginning at 7:00 p.m. in the Main Drill Hall at the Post of Snyder, Florida Army National Guard Center, 9900 Normandy Boulevard, Jacksonville, Florida.

Following a presentation by the Navy, the public will be invited to submit oral comments on the DEIS. Oral statements will be heard and transcribed by a stenographer; however, to ensure accuracy of the record, all statements should be submitted in writing. In the interest of available time, speakers will be asked to limit oral comments to five minutes.

ADDRESSES: Interested parties and agencies are invited to review and comment on the DEIS. Written comments may be mailed to or sent by facsimile to the Department of the Navy at: Commander, Southern Division, Naval Facilities Engineering Command, Attn: Mr. Robert Teague, P.E. (Code 064), P.O. Box 190010, North Charleston, SC 29419–9010, phone: 803/820–5785, facsimile: 803/820–5993. Comments must be postmarked, if mailed, or received, if sent by facsimile, by June 10, 1997 to be considered part of the public record. All written and oral comments received on the DEIS at the hearing and during the 45-day comment period will be considered in a Final Environmental Impact Statement (FEIS) to be prepared by the Navy.

Dated: May 6, 1997.

D.E. Koenig,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 97–12212 Filed 5–8–97; 8:45 am]

BILLING CODE 3810–FF–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Meeting

Pursuant to the provision of the ''Government in the Sunshine Act'' (5 U.S.C. § 552b), notice is hereby given of the Defense Nuclear Facilities Safety Board's (Board) meeting described below.

TIME AND DATE OF MEETING: 9:00 a.m., May 28–29, 1997.

PLACE: The Defense Nuclear Facilities Safety Board Public Hearing Room, 625 Indiana Avenue, NW, Suite 300, Washington, DC 20004.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Defense Nuclear Facilities Safety Board will convene the fourth quarterly briefing over a two-day period to receive the Department of Energy's progress report on activities associated with the Department's Implementation Plan for the Board's Recommendation 95–2, Integrated Safety Management (''ISM''). On the first day, May 28, DOE staff will brief the Board on the current status of Departmental:

- Efforts to identify site-wide applicable requirements and to develop Safety Management descriptions and infrastructure for each site responsible for priority facilities;
- ISM implementation activities at the ten priority facilities; and
- Development of the Functions, Responsibilities, and Authorities Manuals. On May 29, also starting at 9 a.m., DOE staff will brief the Board on:
- Efforts to reconcile and integrate existing directives and ongoing initiatives with the ISM System;
- DOE enforcement policy relevant to 95–2 assessment/feedback safety functions; and
- Results from the May 7–8 Denver Workshop on DOE Oversight Policy, and the May 13–15, 1997, 95–2 Lessons Learned Workshop.

CONTACT PERSON FOR MORE INFORMATION: Richard A. Azzaro, Deputy General Counsel, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW, Suite 700, Washington, DC 20004, (800) 788–4016. This is a toll-free number.

SUPPLEMENTARY INFORMATION: The Defense Nuclear Facilities Safety Board reserves its right to further schedule and otherwise regulate the course of this meeting, to recess, reconvene, postpone or adjourn the meeting, and otherwise exercise its authority under the Atomic Energy Act of 1954, as amended.

Dated: May 6, 1997.

John T. Conway,

Chairman.

[FR Doc. 97–12286 Filed 5–6–97; 4:19 pm]

BILLING CODE 3670–01–M

DEPARTMENT OF EDUCATION

[CFDA No.: 84.255A]

Life Skills for State and Local Prisoners Program

AGENCY: Department of Education.

ACTION: Notice: Extension of closing date for transmittal of applications.

SUMMARY: On April 3, 1997, a notice was published in the **Federal Register** (62 FR 15880–15881) that established a closing date for transmittal of applications for the Fiscal Year 1997 Life Skills for State and Local Prisoners Program grants. The purpose of this notice is to extend the closing date for transmittal of applications. This action is taken as a result of unavoidable delays in the production and the distribution of the application packages. The closing date for applications is extended from May 19, 1997 to June 2, 1997.

FOR APPLICATIONS OR INFORMATION CONTACT: Lillian Logan, Office of Correctional Education, U.S. Department of Education, 600 Independence Avenue SW, MES Room 4529, Washington, DC 20202–7242. Telephone: (202) 205–5621. Individuals who use a telecommunication device for the deaf (TDD) may call the Federal Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Authority: 20 U.S.C. 1211–2.

Dated: May 6, 1997.

Patricia W. McNeil,

Assistant Secretary for Vocational and Adult Education.

[FR Doc. 97–12196 Filed 5–8–97; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT97–24–000]

Algonquin LNG, Inc.; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on April 30, 1997, Algonquin LNG, Inc. (Algonquin LNG) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheet with an effective date of June 1, 1997:

Fifth Revised Sheet No. 200

Algonquin LNG states that the purpose of this filing is to reflect a change in Algonquin LNG's index of customers.

Algonquin LNG states that copies of this filing were served upon each affected party and interested state commissions.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed as provided in Section 154.210 of the Commission's Regulations. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12111 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT97–23–000]

ANR Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on April 30, 1997, ANR Pipeline Company (ANR) tendered for filing as part of its FERC Gas Tariff, the following tariff sheets, to become effective May 30, 1997:

Second Revised Sheet No. 4
First Revised Sheet Nos. 4D, 4H, and 4I

ANR states that the revised tariff sheets (maps) reflect the abandonment of its Southwest Area gathering facilities. ANR also states that its Southwest Area gathering facilities were transferred December 31, 1996, pursuant to abandonment orders received in Docket Nos. CP96–185–000, CP96–186–000 and CP97–64–000. ANR also states that it is correcting a typographical error on Sheet No. 4.

ANR states that a copy of this filing was mailed to its FERC Gas Tariff,

Second Revised Volume No. 1 customers and to interested state commissions.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington D.C., 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12110 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–360–000]

ANR Pipeline Company; Notice of Annual System Cashout Report

May 5, 1997.

Take notice that on May 1, 1997, ANR Pipeline Company (ANR) tendered for filing its annual report of the net revenues attributable to the operation of its cashout program.

ANR states that this filing covers the period January 1, 1996 to December 31, 1996. The Net Cashout Activity for the twelve month period ending December 31, 1996 is ($3,537,246). As provided in Section 15.5(b) of the General Terms and Conditions of ANR's FERC Gas Tariff, Second Revised Volume No. 1, this amount will be carried forward and applied to the next succeeding redetermination of Net Cashout Activity for the calendar year ended December 31, 1997.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before May 12, 1997. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12134 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–356–000]

Arkansas Western Pipeline Company; Notice of Petition of Arkansas Western Pipeline Company for One-Year Waiver of or Exemption From GISB Standard 4.3.6

May 5, 1997.

Take notice that on May 1, 1997, Arkansas Western Pipeline Company (AWP), filed a petition pursuant to Rule 207 of the Commission's Rules of Practice and Procedure for waiver or exemption of the requirements concerning the establishment of a HTML page accessible via the Internet's World Wide Web, as more fully set forth in the petition of file with the Commission and open to public inspection.

AWP states that the establishment of a HTML page is not necessary on the AWP system in order to achieve the Commission's goals. AWP states that the expense of compliance with the HTML page requirement, prior to the establishment or use of an Internet server model and web browser model and the ability to perform EDI transactions is significant to AWP, and the benefits to AWP's customers are nonexistent given the nature of the AWP system.

Any person desiring to be heard or to protest this petition should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12130 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–1676–000]

Black Brook Energy Co.; Notice of Issuance of Order

May 6, 1997.

Black Brook Energy Co. (Black Brook) submitted for filing a rate schedule under which Black Brook will engage in wholesale electric power and energy transactions as a marketer. Black Brook also requested waiver of various Commission regulations. In particular, Black Brook requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Black Brook.

On April 18, 1997, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Black Brook should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First 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).

Absent a request for hearing within this period, Black Brook is authorized to issue securities and assume obligations or liabilities as a guarantor, endorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Black Brook's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is May 19, 1997.

Copies of the full text of the orders are available from the Commission's Public Reference Branch, 888 First Street, N.E. Washington, D.C. 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12163 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2622–000]

Cinergy Services, Inc.; Notice of Filing

May 5, 1997.

Take notice that on April 16, 1997, Cinergy Services, Inc. (Cinergy) tendered for filing a service agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff) entered into between Cinergy and Western Resources (Western).

Cinergy and Western are requesting an effective date of April 15, 1997.

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, 888 First 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 May 16, 1997. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12109 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OA97–576–000]

Cleveland Electric Illuminating Company; Notice of Filing

May 5, 1997.

Take notice that on April 14, 1997, The Cleveland Electric Illuminating Company filed pursuant to Section 205 of the Federal Power Act and the Commission's regulations thereunder an original and six copies of an amendment to the interconnection agreement (Agreement) between CEI and the City of Cleveland (City). This filing is being made for the purpose of complying with the Commission's unbundling requirements without raising rates or charges to the City. CEI states that it has mailed a copy of its filing upon the City. The proposed effective date under the Service Agreements is January 1, 1997.

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, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before May 13, 1997. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12113 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–420–000]

CNG Transmission Corporation; Notice of Request Under Blanket Authorization

May 5, 1997.

Take notice that on April 30, 1997, CNG Transmission Corporation (CNG), 445 West Main Street, Clarksburg, West Virginia 26301, filed in the above docket, a request pursuant to Sections 157.205, and 157.208 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.208) for authorization to convert four (4) observation wells to storage wells. This work will include the installation of 4 new storage pipelines and appurtenant facilities to be located at the Oakford Station located in Westmoreland County, Pennsylvania. CNG jointly owns the Oakford Station with Texas Eastern Transmission Corporation, however, CNG is the operator of the Oakford Station. The facilities will allow CNG and Texas Eastern to recover gas that has migrated from the Oakford storage pool, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

CNG requests authorization to convert four existing observation wells, JW–253, JW–283, JW–284, and JW–285, to storage withdrawal wells. CNG states that the connection of these wells for withdrawal purposes only, will allow for CNG to more effectively and efficiently operate the reservoir by the recycling of migrated gas from currently isolated areas of the reservoir in which these wells are located. CNG states that the recycling of this gas will allow CNG to maintain the certificated capacity and deliverability of the Oakford storage pool. The maximum daily design capacity from construction of the pipelines to the observation wells is 85 MMcf per day. The maximum operating pressures for each of the pipelines is 555 PSIG. The proposed facilities and service are not prohibited by CNG's existing tariff.

CNG states that this project will require the construction of the following pipelines to connect the observation wells to existing gathering lines:

1. 1,643′ of 6″ pipe (0.280 wall) to be known as Line JP–298 for the conversion of well number JW–284,
2. 263′ of 6″ pipe (0.280 wall) to be known as Line JP–299 for the conversion of well number JW–283,
3. 1,200′ of 6″ pipe (0.280 wall) to be known as Line JP–301 for the conversion of well number JW–253, and
4. 1,524′ of 8″ pipe (0.280 wall) to be known as Line JP–300 for the conversion of well number JW–285.

CNG states that the approximate cost of the facilities is $292,000. CNG indicates that it will continue to operate the Oakford storage pool. CNG further states that there will be no appreciable impact on its current system rates. The proposed facilities and service are not prohibited by CNG's existing tariff.

CNG states that the effect on its peak and annual delivery obligations is minimal; this project will pose no detriment to its firm service to any other

customer. CNG verifies that the proposed construction complies with the requirements of Subpart F of Part 157 of the Commission's Regulations under the Natural Gas Act.

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 Rules of Practice and Procedure (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity is deemed to be authorized effective on the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12103 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–181–003]

CNG Transmission Corporation; Notice of Compliance Tariff Filing

May 5, 1997.

Take notice that on May 1, 1997, CNG Transmission Corporation (CNG), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following revised tariff sheet, with an effective date of June 1, 1997:

Pro Forma Third Revised Sheet No. 386
Pro Forma Original Sheet No. 386A

CNG states that the purpose of this filing is to revise CNG's FERC Gas Tariff, to further implement the Version 1.1 business practice standards of the Gas Industry Standards Board (GISB). These GISB standards have been incorporated by reference in the Commission's regulations through Order No. 587–C. CNG has listed the additional GISB Business Practice Standards that are to be adopted by reference, at Section 31 in the General Terms and Conditions. CNG also requests Commission authorization to defer its implementation of several systems-based and EDI-related Version 1.0 business practice standards from the target date of June 1, 1997, to August 1, 1997. CNG states that granting this partial extension will enhance the likelihood of a successful GISB standards implementation for both CNG and its customers.

CNG states that copies of its filing have been mailed to CNG's customers and interested state commissions, and to parties to the captioned proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C., 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12124 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–355–000]

CNG Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, CNG Transmission Corporation (CNG), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets:

Original Sheet Nos. 208–212
Sheet No. 213
Original Sheet Nos. 444–449
Sheet No. 450

CNG requests an effective date of June 1, 1997, for these proposed tariff sheets.

CNG states that the purpose of this filing is to add a mainline pooling service to CNG's FERC Gas Tariff, as directed by the Commission in response to CNG's filing to implement the Gas Industry Standards Board (GISB) business practice standards, Version 1.0. The proposed rate schedule and related agreement form reflect administrative procedures by which CNG will accommodate the aggregation of nominated quantities at a receipt point or points.

CNG states that copies of this letter of transmittal and enclosures are being mailed to CNG's customers and interested state commissions.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12129 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–370–000]

Colorado Interstate Gas Company; Notice of Application

May 5, 1997.

Take notice that on April 21, 1997, as supplemented on April 30, 1997, Colorado Interstate Gas Company (CIG), 2 N. Nevada St., Colorado Springs, Colorado 80944, filed in Docket No. CP97–370–000 an abbreviated application pursuant to Section 7(b) of the Natural Gas Act and Sections 157.7 and 157.18 of the Commission's Regulations to abandon certain miscellaneous facilities used in connection with interstate gas transmission service, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Specifically, CIG seeks Commission approval to abandon the following facilities:

(1) Adena Gas Plant Purchase Meter Station and lateral located in Section 12, Township 1 North, Range 58 West, Morgan County, Colorado;

(2) Cominco Meter Station [1] located in Section 15, Block Y–2, GB & CNG, Hutchison County, Texas;

[1] Formerly Hill Chemicals, Inc.

(3) Green River Questar Meter Station [2] and lateral located in Section 26, Township 18 North, Range 107 West, Sweetwater County, Wyoming;

(4) Palo Dura Meter Station located in Section 6, Block 2T, T&NORR Survey, Sherman County, Texas;

(5) Sun Purchase Meter Station located in Section 5, Township 5 South, Range 62 West, Arapahoe County, Colorado and lateral located in Sections 5, 8 and 17, Township 5 South, Range 62 West, Arapahoe County, Colorado; and

(6) Ralston Inlet Meter located in Section 35, Township 52 North, Range 100 West, Park County, Wyoming and the Ralston Outlet Meter located in Section 8, Township 51 North, Range 100 West, Park County, Wyoming.

According to CIG, the facilities proposed for abandonment, which were constructed and operated under certificate authority issued in various dockets, are no longer of use in the services for which they were originally certificated. Further, CIG states that the abandonment of these facilities will not affect any jurisdictional service that CIG currently renders.

CIG intends to remove salvageable material for use elsewhere upon abandonment.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 27, 1997, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 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 the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a 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 CIG to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12102 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

[2] Formerly Mountain Fuel Supply Company.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–1932–000]

Competitive Utility Services Corporation; Notice of Issuance of Order

May 6, 1997.

Competitive Utility Services Corporation (CUSCo), filed an application for authorization to sell power at market-based rates, and for certain waivers and authorizations. In particular, CUSCo requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liabilities by CUSCo. On April 18, 1997 the Commission issued an Order Conditionally Accepting For Filing Proposed Market-Based Rates (Order), in the above-docketed proceeding.

The Commission's April 18, 1997 Order granted the request for blanket approval under Part 34, subject to the conditions found in Ordering Paragraphs (D), (E), and (G):

(D) Within 30 days of the date of this order, any person desiring to be heard or to protest the Commission's blanket approval of issuances of securities or assumptions of liabilities by CUSCo should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First 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.

(E) Absent a request to be heard within the period set forth in Ordering Paragraph (D) above, CUSCo is hereby authorized to issue securities and to assume obligations or liabilities as guarantor, endorser, surety or otherwise in respect of any security of another person; provided that such issue or assumption is for some lawful object within the corporate purposes of CUSCo, compatible with the public interest, and reasonably necessary or appropriate for such purposes.

(G) The Commission reserves the right to modify this order to require a further showing that neither public nor private interests will be adversely affected by continued Commission approval of CUSCo's issuances of securities or assumptions of liabilities. * * *

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is May 19, 1997. Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12164 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–346–000]

Equitrans, L.P.; Notice of Proposed Changes in FERC Gas Tariff

Take notice that on April 30, 1997, Equitrans, L.P. (Equitrans) tendered for filing as part of its FERC Gas Tariff revised tariff sheets reflecting a rate change from currently effective rates and other changes in its tariff. This rate filing will increase the level of Equitrans' jurisdictional rates to provide an overall annual increase in jurisdictional cost of service of approximately $442,594 and stranded rate cost recovery of the net book value of Equitrans' gathering plant, to be amortized over five-years and allocated to open-access firm transportation service, interruptible transportation service and firm storage, of approximately $39.78 million.

Equitrans states that the rates reflected in the revised tariff sheets are designed by Equitrans to bring Equitrans' revenues to a level of its jurisdictional cost of service and known and measurable jurisdictional stranded cost recovery, all based on costs for the twelve-month period ending December 31, 1997 as adjusted.

Among the rate changes proposed by Equitrans is elimination of its negotiated five cent per Dth gathering charge in accordance with the Commission-approved settlement in Docket Nos. RP93–187–000. *et al.* In order that the five cent rate be replaced with Equitrans' proposed 12.28¢ per Dth

gathering rate on August 1, 1997, the agreed-upon expiration dated under the Docket No. RP93–187 settlement, Equitrans proposes a shortened suspension period, whereby the tendered tariff sheets will become effective, on a subject-to-refund basis, on August 1, 1997.

Equitrans states that copies of this rate filing were served on Equitrans' jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest the filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20046, in accordance with Rules 211 and 214 of the Commisssion's Rules of Practice and Procedure. All such motions or protests should be filed as provided in Section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining appropriate action, 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.

Lois D. Shell,

Secretary.

[FR Doc. 97–12125 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–153–002]

Granite State Gas Transmission Inc.; Notice of Compliance Tariff Filing

May 5, 1997.

Take notice that on May 1, 1997, Granite State Gas Transmission, Inc. (Granite State) filed Second Substitute First Revised Sheet No. 289 in its FERC Gas Tariff, Third Revised Volume No. 1, to comply with the requirements of Order No. 587–C issued March 4, 1997, adopting additional standard business practices published by the Gas Industry Standards Board. Granite State proposes to make the revised tariff sheet effective June 1, 1997.

Granite State further states that copies of its filing have been served on its firm and interruptible customers, on the regulatory agencies of the states of Maine, Massachusetts and New Hampshire and the intervenor in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of Granite State's filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12122 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2609]

International Paper Company and Curtis/Palmer Hydroelectric Company L.P.; Notice of Availability of Study Results and Request for Additional Studies

May 5, 1997.

International Paper Company and Curtis/Palmer Hydroelectric Company L.P. are currently engaged in the process of obtaining from the Federal Energy Regulatory Commission (the Commission) a new operating license for the Curtis/Palmer Falls Hydroelectric Project (FERC No. 2609). The current license for the project is due to expire on April 30, 2000. The project is located on the Hudson River in the Village of Corinth and the Towns of Corinth, Lake Luzerne and Hadley, in Saratoga and Warren Counties, New York. Under the Commission's Regulations, an application for licensing for the project must be filed by April 30, 1998. International Paper Company is managing relicensing activities in cooperation with a team of state and federal resource agencies, conservation groups and local governments (the Cooperative Team).

Pursuant to the Energy Policy Act of 1992 and the Commission's regulations, Curtis/Palmer Hydroelectric Company L.P. and International Paper Company intend to prepare a Draft Environmental Assessment (DEA) as part of the license application, to be filed with the Commission for the project. Public scoping meetings were held on January 10, 1996 and February 8, 1996 to identify the scope of environmental issues and alternatives that should be analyzed in the DEA.

Based on information contained in Scoping Document 1 and comments received from resource agencies and other interested parties during the scoping meetings and comment period, the Cooperative Team prepared study plans to address issues raised during the scoping process and published them in Scoping Document 2. Study plans were subsequently finalized and studies were undertaken throughout the spring, summer, and fall of 1996. The majority of the study reports were completed and published as Volume 1 Study Reports. During the period from January 31, 1997 until March 3, 1997, the Volume I Reports were available for public review and comment. Those reports not included in Volume 1 have been completed and compiled as Volume 2 Study Reports. The Volume 2 Reports will be available for public review from May 5, 1997 until June 6, 1997 at the International Paper Administration Building at the Hudson River Mill on Pine Street in Corinth, New York. The Volume 2 Reports will also be available in the Corinth Town Office at 600 Palmer Avenue in Corinth, New York and in the Commissions Public Reference Room at 888 First Street N.E. in Washington, D.C. The public is invited to review these documents and to file comments on the adequacy of these studies in addressing issues raised during scoping. Comments on these studies and requests for any additional studies are due by June 6, 1997.

Because Section 4.32(b)(7) of the Commission's Regulations has been waived as to time framerame for requesting additional studies, we are requesting that if any resource agency, Indian tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the project on its merit, the resource agency, Indian tribe, or person file a request for any such study with the Secretary of the Commission at 888 First Street, N.E., Washington, D.C. 20426 by June 6, 1997 and serve a copy of the request on Mr. Robert McK. Hunziker, International Paper Company, Two Manhattanville Road, Purchase, NY 10577 and Mr. Andrew Sims, Kleinschmidt Associates, 75 Main Street, Pittsfield, ME 04967. Any comments or recommendations for further study should be supported by appropriate documentation.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12116 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–59–003]

Midwestern Gas Transmission Company; Notice of Tariff Filing

May 5, 1997.

Take notice that on May 1, 1997, Midwestern Gas Transmission Company (Midwestern), filed the revised tariff sheets listed on Appendix A to the filing, in compliance with the Commission's April 21, 1997, order in this proceeding. Midwestern Gas Transmission Company, 79 FERC ¶ 61,062 (1997) (April 21 Order). Midwestern proposes an effective date of June 1, 1997, for the revised sheets.

Midwestern submits that the revised tariff sheets reflect the changes required by the April 21, Order to the tariff sheets submitted with Midwestern's March 3, 1997, GISB compliance filing.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to this proceeding. Copies of this filing are on file with the Commission and available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12118 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–73–005]

Mississippi River Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, Mississippi River Transmission Corporation (MRT) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the tariff sheets listed on Appendix A to this filing, to be effective May 1, 1997.

MRT states that the compliance tariff sheets attached as Appendix B incorporate changes to MRT's Tariff required by the Commission's Order on Rehearing and on Second GISB Compliance Filing, Docket Nos. RP97–73–001 and RP97–73–002, issued April 18, 1997.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12120 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2574–000]

Montaup Electric Company; Notice of Filing

May 5, 1997.

Take notice that on April 14, 1997, Montaup Electric Company (Montaup) filed an executed letter agreement concerning Montaup's transmission service to MASSPOWER and Pittsfield Generating Company under the two alternatives proposed by the NEPOOL Participants in filing the Restated NEPOOL Agreement and NEPOOL transmission tariff: (1) Alternate A, under which Excepted Transactions will terminate after a five-year transition period and (2) Alternate B, which allows Excepted Transactions to continue in effect.

The letter agreement provides for a rate of $8 per kW/year to be effective subject to refund on March 1, 1997. Montaup requests waiver of the notice requirement in order to permit the $8 per kW/year rate to become effective subject to refund on March 1, 1997.

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, 888 First, N.E., Washington, D.C. 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 18 CFR 385.214). All such motions or protests should be filed on or before May 15, 1997. 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 must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12106 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TM97–10–16–000]

National Fuel Gas Supply Corporation; Notice of Tariff Filing

May 5, 1997.

Take notice that on April 30, 1997, National Fuel Gas Supply Corporation (National) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, Twenty-Second Revised Sheet No. 5A, with a proposed effective date of May 1, 1997.

National states that pursuant to Article II, Section 2, of the approved settlement at Docket Nos. RP94–367–000, *et al.*, National is required to recalculate the maximum Interruptible Gathering (IG) rate monthly and to charge that rate on the first day of the following month if the result is an IG rate more than 2 cents above or below the IG rate as calculated under Section 1 of Article II. The recalculation produced an IG rate of 16 cents per dth.

National further states that, as required by Article II, Section 4, National is filing a revised tariff sheet within 30 days of the effective date for the revised IG rate.

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, 888 First Street, N.E., Washington, D.C., 20426, in accordance with Section 385.211 or 385.214 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12136 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–353–000]

Natural Gas Pipeline Company of America; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, Natural Gas Pipeline Company of America (Natural) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, Eighth Revised Sheet No. 22, to be effective June 1, 1997.

Natural states that the filing is submitted pursuant to Section 21 of the General Terms and Conditions of Natural's FERC Gas Tariff, Sixth Revised Volume No. 1 (Section 21), as the eighth semiannual limited rate filing to recover Account No. 858 stranded costs incurred by Natural under contracts for transportation capacity on other pipelines. Costs for any Account No. 858 contracts specifically excluded under Section 21 are not reflected in this filing.

Natural states that copies of the filing are being mailed to Natural's jurisdictional customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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 in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12127 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–200–021]

NorAm Gas Transmission Company; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, NorAm Gas Transmission Company (NGT) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, the following revised tariff sheets to be effective May 1, 1997:

Thirteenth Revised Sheet No. 7
Sixth Revised Sheet No. 7A
Fourth Revised Sheet No. 7E
Second Revised Sheet No. 7G
First Revised Sheet No. 7K

NGT states that these tariff sheets are filed herewith to reflect specific negotiated rate transactions for the month of May, 1997.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests must be filed as provided in Section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestant parties to the proceeding. Copies of this filing on are file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12117 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–354–000]

Northern Border Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, Northern Border Pipeline Company (Northern Border) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheet to become effective July 1, 1997:

Original Sheet Number 300G

Northern Border states that this filing is made in compliance with the Commission's order issued in Docket No. RP97–22–001 and RP97–22–002 on February 18, 1997. The tariff sheet reflects Northern Border's pooling proposal.

Northern Border states that copies of this filing are being served on all affected customers.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.214 and Section 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12128 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TM97–2–59–000]

Northern Natural Gas Company; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1977.

Take notice that on May 1, 1997, Northern Natural Gas Company (Northern), tendered for filing to become part of Northern's FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets proposed to become effective on June 1, 1997:

Fifth Revised Sheet No. 54
Fifth Revised Sheet No. 61
Fifth Revised Sheet No. 62
Fifth Revised Sheet No. 63
Fifth Revised Sheet No. 64

Northern states that the revised tariff sheets are being filed in accordance with the methodology set forth in Section 53 of Northern's General Terms and Conditions, Tariff Sheet Nos. 300–301 (as filed on April 29, 1997), which requires Northern to adjust its fuel percentages each June 1 based on actual data for the 12-month period ended March 31. Northern has also filed to

adjust its Unaccounted For (UAF) gas also in accordance with the PRA mechanism. This filing constitutes Northern's initial filing under its PRA mechanism to adjust the fuel and UAF percentages which are proposed to be effective June 1, 1997.

Northern states that copies of the filing were served upon Northern's customers and interested State Commissions.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such petitions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken in this proceeding, but will not serve to make protestant a party 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 inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12135 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2591–000]

Ohio Valley Electric Corporation Indiana-Kentucky Electric Corporation; Notice of Filing

May 5, 1997.

Take notice that on April 14, 1997, Ohio Valley Electric Corporation (including its wholly-owned subsidiary, Indiana-Kentucky Electric Corporation) (OVEC) tendered for filing a Service Agreement for Non-Firm Point-To-Point Transmission Service, dated April 2, 1997 (the Service Agreement) between Ohio Edison Company (including its wholly owned subsidiary, Pennsylvania Power Company) (the Ohio Edison System) and OVEC. OVEC proposes an effective date of April 2, 1997 and requests waiver of the Commission's notice requirement to allow the requested effective date. The Service Agreement provides for non-firm transmission service by OVEC to the Ohio Edison System.

In its filing, OVEC states that the rates and charges included in the Service agreement are the rates and charges set forth in OVEC's Order No. 888 compliance filing (Docket No. OA96–190–000).

copies of this filing were served upon the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission and the Ohio Edison System.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 18 CFR 385.214). All such motions or protests should be filed on or before May 15, 1997. 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 must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12107 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–357–000]

Ozark Gas Transmission System; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, Ozark Gas Transmission System (Ozark) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the tariff sheets listed on Appendix A to the filing, to become effective June 1, 1997.

Ozark states that the enclosed tariff sheets are intended to implement a pooling and a title transfer service, both at no charge.

Although Ozark set forth a pooling proposal in its initial GISB compliance filing in Docket No. RP97–179, the Commission's March 5, 1997, order required Ozark to make a separate Section 4 filing to implement its pooling service. Ozark has had a customer request pooling service, and, as pooling service includes the transfer of title, the customer also requested that Ozark provide for title transfer service. Thus, Ozark has included in this compliance filing both a pooling and title transfer service.

Ozark states that copies of this filing are being served on all jurisdictional customers and applicable state regulatory agencies.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12131 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER97–1770–000, ER97–1802–000, ER97–1896–000, and ER97–1905–000]

Pacific Northwest Generating Cooperative; Notice of Filing

May 5, 1997.

Take notice that on April 4, 1997, Pacific Northwest Generating Cooperative (PNGC) filed a letter withdrawing its filing of service agreements for short-term power sales transactions under Docket Nos. ER97–1770–000, ER97–1802–000, ER97–1896–000, and ER97–1905–000. On the basis of the Commission's Order of March 12, 1997, Docket Nos. ER97–504–001 and OA97–32–001, which eliminated a requirement that PNGC file umbrella agreements of service agreements for short-term power sales transactions, PNGC has requested that the Commission amend Docket Nos. ER97–1770–000, ER97–1802–000, ER97–1896–000, and ER97–1905–000 to reflect that PNGC has withdrawn the filing of those service agreements.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before May 15, 1997. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12104 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2225–000]

PacifiCorp; Notice of Filing

May 5, 1997.

Take notice that on April 10, 1997, PacifiCorp tendered for filing an amendment in the above-referenced docket.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before May 15, 1997. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12105 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–358–000]

Panhandle Eastern Pipe Line Company; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, Panhandle Eastern Pipe Line Company (Panhandle) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the tariff sheets listed on Appendix A to the filing, to become effective June 1, 1997.

Panhandle states that this filing removes from its currently effective rates the Additional Take-or-Pay volumetric Surcharge established by Section 18.10 of the General Terms and Conditions of Panhandle's tariff. On May 1, 1996, Panhandle filed in Docket No. RP96–223–000 to establish a surcharge for the Reconciliation Recovery Period. The May 1, 1996 filing was approved by a Commission letter order issued May 29, 1996. In accordance with Sections 18.10(b)(4) and 18.10 (g) of the General Terms and Conditions, Panhandle established a surcharge to be in effect during the twelve month Reconciliation Recovery period commencing June 1, 1996 through May 31, 1997. Accordingly, the Reconciliation Recovery Period will terminate on June 1, 1997. Therefore, Panhandle is now proposing to remove Section 18.10 (Additional Take-or-Pay Volumetric Surcharge) from its General Terms and Conditions and remove the 0.10¢ surcharge from its rates effective June 1, 1997.

Panhandle states that copies of this filing are being served on all affected customers and applicable state regulatory agencies.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12132 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–109–003]

Sabine Pipe Line Company; Notice of Compliance Filing

May 5, 1997.

Take notice that on May 1, 1997, Sabine Pipe Line Company (Sabine) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following revised tariff sheet proposed to be effective June 1, 1997:

First Revised Sheet No. 201

Sabine states that the revised sheet adds a reference to Section 23, GISB Standards, to the Table of Contents for the General Terms and Conditions section of Sabine's FERC Gas Tariff, Second Revised Volume No. 1.

Sabine states that copies of this filing are being mailed to its customers, state commissions and other interested parties.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12121 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–60–003]

Tennessee Gas Pipeline Company; Notice of Tariff Filing

May 5, 1997.

Take notice that on May 1, 1997, Tennessee Gas Pipeline Company (Tennessee), filed the revised tariff sheets listed on Appendix A to the filing, in compliance with the Commission's April 21, 1997, order in this proceeding. Tennessee Gas Pipeline Company, 79 FERC ¶ 61,063 (1997) (April 21 Order). Tennessee proposes an effective date of June 1, 1997, for the revised sheets.

Tennessee submits that the revised tariff sheets reflect the changes required by the April 21, Order to the tariff sheets submitted with Tennessee's March 3, 1997, GISB compliance filing.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to this proceeding. Copies of this filing are on file with the Commission and available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12119 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–359–000]

Texas Eastern Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following tariff sheets with a proposed effective date of June 1, 1997:

First Revised Sheet No. 456
Original Sheet No. 456A
Original Sheet No. 456B
Original Sheet No. 456C

Texas Eastern states that the purpose of this filing is to revise Section 3.12 of the General Terms and Conditions (GT&C) of Texas Eastern's Tariff to implement a provision to allocate available firm forward-haul capacity based on net present value criteria. Texas Eastern states that its existing Tariff provides for allocation of capacity on a first come, first served basis, an allocation methodology that is outdated and ill-equipped to allocate capacity under current regulatory and market conditions.

Texas Eastern states that copies of the filing were served on all firm customers of Texas Eastern and applicable state commissions.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12133 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–168–003]

Tuscarora Gas Transmission Company; Notice of Compliance Filing

May 5, 1997.

Take notice that on May 1, 1997, Tuscarora Gas Transmission Company (Tuscarora) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, effective June 1, 1997:

Sub First Sheet No. 37A

Tuscarora asserts that the purpose of this filing is to reflect standards adopted in Order Nos. 587–B and 587–C. Tuscarora states that copies of this filing were mailed to all parties on the service list in this docket, all customers of Tuscarora and interested state regulatory agencies.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12123 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2588–000]

Washington Water Power Company; Notice of Filing

May 2, 1997.

Take notice that on April 17, 1997, The Washington Water Power Company tendered for filing Amended Procedures for Implementing Standards of Conduct Under Commission Order No. 889–A.

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, 888 First Street, N.E. Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions and protests should be filed on or before May 16, 1997. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12101 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2592–000]

Watt Works, L.L.C.; Notice of Filing

May 5, 1997.

Take notice that on April 16, 1997, Watt Works, L.L.C. tendered for filing with the Federal Energy Regulatory Commission Rate Schedule No. 1, which permits Watt Works, L.L.C. to make wholesale power sales at market-based rates.

Any persons desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions and protests should be filed on or before May 15, 1997. Protests will be considered by the Commission to determine 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.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12108 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT97–25–000]

Williston Basin Interstate Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

May 5, 1997.

Take notice that on May 1, 1997, Williston Basin Interstate Pipeline Company (Williston Basin), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the revised tariff sheets listed on the filing, to become effective June 1, 1997.

Williston Basin states that the revised tariff sheets are being filed to update its Master Receipt/Delivery Point List as a result of a recent review of such list. Williston Basin states it is proposing to delete all of the gathering/production receipt points currently included in the master list in order to reduce the number of tariff filings caused by additions and deletions of such non-jurisdictional gathering/production receipt points. Williston Basin states it will continue to maintain its Master Receipt/Delivery Point List on its EBB and in addition the EBB will include an updated list of all the gathering/production receipt points proposed to be deleted from such list.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12112 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP–97–352–000]

Williston Basin Interstate Pipeline Company; Notice of Tariff Filing

May 5, 1997.

Take notice that on May 1, 1997, Williston Basin Interstate Pipeline Company (Williston Basin), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the revised tariff sheets listed on Appendix A to the filing, to become effective June 1, 1997.

Williston Basin states that the revised tariff sheets reflect certain proposed changes to the nominations, electronic communication mechanisms, balancing and payment sections of Williston Basin's FERC Gas Tariff, all as more fully set forth in the instant tariff filing which is on file with the Commission and open for public inspection.

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, 888 First 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 must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to the proceeding must file a motion to intervene. Copies of the filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12126 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER96–2493–000, et al.]

New York State Electric & Gas Corp., et al.; Electric Rate and Corporate Regulation Filings

May 2, 1997.

Take notice that the following filings have been made with the Commission:

1. New York State Electric & Gas Corporation

[Docket No. ER96–2493–000]

Take notice that New York State Electric & Gas Corporation (NYSEG) on April 21, 1997, tendered for filing pursuant to Section 35.13 of the Federal Energy Regulatory Commission's Rules of Practice and Procedure, 18 CFR 35.13, an agreement with Sonat Power Marketing, Inc. (Sonat) as an amendment to, and a complete substitute for, a rate schedule filed on July 22, 1996, the consideration of which has been deferred by the FERC. The agreement provides a mechanism pursuant to which the parties can enter into separately scheduled transactions under which NYSEG will sell to Sonat and Sonat will purchase from NYSEG either capacity and associated energy or energy only as the parties may mutually agree.

NYSEG requests that the agreement become effective on April 22, 1997, so that the parties may, if mutually agreeable, enter into separately scheduled transactions under the agreement. NYSEG has requested waiver of the notice requirements for good cause shown.

NYSEG served copies of the filing upon the New York State Public Service Commission and Sonat.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

2. Florida Power & Light Company

[Docket Nos. ER96–2751–000 and ER96–2902–000]

On April 18, 1997, Florida Power & Light Company filed requesting that the requested effective dates in Docket Nos. ER96–2751 and ER96–2902 be changed to January 1, 1997. FPL requests that the filing be made effective on January 1, 1997.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

3. New York State Electric & Gas Corporation

[Docket No. ER96–3028–000]

Take notice that New York State Electric & Gas Corporation (NYSEG) on April 21, 1997, tendered for filing pursuant to Section 35.13 of the Federal Energy Regulatory Commission's Rules of Practice and Procedure, 18 CFR 35.13, an agreement with Williams Energy Services Company (Williams) as an amendment to, and a complete substitute for, a rate schedule filed on September 17, 1996, the consideration of which has been deferred by the FERC. The agreement provides a mechanism pursuant to which the parties can enter into separately scheduled transactions under which NYSEG will sell to Williams and Williams will purchase from NYSEG either capacity and associated energy or energy only as the parties may mutually agree.

NYSEG requests that the agreement become effective on April 22, 1997, so that the parties may, if mutually agreeable, enter into separately scheduled transactions under the agreement. NYSEG has requested waiver of the notice requirements for good cause shown.

NYSEG served copies of the filing upon the New York State Public Service Commission and Williams.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

4. Florida Power Corporation

[Docket No. ER97–356–000]

Take notice that Florida Power Corporation (Florida Power), on April 23, 1997, tendered for filing a fully executed copy of Amendment No. 1 to Contract for Interchange Service between Florida Power and SCANA Energy Marketing, Inc. (SCANA).

On February 4, 1997, Florida Power tendered for filing a partially executed copy of Amendment No. 1 to its interchange contract with SCANA. The sole purpose of this filing is to provide the Commission with a fully executed copy of Amendment No. 1.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

5. Florida Power Corporation

[Docket Nos. ER97–515–002, ER97–516–002, and ER97–606–002]

Take notice that Florida Power Corporation, on April 23, 1997, tendered for filing in the above-referenced dockets revised rate sheets which specifically state the transmission and each ancillary service component of the rate. Florida Power Corporation also tendered for filing unbundling work papers which show the specific wholesale generation price that results from the subtraction of transmission and ancillary prices from the total bundled charge.

Florida Power Corporation is submitting the revised rate sheets and unbundling work papers in compliance with the Commission's Letter Order dated April 8, 1997.

Copies of the filing were served upon all persons listed on the official service list in the three dockets listed above.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

6. South Carolina Electric & Gas

[Docket No. ER97–947–001]

Take notice that on April 16, 1997, South Carolina Electric & Gas Company (SCE&G) submitted a report, indicating the refund of the time value of money to PanEnergy Trading & Market Services, L.L.C. (PanEnergy) as a customer under SCE&G's Negotiated Market Sales Tariff.

Copies of this filing were served upon PanEnergy and the South Carolina Public Service Commission.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

7. Northern States Power Company (Minnesota Company)

[Docket No. ER97–991–000]

Take notice that on April 17, 1997, Northern States Power Company, Minnesota (NSP) tendered its filing of Amendment No. 2 to the Municipal Interconnection and Interchange Agreement between NSP and the City of Buffalo, Minnesota. The filing contains cost support and the unbundled power sale rate information.

A copy of the filing was served upon each of the parties named in the Service List.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

8. Northern States Power Company, (Minnesota Company)

[Docket No. ER97–1009–000]

Take notice that on April 17, 1997, Northern States Power Company Minnesota (NSP) tendered its filing of Amendment No. 3 to the Municipal Interconnection and Interchange Agreement between NSP and the City of Kasson, Minnesota. The filing contains cost support and the unbundled power sale rate information.

A copy of the filing was served upon each of the parties named in the Service List.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

9. Orange and Rockland Utilities Inc.

[Docket No. ER97–1400–001]

Take notice that on April 10, 1997, Orange and Rockland Utilities, Inc. (Orange and Rockland) pursuant to the Commission's order Conditionally Accepting for Filing Proposed Market-Based Rates issued March 27, 1997, tendered for filing its revised market-based power sales tariff.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

10. Idaho Power Company

[Docket No. ER97–1481–001]

Take notice that on April 10, 1997, Idaho Power Company (IPCo) tendered a compliance filing in response to the Commission's Letter Order of March 27, 1997 in the above Docket.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

11. Northern States Power Company (Minnesota Company)

[Docket No. ER97–1484–000]

Take notice that on April 17, 1997, Northern States Power Company, Minnesota (NSP) tendered its filing of Amendment No. 2 to the Municipal Interconnection and Interchange Agreement between NSP and the City of Kasota, Minnesota. The filing contains cost support and the unbundled power sale rate information.

A copy of the filing was served upon each of the parties named in the Service List.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

12. Tucson Electric Power Company

[Docket No. ER97–1625–001]

Take notice that on April 18, 1997, Tucson Electric Power Company submitted a refund report in this proceeding.

Comment date: May 15, 1997, in accordance with Standard Paragraph E at the end of this notice.

13. Arizona Public Service Company

[Docket No. ER97–1672–000]

Take notice that on April 17, 1997, Arizona Public Service Company (APS) tendered for filing Amendments to its Market Rate Tariff in Compliance with Commission Order dated April 11, 1997 in the above referenced docket number.

A copy of this filing has been served on all parties on the official service list.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

14. New York State Electric & Gas Corporation)

[Docket No. ER97–1824–000]

Take notice that on April 11, 1997, New York State Electric & Gas Corporation (NYSEG) supplemented its filing in this docket for the provision of Economic Development Power (EDP) service to eligible customers, Rate Schedule FERC No. 179. The proposed supplement clarifies information provided related to NYSEG's request to implement revised rates for EDP service.

NYSEG has sent a copy of this filing to the following: the New York State Public Service Commission, counsel for the Multiple Intervenors, the New York Power Authority, the New York State Department of Economic Development and EDP Customers.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

15. Northern States Power Company

[Docket No. ER97–1914–000]

Take notice that on April 17, 1997, Northern States Power Company tendered its filing of Amendment No. 2 to the Municipal Interconnection and Interchange Agreement between NSP and the City of Madelia, Minnesota. The filing contains cost support and the unbundled power sale rate information.

A copy of the filing was served upon each of the parties named in the Service List.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

16. Northeast Utilities Service Company

[Docket No. ER97–1931–000]

Take notice that on April 18, 1997, Northeast Utilities Service Company (NUSCO), on behalf of The Connecticut Light and Power Company, Western Massachusetts Electric Company, Holyoke Water Power Company (including Holyoke Power and Electric Company) and Public Service Company of New Hampshire, tendered for filing pursuant to Section 205 of the Federal Power Act and Section 35.13 of the Commission's Regulations, supplemental information regarding a rate schedule change for sales of electric energy to Middleton Municipal Electric Department.

NUSCO states that a copy of this filing has been mailed to Middleton Municipal Electric Department.

NUSCO requests that the rate schedule change become effective on May 1, 1997.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

17. Nantucket Electric Company & New England Power Company

[Docket No. ER97–2368–000]

Take notice that on April 11, 1997, Nantucket Electric Company and New England Power Company submitted an amendment to their filing in this docket requesting a new effective date of April 2, 1997.

Comment date: May 15, 1997, in accordance with Standard Paragraph E at the end of this notice.

18. Engage Energy US, L.P.

[Docket No. ER97–2421–000]

Take notice that on April 21, 1997, Engage Energy US, L.P., tendered for filing a copy of a Notice of Succession in Ownership. This filing serves as notice that the name of Newco US, L.P. has been changed to Engage Energy US, L.P.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

19. Pennsylvania Power & Light Company

[Docket No. ER97–2464–000]

Take notice that on April 8, 1997, Pennsylvania Power & Light Company (PP&L) filed a Service agreement dated March 19, 1997, with Southern Energy Trading & Marketing, Inc. (Southern Energy) for non-firm point-to-point transmission service under PP&L's Open Access Transmission Tariff. The Service Agreement adds Southern Energy as an eligible customer under the Tariff.

PP&L requests an effective date of April 8, 1997, for the Service Agreement.

PP&L states that copies of this filing have been supplied to Southern Energy and to the Pennsylvania Public Utility Commission.

Comment date: May 15, 1997, in accordance with Standard Paragraph E at the end of this notice.

20. Duke Power Company

[Docket No. ER97–2601–000]

Take notice that on April 15, 1997, Duke Power Company (Duke), tendered for filing with the Commission a true-up filing for the calendar year 1996 under Article II.3 of the Settlement Agreement in this docket.

Copies of this filing were mailed to Southeastern Power Administration, North Carolina Electric Membership Corp., Saluda River Electric Cooperative, Inc. and Blue Ridge Electric Membership Corp.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

21. Virginia Electric and Power Company

[Docket No. ER97–2606–000]

Take notice that on April 18, 1997, Virginia Electric and Power Company (Virginia Power), tendered for filing a Service Agreement between Virginia Electric and Power Company and EnerZ Corporation under the Power Sales Tariff to Eligible Purchasers dated May 27, 1994, as revised on December 31, 1996. Under the tendered Service Agreements Virginia Power agrees to provide services to EnerZ Corporation under the rates, terms and conditions of the Power Sales Tariff as agreed by the parties pursuant to the terms of the applicable Service Schedules included in the Power Sales Tariff.

Copies of the filing were served upon the Virginia State Corporation Commission, and the North Carolina Utilities Commission.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

22. Boston Edison Company

[Docket No. ER97–2607–000]

Take notice that on April 18, 1997, Boston Edison Company (Boston Edison), tendered for filing a Service Agreement and Appendix A under Original Volume No. 6, Power Sales and Exchange Tariff (Tariff) for Tosco Power, Inc. (Tosco). Boston Edison requests that the Service Agreement become effective as of April 1, 1997.

Edison states that it has served a copy of this filing on Tosco and the

Massachusetts Department of Public Utilities.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

23. New York State Electric & Gas Corporation

[Docket No. ER97–2608–000]

Take notice that New York State Electric & Gas Corporation (NYSEG) on April 18, 1997, tendered for filing pursuant to Part 35 of the Federal Energy Regulatory Commission's Rules of Practice and Procedure, 18 CFR 35, service agreements under which NYSEG will provide capacity and/or energy to Citizens Lehman Power Sales (Citizens), Duke/Louis Dreyfus, L.L.C. (Duke/Louis), Federal Energy Sales, Inc. (Federal), Koch Energy Trading, Inc. (Koch), and Rainbow Energy Marketing Corporation (Rainbow) in accordance with the NYSEG market-based power sales tariff.

NYSEG has requested waiver of the notice requirements so that the service agreements with Citizens, Duke/Louis, Federal, Koch, and Rainbow become effective as of April 19, 1997.

NYSEG served copies of the filing upon the New York State Public Service Commission, Citizens, Duke/Louis, Federal, Koch, and Rainbow.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

24. Southern California Edison Company

[Docket No. ER97–2609–000]

Take notice that on April 18, 1997, Southern California Edison Company (Edison), tendered for filing Service Agreements (Service Agreements) with the City of Vernon for Firm Point-To-Point Transmission Service under Edison's Open Access Transmission Tariff (Tariff) filed in compliance with FERC Order No. 888, and a Notice of Cancellation of Service Agreement Nos. 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, and 74 under FERC Electric Tariff, Original Volume No. 4.

Edison filed the executed Service Agreements with the Commission in compliance with applicable Commission Regulations. Edison also submitted a revised Sheet No. 152 (Attachment E) to the Tariff, which is an updated list of all current subscribers. Edison requests waiver of the Commission's notice requirement to permit an effective date of April 19, 1997, for Attachment E, and to allow the Service Agreements to become effective and terminate according to their terms.

Copies of this filing were served upon the Public Utilities Commission of the State of California and all interested parties.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

25. Cinergy Services, Inc.

[Docket No. ER97–2610–000]

Take notice that Cinergy Services, Inc. (Cinergy), on April 18, 1997, tendered for filing on behalf of its operating companies, The Cincinnati Gas & Electric Company (CG&E) and PSI Energy, Inc. (PSI), an Interchange Agreement, dated March 1, 1997 between Cinergy, CG&E, PSI and North American Energy Conservation, Inc. (NAEC).

The Interchange Agreement provides for the following service between Cinergy and NAEC:

1. Exhibit A—Power Sales by NAEC.
2. Exhibit B—Power Sales by Cinergy.

Cinergy and NAEC have requested an effective date of one day after this initial filing of the Interchange Agreement.

Copies of the filing were served on North American Energy Conservation, Inc., the Kentucky Public Service Commission, the New York Public Service Commission, the Public Utilities Commission of Ohio and the Indiana Utility Regulatory Commission.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

26. Commonwealth Edison Company

[Docket No. ER97–2611–000]

Take notice that on April 18, 1997, Commonwealth Edison Company (ComEd), submitted for filing an unexecuted firm Service Agreement with Delhi Energy Services, Inc. (Delhi), under the terms of ComEd's Open Access Transmission Tariff (OATT).

ComEd requests an effective date of March 20, 1997, and accordingly seeks waiver of the Commission's notice requirements. Copies of this filing were served upon Delhi and the Illinois Commerce Commission.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

27. Southern Company Services, Inc.

[Docket No. ER97–2612–000]

Take notice that on April 18, 1997, Southern Company Services, Inc. (SCSI), acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (collectively referred to as Southern Companies) filed one (1) service agreement under Southern Companies' Market-Based Rate Power Sales Tariff (FERC Electric Tariff, Original Volume No. 4) with the following entity: Florida Power and Light Company. SCSI states that the service agreement will enable Southern Companies to engage in short-term market-based rate transactions with this entity.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

28. Pacific Gas and Electric Company

[Docket No. ER97–2613–000]

Take notice that on April 18, 1997, Pacific Gas and Electric Company (PG&E), tendered for filing two Service Agreements between PG&E and (1) Western Power Services, Inc. (WPS); and (2) Salt River Project (Salt River); each entitled, Service Agreement for Non-Firm Point-to-Point Transmission Service (Service Agreements).

PG&E proposes that the Service Agreements become effective on March 19, 1997 for WPS and April 7, 1997 for Salt River. PG&E is requesting any necessary waivers.

Copies of this filing have been served upon the California Public Utilities Commission, WPS and Salt River.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

29. Boston Edison Company

[Docket No. ER97–2614–000]

Take notice that on April 18, 1997, Boston Edison Company (Boston Edison), tendered for filing a Service Agreement under Original Volume No. 8, FERC Order No. 888 Tariff (Tariff) for Aquila Power Corporation (Aquila). Boston Edison requests that the Service Agreement become effective as of April 1, 1997.

Edison states that it has served a copy of this filing on Aquila and the Massachusetts Department of Public Utilities.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

30. Allegheny Power Service Corporation, on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (Allegheny Power)

[Docket No. ER97–2615–000]

Take notice that on April 16, 1997, Allegheny Power Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (Allegheny Power) filed Supplement No. 22 to add two (2) new Customers to the Standard Generation

Service Rate Schedule under which Allegheny Power offers standard generation and emergency service on an hourly, daily, weekly, monthly or yearly basis. Allegheny Power requests a waiver of notice requirements to make service available as of April 11, 1997, to American Energy Solutions, Inc. And NIPSCO Energy Services, Inc.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

31. Allegheny Power Service Corporation, on behalf of Monongahela Power Company, The Potomac Edison Company, and West Penn Power Company (Allegheny Power)

[Docket No. ER97–2616–000]

Take notice that on April 16, 1997, Allegheny Power Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (Allegheny Power), filed Supplement No. 14 to add American Energy Solutions, Inc., CMS Marketing, Services and Trading Company, Delmarva Power & Light Company, and MidCon Power Services Corp. to Allegheny Power Open Access transmission Service Tariff which has been submitted for filing by the Federal Energy Regulatory Commission in Docket No. OA96–18–000. The proposed effective date under the Service Agreements is April 11, 1997.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

32. Northeast Utilities Service Company

[Docket No. ER97–2617–000]

Take notice that on April 18, 1997, Northeast Utilities Service Company (NUSCO), on behalf of The Connecticut Light and Power Company, Western Massachusetts Electric Company, Holyoke Water Power Company (including Holyoke Power and Electric Company) and Public Service Company of New Hampshire, tendered for filing pursuant to Section 205 of the Federal Power Act and Section 35.13 of the Commission's Regulations, supplemental information regarding a rate schedule change for sales of electric energy to Middleton Municipal Electric Department.

NUSCO states that a copy of this filing has been mailed to Middleton Municipal Electric Department.

′NUSCO requests that the rate schedule change become effective on May 1, 1997.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

33. Montana-Dakota Utilities Co., a Division of MDU Resources Group, Inc.

[Docket No. ER97–2618–000]

Take notice that on April 21, 1997, Montana-Dakota Utilities Co., a division of MDU Resources Group, Inc. (Montana-Dakota) tendered for filing Supplements Nos. 1 and 2 to two agreements between Montana-Dakota and Capital Electric Cooperative, Inc. (Capital).

Montana-Dakota asserts that the filing has been served on Capital and on all interested state regulatory agencies.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

34. Northern Indiana Public Service Company

[Docket No. ER97–2619–000]

Take notice that on April 21, 1997, Northern Indiana Public Service Company tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and Wisconsin Public Service Corporation.

Under the Service Agreement, Northern Indiana Public Service Company agrees to provide services to Wisconsin Public Service Corporation under Northern Indiana Public Service Company's Power Sales Tariff. Northern Indiana Public Service Company and Wisconsin Public Service Corporation request waiver of the Commission's sixty-day notice requirement to permit an effective date of April 15, 1997.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

35. Northern Indiana Public Service Company

[Docket No. ER97–2620–000]

Take notice that on April 21, 1997, Northern Indiana Public Service Company tendered for filing an executed Standard Transmission Service Agreement for Non-Firm Point-to-Point Transmission Service between Northern Indiana Public Service Company and Wisconsin Public Service Corporation.

Under the Transmission Service Agreement, Northern Indiana Public Service Company will provide Point-to-Point Transmission Service to Wisconsin Public Service Corporation pursuant to the Transmission Service Tariff filed by Northern Indiana Public Service Company in Docket No. OA96–47–000 and allowed to become effective by the Commission. Northern Indiana Public Service Company has requested that the Service Agreement be allowed to become effective as of April 15, 1997.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

36. Northern Indiana Public Service Company

[Docket No. ER97–2621–000]

Take notice that on April 21, 1997, Northern Indiana Public Service Company tendered for filing an executed Standard Transmission Service Agreement for Non-Firm Point-to-Point Transmission Service between Northern Indiana Public Service Company and Pennsylvania Power & Light Company.

Under the Transmission Service Agreement, Northern Indiana Public Service Company will provide Point-to-Point Transmission Service to Pennsylvania Power & Light Company pursuant to the Transmission Service Tariff filed by Northern Indiana Public Service Company in Docket No. OA96–47–000 and allowed to become effective by the Commission. Northern Indiana Public Service Company has requested that the Service Agreement be allowed to become effective as of April 15, 1997.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

37. UtiliCorp United Inc.

[Docket No. ER97–2623–000]

Take notice that on April 21, 1997, UtiliCorp United Inc. (UtiliCorp) filed service agreements with Delhi Energy Services, Inc. for service under its non-firm point-to-point open access service tariff for its operating divisions, Missouri Public Service, WestPlains Energy—Kansas and WestPlains Energy—Colorado.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

38. Wisconsin Public Service Corporation

[Docket No. ER97–2624–000]

Take notice that on April 21, 1997, Wisconsin Public Service Corporation tendered for filing executed service agreements with Illinois Power Company under its CS–1 Coordination Sales Tariff.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

39. New York State Electric & Gas Corporation

[Docket No. ER97–2625–000]

Take notice that New York State Electric & Gas Corporation (NYSEG) on April 21, 1997, tendered for filing pursuant to Section 35.12 of the Federal Energy Regulatory Commission's Rules of Practice and Procedure, 18 CFR 35.12, as an initial rate schedule, an agreement with Cincinnati Gas & Electric Company and PSI Energy, Inc., collectively referred to as the Cinergy Operating Companies (Cinergy). The agreement provides a mechanism pursuant to which the parties can enter into separately scheduled transactions under which NYSEG will sell to Cinergy and Cinergy will purchase from NYSEG either capacity and associated energy or energy only as the parties may mutually agree.

NYSEG requests that the agreement become effective on April 22, 1997, so that the parties may, if mutually agreeable, enter into separately scheduled transactions under the agreement. NYSEG has requested waiver of the notice requirements for good cause shown.

NYSEG served copies of the filing upon the New York State Public Service Commission and Cinergy.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

40. Carolina Power & Light Company

[Docket No. ER97–2626–000]

Take notice that on April 22, 1997, Carolina Power & Light Company (CP&L), tendered for filing separate Service Agreements for Non-Firm Point to Point Transmission Service executed between CP&L and the following Eligible Transmission Customers: Progress Power Marketing, Inc., and Kentucky Utilities Company. Service to each Eligible Customer will be in accordance with the terms and conditions of Carolina Power & Light Company's Open Access Transmission Tariff.

Copies of the filing were served upon the North Carolina Utilities Commission and the South Carolina Public Service Commission.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

41. Western Resources, Inc.

[Docket No. ER97–2627–000]

Take notice that on April 22, 1997, Western Resources, Inc., tendered for filing a non-firm transmission agreement between Western Resources and Rainbow Energy Marketing Corporation. Western Resources states that the purpose of the agreement is to permit non-discriminatory access to the transmission facilities owned or controlled by Western Resources in accordance with Western Resources' open access transmission tariff on file with the Commission. The agreement is proposed to become effective March 27, 1997.

Copies of the filing were served upon Rainbow Energy Marketing Corporation and the Kansas Corporation Commission.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

42. UtiliCorp United Inc.

[Docket No. ES97–28–000]

Take notice that on April 21, 1997, UtiliCorp United Inc. filed an application, under Section 204 of the Federal Power Act, seeking authorization to issue corporate guaranties in an amount not to exceed $25 million (Canadian) to be issued by West Kootenay Power, Ltd. (WKP) on or before December 31, 1997, which have estimated maturity dates of not more than thirty years after the issuance, and for an exemption from the Commission's competitive bidding and negotiated placement requirements. WKP is a wholly-owned subsidiary of UtiliCorp British Columbia Ltd., which in turn is a wholly-owned subsidiary of Utilicorp.

Comment date: May 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

43. Oregon Trail Electric Consumers Cooperative Inc.

[Docket No. ES97–29–000]

Take notice that on April 24, 1997, Oregon Trail Electric Consumers Cooperative Inc. (Oregon Trail) filed an application, under Section 204 of the Federal Power Act, seeking authorization to enter and borrow funds under a two-year, $5 million line of credit agreement. Under the agreement, Oregon Trail will be obligated to repay any advances with interest within 360 days of the advances.

Comment date: May 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

44. Florida Power Corporation

[Docket No. OA97–395–000]

Take notice that on April 15, 1997, Florida Power Corporation (FPC) tendered for filing a revision to Amendment No. 2 to its contract for the provision of interchange service between itself and Kissimmee Utility Authority. The sole purpose of the revision is to acknowledge that Kissimmee Utility Authority is the successor to the City of Kissimmee.

Comment date: May 16, 1997, in accordance with Standard Paragraph E at the end of this notice.

45. Idaho Power Company

[Docket No. TX97–6–000]

On April 16, 1997, Idaho Power Company (IPCo),1221 W. Idaho, Boise, Idaho, filed with the Federal Energy Regulatory Commission an Application requesting that the Commission order The Bonneville Power Administration to provide transmission services pursuant to Section 211 of the Federal Power Act.

Said request for transmission was for firm transmission of 30 megawatts of capacity and energy, to commence upon the effective date of a Commission Order and terminating June 30, 2001. Said services are sought in connection with IPCo's response to the Request for Proposal of Salmon River Electric Cooperative dated July 25, 1996.

Comment date: May 21, 1997, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the

Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12100 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Filed With the Commission

May 5, 1997.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Amendment of License.

b. *Project No.:* 2142–025.

c. *Date filed:* December 30, 1996.

d. *Applicant:* Central Maine Power.

e. *Name of Project:* Indian Pond.

f. *Location:* The project is located on the Kennebec River, in Somerset and Piscataquis Counties, Maine.

g. *Filed pursuant to:* Federal Power Act, 16 U.S.C. § 791(a)–825(r).

h. *Applicant Contact:* William Campbell, Central Maine Power, 83 Edison Drive, Augusta, ME 04336, Phone: (207) 621–4493.

i. *FERC Contact:* Jake H. Tung, (202) 219–2663.

j. *Comment Date:* June 12, 1997.

k. *Description of Amendment:* The licensee, Central Maine Power, applied for an amendment of license to remove all long-term leased lands from the Indian Pond Project. The redrawn project boundary removes the existing long-term leases from the project and allows continued shoreline erosion control by maintaining at least 50 feet of the project land on the shore side of the leased lands.

1. This notice also consists of the following standard paragraphs; B, C1, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: the Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invite to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12114 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Filed With the Commission

May 5, 1997.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Amendment to Licenses.

b. *Project Nos.:* 2322–023, 2325–021, 2552–022, 2574–021, 5073–051, 2611–030, and 11472–002.

c. *Date Filed:* April 23, 1997.

d. *Applicants:* Kennebec Hydro Developers Group (Central Maine Power Company, Merimil Limited Partnership, Benton Falls Associates, Kimberly-Clark Tissue Co./UAH Hydro-Kennebec Limited Partnership, and Ridgewood Maine Hydro Partners, L.P.).

e. *Name of Projects:* Shawmut, Weston, Ft. Halifax, Lockwood, Benton Falls, Hydro-Kennebec, and Burnham.

f. *Location:* Kennebec and Sebasticook Rivers, Kennebec, Somerset and Waldo Counties, Maine.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* F. Allen Wiley, P.E., Managing Director, Generation, Central Maine Power Company, North Augusta Office Annex, 41 Anthony Avenue, Augusta, ME 04430, (207) 626–9620.

i. *FERC Contact:* Robert Grieve, (202) 219–2655.

j. *Comment Date:* June 16, 1997.

k. *Description of Application:* By order issued October 22, 1992, the Commission incorporated provisions of the Kennebec Hydro Developers Group (KHDG) agreement into the licenses for six licensed projects (Project Nos. 2322, 2325, 2552, 2574, 5073, and 2611). The order set the dates for filing of fish passage drawings (1997–1999) and construction of fish passage facilities (1999–2001). For Project No. 11472, an existing unlicensed project, the applicant has proposed in its application for license to provide downstream fish passage within 2 years of licensing and upstream passage within 2 years of licensing or by the year 2000, whichever is later, in accordance with the KHDG agreement.

KHDG applicants request: (1) amendment of the existing licenses to require that fish passage facilities be installed only when (a) either permanent fish passage is available at the Edwards Dam Project No. 2389 or that dam is removed, and (b) a biological assessment process determines that restoration efforts have advanced sufficiently to require fish passage; (2) an extension of time for Project Nos. 2552, 5073, 2574, and 2611 to file functional design drawings, now due April 30, 1997, until it has been determined through an assessment process that permanent fish passage facilities are necessary; (3) a stay of the requirement to file said drawings by April 30, 1997; (4) revision of Commission staff's recommendations in the Kennebec River Basin Draft Environmental Impact Statement that

fish passage facilities be installed for Project Nos. 2552 and 2325 by 1999 and 2001, respectively, to be consistent with the request for license amendment; (5) revision of Commission staff's recommendation in the Environmental Assessment for Project No. 11472, issued November 1, 1996, that fish passage facilities be installed by 2000, to be consistent with the request for license amendment; and (6) to the extent that there is any opposition to these requests, a technical conference with the Commission and interested parties to discuss the issues presented by these requests, including, in particular, the conditions under which the KHDG dam owners would continue to conduct trap and truck operations after 1998, at which time their existing obligation to conduct such operations ceases.

l. This notice also consists of the following standard paragraphs: B, C1, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, D.C. 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Lois D. Cashell,

Secretary.

[FR Doc. 97–12115 Filed 5–8–97; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5480–2]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared April 21, 1997 Through April 25, 1997 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of FEDERAL ACTIVITIES AT (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 04, 1997 (62 FR 16154).

Draft EISs

ERP No. D–BLM–K65196–CA Rating EO2, Interlakes Special Recreation Management Area Plan, Implementation, Federal and Private Lands Issues, Shasta County, CA.

Summary

EPA expressed environmental objections with the lack of information regarding monitoring and mitigation proposals to offset significant environmental impacts associated with OHV use in the Chappie-Shasta OHV Management Areas.

ERP No. D–COE–C35011–00 Rating EC2, Newark Bay Confined Disposal Facility (NBCDF), Construction, Dredged Material Disposal Site, NY and NJ.

Summary

EPA expressed environmental concerns about the proposed project and requested that additional information be presented in the Final EIS to address these concerns. EPA expressed concerns with the project's monitoring plan and requested a complete assessment of the project's potential impacts to buried prehistoric deposits as well.

ERP No. D–FHW–E40700–GA Rating EC2, Harry S. Truman Parkway, Construction from the Abercorn Street Extension (GA–204) to Derenne Avenue, COE Section 404 Permit and U.S. Coast Guard Permit, Chatham County, GA.

Summary

EPA expressed environmental concerns regarding impacts to estuarine marshes. EPA recommended that additional mitigation be provided to reduce marsh impacts.

ERP No. D–UAF–G11032–TX Rating LO, Reese Air Force Base (AFB) Disposal and Reuse, Implementation, NPDES Permit and COE Section 404 Permit, Lubbock and Terry Counties, TX.

Summary

EPA had no objections to the selection of the preferred alternative.

ERP No. D–USN–K11078–00 Rating EO2, Marianas Islands Military Training, Implementation, Marianas Training Plan, Guam, Commonwealth of the Northern Mariana Islands, Asia, Hawaii and Alaska.

Summary

EPA expressed environmental objections due to significant impact to biological resources and coral reefs. EPA requested additional information regarding project description, purpose and need, alternative development and cumulative impacts.

ERP No. DA–COE–C32034–00 Rating EC2, Delaware River Comprehensive Navigation Channel Improvement, Additional Information, Beckett Street Terminal in New Jersey through Philadelphia Harbor, Implementation, several counties, NJ, DE and PA.

Summary

EPA expressed environmental concerns about the design and monitoring plan for Kelly Island, and the stockpiling of sand at Slaughter and Broadkill Beaches. Additional information should be presented in the final SEIS to address these issues.

ERP No. DS–AFS–L65202–ID Rating LO, Katka Peak Timber Sale and Road Construction, Implementation, New Information from Interior Columbia Basin Ecosystem Management Project, to implement Ecosystem Restoration Treatment, Bonners Ferry Ranger District, Idaho Panhandle National Forests, Boundary County, ID.

Summary

Our abbreviated review has revealed no EPA concerns on this project.

ERP No. DS–AFS–L67028–AK Rating EC1, Kensington Venture Underground Gold Mine Project, Additional Information, Development, Construction and Operation, Operating Plan Approval, NPDES, Section 10 and 404

Permits, Tongass National Forest, Sherman Creek, City of Juneau, AK.

Summary

EPA continued to express environmental concerns regarding impacts to air quality diesel fuel spill risks to water quality, visual impacts, the feasibility of mitigation and reclamation measures, and the need to minimize impacts associated with effluent discharges. The Final SEIS should provide additional information on evaluation of project component options and mitigation measures.

ERP No. DS–FAA–L51014–WA Rating EC2, Seattle-Tacoma International Airport Improvement, South Aviation Support Area, Airport Layout Plan, Airport Master Plan; Updated Information on Master Plan Development Actions, Funding, Section 10 and 404 Permits and NPDES Permit, Port of Seattle, King County, WA.

Summary

EPA expressed reservations/concerns with the conclusion that the conforms to the State Implementation Plan. Should the final conformity determination significantly differ from the updated draft conformity analysis, it may be necessary for the FAA to allow for additional public comments on that analysis prior to making a decision. In particular, an additional public comment period should be considered if the de minimis thresholds have been exceeded for carbon monoxide and/or oxides of nitrogen.

Final EISs

ERP No. F–AFS–K65186–NV, Spring Mountains National Recreation Area General Management Plan, Toiyabe National Forest Land and Resource Management Plan, Amendment, Implementation, Clark and Nye Counties, NV.

Summary

Review of the FEIS was not deemed necessary. No formal comment letter was sent to the preparing agency.

ERP No. F–DOE–L09806–WA, Northwest Regional Power Facility (NRPF), Construction and Operation if a 838 Megawatt (MW) Gas-fired Combustion Turbine Facility, Approval of Permits, Located near the Town of Creston, WA.

Summary

EPA continued to express environmental concerns regarding water quality and wetlands impacts based upon indirect effects and project segmentation. EPA encourages BPA to issue a single EIS with the Federal Energy Regulatory Commission that considers alternative sites for the project.

ERP No. F–FHW–40756–SC, and Greenville Southern Connectors Construction and Operation, I–185 at I–85 south of Donaldson Center Industrial Air Park to I–385 at US 276 and SC–153 Connector from existing SC–153 at I–85 to the Southern Connector, Funding and COE Section 404 Permit, Anderson and Greenville Counties, SC.

Summary

EPA expressed environmental concerns over floodplain crossings and associated impacts, and the loss of terrestrial habitat.

ERP No. F–FRC–L05053–WA, Condit Hydroelectric Project (FERC No. 2342–005), Relicensing, White Salmon River, Klickitat and Skamania Counties, WA.

Summary

EPA expressed objection to the proposed action based on adverse impacts to fish and other aquatic life in the White Salmon River. EPA also expressed concern over FERC's method of assessing impacts of the proposed alternative.

Dated: May 6, 1997.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97–12243 Filed 5–8–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5480–1]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or (202) 564–7153. Weekly receipt of Environmental Impact Statements Filed April 28, 1997 Through May 2, 1997 Pursuant to 40 CFR 1506.9. Reese (208) 624–3151.

EIS No. 970159, Final EIS, USN, AZ, CA, Yuma Training Range Complex Management, Operation and Development, Marine Corps Air Station Yuma, Goldwater Range, Yuma and La Paz Cos; and Chocolate Mountain Range, Imperial and Riverside Counties, CA, Due: June 9, 1997, Contact: Ron Pearc (520) 341–3318.

EIS No. 970160, Draft EIS, COE, AZ, Tucson Drainage Area Arizona, Implementation, Reduce Flooding, City of Tucson, Pima County, AZ, Due: June 23, 1997, Contact: William O. Butler (213) 452–3845.

EIS No. 970161, Draft EIS, AFS, MT, Jericho Salvage Timber Sale, Implementation, Salvage Treatments and Temporary Road Construction, Helena Natioal Forest, Helena Ranger District, Powell County, MT, Due: June 23, 1997, Contact: Dan Mainwaring (406) 449–5490.

EIS No. 970162, Draft EIS, UAF, ID, Idaho Enhanced Training Project, Training for the 366th Wing at Mountain Home Air Force Base (AFB), Approval for Rights-of-Way Permit by (BLM) and Airspace Modifications by (FAA), Owyhee County, ID, Due: August 14, 1997, Contact: Brenda Cook (757) 764–6197.

EIS No. 970163, Draft EIS, COE, VA, KY, Levisa Fork/Haysi Dam Project, Implementation, Section 202 General Plan for Flood Damage Reduction, Flood Control Project, Buchanan County, VA and Pike County, KY, Due: June 23, 1997, Contact: A. Benjamim Borda (304) 529–5712.

EIS No. 970164, Final EIS, AFS, CO, Aspen Highlands Ski Area Expansion, Amend to Master Development Plan, COE 404 Permit and Special-Use-Permit, White River National Forest, Aspen Ranger District, Pitkin County, CO, Due: June 9, 1997, Contact: Arthur Bauer (970) 925–3445.

EIS No. 970167, Draft EIS, FHW, RI, Newport Marine Facilities Project, To Develop the Marine Mode of the Intermodal Gateway Transportation Center, Selected siting in various locations within the City of Newport, Towns of Middletown and Portsmouth, Funding, COE Section 404 Permit and US Coast Guard Permit, Aquidreck Island, RI, Due: June 23, 1997, Contact: Daniel Berman (401) 528–4541.

EIS No. 971059, Draft EIS, DOI, TT, Palau Compact Road Construction, Implementation, Funding, Republic of Palau. Babeldaob Island, Trust Territory of the Pacific Islands , Due: June 23, 1997, Contact: Allen Chin (808) 438–6974.

Amended Notices

EIS No. 970152, Draft EIS, AFS, CA, Canyons Project, Implementation, Truckee Ranger District, Tahoe National Forest, Sierra and Nevada Counties, CA, Due: June 16, 1997, Contact: Caryn Hunter (916) 587–3558. Published FR—05–02–97—Due Date Correction.

EIS No. 970153, Final EIS, GSA, MD, U.S. Food and Drug Administration (FDA) Consolidation of the following: Center for Drug Evaluation and

Research (CDER), Center for Devices and Radiological Health (CDRH), Center for Biologics Evaluation and Research (CBER) and Office of Commissioner (OC), Site Selection, White Oak Naval Surface Weapons Center, Montgomery, MD, Due: June 2, 1997, Contact: Jag Bhargava (202) 708–7248. Published FR—05–02–97—Due Date Correction.

EIS No. 970154, Draft EIS, AFS, MT, Poorman Project, Implementation, Harvesting and Road Construction, Helena National Forest, Lincoln Ranger District, Lewis and Clark County, MT, Due: June 16, 1997, Contact: Thomas J. Andersen (406) 449–5201. Published FR—05–02–97—Due Date Correction.

EIS No. 970155, Draft EIS, AFS, CA, Damon Fire Salvage and Restoration Project, Implementation, Modoc National Forest, Modoc County, CA, Due: June 16, 1997, Contact: Paul Bailey (916) 233–5811. Published FR—05–02–97—Due Date Correction.

EIS No. 970156, Draft EIS, SCS, OK, Middle Deep Red Run Creek Watershed Plan, Implementation, Funding and Possible COE Section 404 Permit, Central Rolling Red Plains, Tillman, Comanche and Kiowa Counties, OK, Due: June 16, 1997, Contact: Ronnie L. Clark (405) 742–1200. Published FR—05–02–97—Agency Correction.

EIS No. 970157, Final EIS, AFS, NV, Griffon Mining Project, Implementation, Issuance Plan of Operations Approval, Humboldt-Toiyabe National Forests, Ely Ranger District, White Pine County, NV, Due: June 2, 1997, Contact: David Valenzaela (702) 289–3031. Published FR—05–02–97—Due Date Correction.

EIS No. 970158, Final EIS, FTA, TX, North Central Corridor Light Rail Transit (LRT) Extension, Transportation Improvements, Funding, NPDES Permit and COE Section 404 Permit, Dallas and Collin Counties, TX, Due: June 2, 1997, Contact: Jesse Balleza (817) 860–9663. Published FR—05–02–97—Due Date Correction.

Dated: May 6, 1997.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97–12244 Filed 5–8–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5480–3]

Intent To Prepare an Environmental Impact Statement for the Final Rule for Environmental Impact Assessment of Nongovernmental Activities in Antarctica

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of Intent To Prepare an Environmental Impact Statement (EIS) for the Final Rule for Environmental Impact Assessment (EIA) of Nongovernmental Activities in Antarctica.

PURPOSE: The U.S. EPA, in accordance with Section 102(2)(c) of the National Environmental Policy Act (NEPA), will prepare a Draft EIS for the proposed final regulations that will provide for: (1) Environmental impact assessment of nongovernmental activities, including tourism, in Antarctica for which the United States is required to give advance notice under paragraph 5 of Article VII of the Antarctic Treaty of 1959, and (2) coordination of the review of information regarding environmental impact assessments received by the United States from other Parties to the Protocol on Environmental Protection to the Antarctic Treaty. These final regulations will be prepared pursuant to the Antarctic Science, Tourism, and Conservation Act of 1996. EPA invites comments and suggestions on the scope of the rulemaking and analysis including the environmental and regulatory issues to be addressed in the EIS.

DATES: Written comments from the public regarding the environmental and regulatory issues and alternatives to be addressed in the Draft EIS will be accepted by EPA through July 15, 1997. The EPA will also hold a public meeting on Tuesday, July 8, 1997, in Washington, DC, metropolitan area to receive public input, either verbal or written, on relevant environmental and regulatory issues that should be addressed in the Draft EIS. The specific location and time of the public meeting will be published in the **Federal Register** at a later date with this information mailed directly to those requesting to be on the project mailing list.

FOR FURTHER INFORMATION AND TO BE PLACED ON THE PROJECT MAILING LIST CONTACT: Mr. Joseph Montgomery or Ms. Katherine Biggs, Office of Federal Activities (2252A), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; telephone: (202) 564–7157 or (202) 564–7144, respectively. Copies of the Environmental Assessment, Finding of No Significant Impact, and Interim Final Rule discussed in the **SUPPLEMENTARY INFORMATION** section below may be requested from these contacts. These documents are also available on the World Wide Web at: http://es.inel.gov/oeca/ofa/.

SUPPLEMENTARY INFORMATION:

I. Background: Environmental Assessment and Interim Final Rule

The Antarctic Science, Tourism, and Conservation Act of 1996 (Act) implements the Protocol on Environmental Protection (Protocol) to the Antarctic Treaty (Treaty). Pursuant to the Act, the EPA is required to promulgate regulations by October 2, 1998, that provide for assessment of the environmental impacts of nongovernmental activities, including tourism, in Antarctica and for coordination of the review of information regarding environmental impact assessments received from other Parties to the Protocol. The EPA promulgated an Interim Final Rule on April 30, 1998, (**Federal Register**/Vol. 62, No. 83/Wednesday, April 30, 1997/23538–23549) so that the United States would have the ability to implement its obligations under the Protocol as soon as the Protocol enters into force. The EPA also prepared an ''Environmental Assessment of Proposed Interim Rules for Non-Governmental Activity in Antarctica'' (EA) to evaluate the environmental and cultural impacts of the interim rule. Based on the EA's analysis, EPA issued a Finding of No Significant Impact (FNSI) concluding that the promulgation of the Interim Final Rule will not have or cause significant impacts on the Antarctic environment. The Interim Final Rule: sets forth appropriate environmental impact assessment and documentation procedures, including documentation regarding planned mitigation and monitoring, if appropriate, by tour operators; enhances the collection of data on effects and intensity of activities by nongovernmental visitors in Antarctica; and reduces the likelihood of inadvertent environmental perturbations that may be avoidable.

II. Description of Final Rule to be Developed and the Issues and Alternatives to be Considered in the EIS for the Final Rule

During the time the Interim Final Rule is in place and before the October 1998 deadline set by the Act, EPA will

promulgate a Final Rule that will provide for assessment of environmental impacts of nongovernmental activities, including tourism, in Antarctica and for coordination of the review of information regarding environmental impact assessments received from other Parties to the Protocol. In support of this regulatory action, EPA is preparing an EIS to consider the environmental and regulatory issues to be addressed in the Final Rule and the alternatives for addressing these issues within the rule-making process. The alternatives considered by EPA in the Draft EIS will include: (1) No Action, i.e., EPA does not promulgate a Final Rule; (2) promulgation of the requirements of the Interim Final Rule as the Final Rule; and (3) other relevant alternatives necessary to address the associated environmental and regulatory issues raised by EPA and the public. In developing the Draft EIS, EPA will be guided by the statutory requirements of the Act including the requirement that ''* * * regulations shall be consistent with Annex I to the Protocol'' 16 U.S.C. 2403a(c)(2). The EPA will also consider other relevant regulatory provisions and programs such as: the enforcement provisions of and authorities under the Antarctic Conservation Act, 16 U.S.C. 2401 *et seq.*; the National Science Foundation's (NSF) management of the U.S. Antarctic Program for governmental activities, 45 CFR Part 641; the National Environmental Policy Act, 42 U.S.C. 4321 to 4370d, and as referenced in 16 U.S.C. 2403a(a)(1)(A); the Council on Environmental Quality's (CEQ) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act, 40 CFR Parts 1500–1508, and EPA's Procedures for Implementing the Requirements of the Council on Environmental Quality on the National Environmental Policy Act, 40 CFR Part 6. The EPA plans to consider the following issues, along with any other relevant alternatives or issues raised by the public, in the Draft EIS:

(1) Do the time frames of the Interim Final Rule for the submittal and review of the environmental documentation need to be changed?

(2) Should EPA's review criteria more explicitly identify factors to assess in determining the environmental impact of proposed actions? Article 3 of the Protocol, ''Environmental Principles,'' identifies a number of environmental principles for the planning and conduct of activities in Antarctica to protect both the Antarctic environment and its value for the conduct of science in Antarctica. Can and/or should these Principles be more fully integrated into the review criteria to ensure that the environmental analysis provides an understanding of the extent to which the activity will comport with the provisions of Article 3?

(3) What is the appropriate monitoring regime, if any, that should be set out for various types of nongovernmental expeditions? The Protocol requires procedures to assess and verify the actual impacts of an activity which proceeds on the basis of an initial environmental evaluation (IEE) or a comprehensive environmental evaluation (CEE). An operator must provide appropriate monitoring of key environmental indicators for an activity proceeding on the basis of a CEE; further, an operator may also need to carry out monitoring for which an IEE has been prepared. The Treaty Parties are still working to identify monitoring approaches which can best support the Protocol's implementation. Until the Parties agree on such an approach, should the procedures provided for in the Interim Final Rule be expanded or remain the same?

(4) Are there other options for streamlining the documentation requirements? The Interim Final Rule provides for incorporation of materials by reference, consolidation of environmental documentation, and waiver of deadlines, options that reduce the burden on the regulated parties. What other streamlining options should be considered? For example, should there be provisions to allow operators to rely on environmental assessment documentation prepared for past expeditions in cases where there are no changes proposed relative to the proposed expedition(s)? Should there be a provision to allow operators to prepare a ''Programmatic'' IEE or CEE? (Drawing on the NEPA analogy, a Programmatic EIS is an area-wide or overview EIS to address similar activities viewed with other reasonably foreseeable or proposed activities that share common timing or geography. A Programmatic EIS may serve as a basis for tiering, including incorporation by referencing general and relevant specific discussions from it into an EIS of a lesser scope).

(5) What mitigation options should be considered as part of the EIA process? Should mitigation be required for certain activities?

(6) What is the best way to address cumulative impacts? Characterization of impacts from single events is direct and relatively uncomplicated as compared to characterization of cumulative impacts since cumulative impacts involve multiple events over time and often result from the effects of more than one source on a single receptor at a single point in time.

(7) Are there activities, or categories of activities, that can be excluded from the environmental documentation requirements (e.g., Categorical Exclusions)? The CEQ regulations define ''categorical exclusion'' as ''a category of actions which do not individually or cumulatively have a significant effect on the human environment * * * and for which, therefore, neither an environmental assessment nor an environmental impact statement is required'' (40 CFR 1508.4).

(8) Should there be provision for public comment on Initial Environmental Evaluations? This is not required by the Protocol. The Interim Final Rule provides for posting notice of receipt of IEEs on the OFA World Wide Web site and to provide copies to the public upon request.

(9) With regard to the review of environmental documents received from other Parties, should the process as delineated in the Interim Final Rule be modified?

(10) Do the paperwork projections in the Interim Final Rule accurately reflect the reporting requirements for those subject to the Final Rule?

Scoping and Public Comments

Although the Interim Final Rule was promulgated without public notice and comment, the Final Rule and the associated EIS will include extensive opportunities for public comment. The EIS process is subject to the public participation requirements of the National Environmental Policy Act (NEPA) (40 CFR parts 1501.7, 1502.19, and 1503) and EPA's NEPA implementing regulations (40 CFR part 6, subpart D), and the Final Rule will be proposed and promulgated in accordance with the applicable provision of the Administrative Procedure Act (5 U.S.C. 553). An integral part of the NEPA process is public participation in the Scoping process, the key purpose of which is to identify the environmental and regulatory issues and alternatives to be addressed in the Draft EIS. The public may participate in the initial scoping process including the scoping meeting discussed in the **DATES** section above. The public will also have an opportunity to comment on the Draft EIS and the proposed Final Rule.

Estimated Date of Release

The Draft EIS and proposed Final Rule will be made available in January 1998.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 97–12242 Filed 5–8–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–181043; FRL–5712–1]

Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted specific exemptions for the control of various pests to six States listed below. A crisis exemption was initiated by the California Department of Pesticide Regulation and one by the Georgia and Texas Departments of Agriculture. These exemptions, issued during the month of February 1997, including the one in July 1996, are subject to application and timing restrictions and reporting requirements designed to protect the environment to the maximum extent possible. Information on these restrictions is available from the contact persons in EPA listed below.

DATES: See each specific and crisis exemption for its effective date.

FOR FURTHER INFORMATION CONTACT: See each emergency exemption for the name of the contact person. The following information applies to all contact persons: By mail: Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 6th Floor, CS 1B1, 2800 Jefferson Davis Highway, Arlington, VA (703–308–8417); e-mail: group.ermus@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has granted specific exemptions to the:

1. Delaware Department of Agriculture for the use of metolachlor on spinach to control weeds; February 10, 1997, to February 1, 1998. (Margarita Collantes)

2. Kansas Department of Agriculture for the use of propiconazole on dry beans to control rust; July 19, 1996, to September 15, 1996. (Pat Cimino)

3. Massachusetts Department of Food and Agriculture for the use of clopyralid on cranberries to control weeds; February 27, 1997, to July 31, 1997. (Libby Pemberton)

4. Oregon Department of Agriculture for the use of clopyralid on cranberries to control weeds; February 27, 1997, to July 31, 1997. (Libby Pemberton)

5. Washington Department of Agriculture for the use of clopyralid on cranberries to control weeds; February 27, 1997, to July 31, 1997. (Libby Pemberton)

6. Wisconsin Department of Agriculture, Trade, and Consumer Services for the use of metolachlor on spinach to control weeds; February 10, 1997, to August 31, 1997. (Margarita Collantes)

Crisis exemptions were initiated by the:

1. California Department of Pesticide Regulation on February 20, 1997, for the use of maneb on walnuts to control walnut blight. This program will end on June 15, 1997. (Libby Pemberton)

2. Georgia Department of Agriculture on February 28, 1997, for the use of norflurazon on bermudagrass to control weeds. This program is expected to last until July 1, 1997. (Libby Pemberton)

3. Texas Department of Agriculture on February 17, 1997, for the use of norflurazon on bermudagrass to control weeds. This program has ended. (Libby Pemberton)

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Crisis exemptions.

Dated: April 30, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–12193 Filed 5–8–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5817–9]

Proposed Settlement, Cherokee Resources Sites

May 1, 1997.

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to settle claims for response costs under Section 122(g) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. 9622(g), with parties qualifying for *de minimis* settlements. These claims relate to removal and response actions undertaken by EPA at the Cherokee Resources Sites on Berryhill Road and Summit Avenue in Charlotte, Mecklenbury County, North Carolina.

EPA will consider public comments on the proposed settlement which are received by EPA within thirty (30) days of the date of this notice. EPA may withdraw or withhold consent to the proposed settlement if such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper or inadequate.

Request for copies of the proposed settlement and a list of proposed settling *de minimis* parties are available from Ms. Paula V. Batchelor at the address below. Written comments may be submitted to Ms. Batchelor at the same address within thirty (30) days of the date of publication.

Ms. Paula V. Batchelor, U.S. Environmental Protection Agency, Region 4, Waste Management Division, Atlanta Federal Center, 61 Forsyth Street, S.W., Atlanta, Georgia 30303–3104, 404/562–8887.

Dated: May 1, 1997.

Robert Jourdan,

Acting Director, Waste Management Division.

Cherokee Oil—Index of Signed de minimis Settlement Offers

3R, Inc.
AAR Powerboss Inc. f/k/a AAR Brook & Perkins
A C Wildenhouse
A D Milling Co. a/k/a Archer Daniels Midland Co.
A E Finley & Associates
Aeroquip Corp. a/k/a Trinova Corp. f/k/a Kusan Manufacturing Company
A G Boone Co.
AKG of America, Inc.
Alan Kulwicki Racing
Alemite Corporation a/k/a Stewart Warner
Alpha America Equipment
Alumax Extrusions, Inc.
Amerace, Microporous Products, L.P.
American Crane Corp.
Ameron Fiberglass Pipe Division
Ametek, Inc.
Arrowood Mills of NC, Inc.
Assured Casting Corp.
Athol Manufacturing Corp.
Automatic Switch Co.
BABN Tech
B E & K Construction Company
Bergemann USA, Inc.
B F Goodrich/Michelin Tire Co.
Blythe Construction, Inc. f/k/a Blythe Industries
Boren Brick Clay Products
Bradford Brothers
Bridgestone/Firestone, Inc.
Bridon American Corporation
Brown Equipment Manufacturing Company
Burkart Foam, Inc.
Burris Chemical
Butler Manufacturing Company
Carolina Foods
Carolina Storage

Carolina Tractor & Equipment Company
Carrier Transicold
Carson Machine Co.
Ccair, Inc.
Chap Liquidation Company, Inc. f/k/a EZE Manufacturing S.E.
Chardon Metals Products
Cherokee Sanford Group, LLC
Cincinnati Milacron
Clariant Corporation f/k/a Sandoz Chemicals Corporation
Clark Equipment a/k/a Ingersoll-Rand Co.
Clark-Hurth Components a/k/a Ingersoll-Rand Co.
Clayton Marcos Company, Inc.
Clifton Precision, Poly-Science Division of Litton Systems, Inc.
Commercial Intertech Corp.
Commscope, Inc. General Instrument Corporation
Concrete Supply Co.
Consolidated Engravers
Container Corp. of Carolina
Cooper Hand Tools, Division of Cooper Ind. f/k/a Cooper-Weller
Coopers Creek Chemical Corp.
Coyne Cylinder Company a/k/a Thermadyne Industries, Inc.
Croda Inks Corporation
Crown Metro, Inc. a/k/a CM Specialty
CSX Corp.
Del Met Corp.
Dillion Supply Co.
Dillion Yarn Corp.
Ditch Witch oF Charlotte
Doran Mill a/k/a Doran Textiles, Inc.
Dowagiac Mfg Company, Inc.
Eagle Transport
Earth Tech Remediation Svcs f/k/a Environmental Technology of North America
Easco Corporation
Eaton Corp. a/k/a U.S. Engine Valve
Edward Valves, Inc.
Ed's Tires of Laurinburg, Inc. (Biggs St)
Ed's Tires (Raeford Road)
Engineered Controls International, Inc. a/k/a Rego Company
Ensite, Inc.
Erdle Perforating
Fasco Controls Corp.
Fibre Chemicals, Inc.
Fina Oil & Chemical Co.
Finishing Systems, Inc.
Fluor Daniel Co.
Forrest City Tools a/k/a Textron, Inc.
Freudenberg Spunweb Co.
Garber Company, The
General Cable Industries, Inc.
Gibson Guitar Corp.
Gowen Oldsmobile
Gravely, Division of Ariens Company
Great Lakes Chemical
Greenwood, City of
Griffin Tire Co., Inc.
Hanson Industries a/k/a Proctor & Schwartz, Inc.
Harvard Industries, Inc., a/k/a Harman Automotive, Inc.
Hendrick Motor Sports Limited Partnership
Hertz Rent-A-Car
Hertz Equipment Rental
Highland Mills, Inc.
Holding Brothers, Inc.
Holland Atlantic Hitch Company
Home Fulfillment of Virginia, The a/k/a HSN Fulfillment, Inc.
Honda Cars of Concord
Hubbell/A.B. Chance Company
Initial USA
International Paper
I R International, Inc. f/k/a Inta-Roto, Inc.
ISI Automation Products Group, Inc. a/k/a ISI Dyna-Matic
Ithaca Industries
Jaars, Inc.
J B Hunt Transport
K mart Corp.
Kent Machine Company L.P.
Kenworth of Charlotte, Inc.
King's Laboratory, Inc.
Krispy Kreme Corp
Kubota Mfg of America
Kyocera Feldmueble n/k/a Kyocera Engineered Ceramics, Inc.
Labelon Corporation
Lake Norman Chrysler Plymouth Dodge
Lance, Inc.
LaPoint Honda
Layne Trane Co.
Leesona Division of Trafalgar House, Inc.
Libbey-Owens-Ford Co. a/k/a L.O.F. Glass Co.
Livingston & Haven
Long-Airdox Co.
LTV Steel Company a/k/a Georgia Tubing Corporation
M & W Manufacturing, Inc.
Mack Molding Company
Made Rite Foods
Magnolia Plastics, Inc.
Manufacturing Service, Inc.
Merita Bakery a/k/a Interstate Brands Corp
Metal Trades
Micromatic Operations, Inc. a/k/a Micromatic Textron
Mid-State Contractors
Modern Tools
Mooresville Ford
Morganite Inc.
Mubea Inc.
NACCO Materials Handling Group, Inc. a/k/a Yale Materials Handling Corp.
N C I, Inc. A Part of Dowty Aerospace
Nekoosa Packaging
Netzsch, Inc.
NN Ball & Roller, Inc. a/k/a N & N Ballbearing
Norandal USA, Inc.
Norfolk Shipbuilding & Drydock Corporation (Norshipco)
Nu-Brite Chemical Co., Inc. a/k/a Sico, Inc. a/k/a Sterling Varnish
Octane Boost Corp.
Overnite Transportation Co.
Owens-Brockway Glass Container, Inc. a/k/a Owens-Illinois, Inc.
Paktank Corp
Parker Hannifin Corporation, Zenity Pumps Division
Performance Fiction
Petroleum Equipment Co.
Piedmont Aviation
Platts Saco Lowell
PM AG Products, Inc.
P M S Administrated Service
Precision Tool & Machine
Premier Precision Co.
Prodelin Corp.
Rand McNally
Raymond Services
Raytheon Aerospace Company f/k/a Beech Aerospace Service, Inc.
Rexroth Corp.
Richmond, City of
Ritchies Auto Parts
Riverdale Color Manufacturing, Inc.
RL Stowe Mills Inc.
Roadway Express, Inc.
Rochester Corp
Rockwell International Corporation
Rollins Leasing Corp.
Rome Industries
Ross Operating Valve Company d/b/a Ross Controls
Ross Chem, Inc. a/k/a Ross Chemical
Ryobi Motor Products Corp.
Sabco Racing, Inc.
Salem Concrete
Salem Leasing Corporation
Scandura
Sears Automotive
Seton Company
Sherman Textile Co.
Southeastern Freight Lines, Inc.
Southern Gear Works, Inc.
Spartanburg Steel
Spring Industries, Inc. f/k/a Dundee Mills
Sta-Rite Industries, Inc. a/k/a Fluid Controls
Sterling Heating Division, Mestek, Inc. a/k/a Reed National
Stone Heavy Equipment
STP Super Service
Subcon, Inc.
Sulzer Escher
Sumitomo Electric Lighwave Corp
Sun Company, Inc. (R&M) a/k/a Mid-State Oil Company
Superior Printing
Sweetheart Cup Company, Inc.
Teledyne Avionics
Teledyne McKay
Teledyne Readco
Torrington Company, The a/k/a Ingersoll-Rand Company
Union Oil Company of California d/b/a Unocal
Uniroyal Chemical Co., Inc.
United Defense, L.P. f/k/a BMY Combat Systems, Division of Harsco Corp.
United Environmental Group, Inc. f/k/a Penn Tank Disposal
Universal Packing Corporation
Upaco Adhesives
U S G Interiors, Inc.
Vangard Supreme
Victory Products a/k/a Shop Towel Rental
Vulcan Electro-Coating, Inc. f/k/a All Spec, Inc.
Vulcan Materials
V V V Corp a/k/a 3V, Inc.
Vytech Industries, Inc.
W & M Truck Clinic, Inc.
Watts Regulator
Webb Forging Co.
Wells Aluminum Corp
Westinghouse Electric Corporation
Wheelabrator
Whimet Inc.
Willard Industries, Inc.
Wilmington, City of
Woodcraft Moulding a/k/a Larson Juhl, Inc.
Yorktown Naval Weapons Station

[FR Doc. 97–12192 Filed 5–8–97; 8:45 am]
BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

[WT Dkt. No. 97–56; FCC 97–38]

Order to Show Cause, Hearing Designation Order and Notice of Opportunity for Hearing for Forfeiture

AGENCY: Federal Communications Commission.

ACTION: Notice; Hearing Designation Order.

(Authority: 47 U.S.C. §§ 312 and 503; 47 CFR § 0.411(c))

SUMMARY: On February 6, 1997, (released February 12, 1997) the Commission designated pending applications and finder's preference requests filed by Marc Sobel, and licenses held by Marc Sobel and Marc Sobel d/b/a Air Wave Communications (collectively ''Sobel'') for hearing to determine if an unauthorized transfer of control occurred in violation of 47 U.S.C. § 310(d). In addition the Commission directed the ALJ to determine if Sobel is qualified to be a licensee, and to determine if an order for forfeiture should issue. The Commission designated these matters for hearing at a time and place to be designated in a subsequent order.

FOR FURTHER INFORMATION CONTACT: Gary Schonman at (202) 418–0569, FCC 1919 M St., NW.

SUPPLEMENTARY INFORMATION: The following is a synopsis of the Commission's order. The full text of the order is available for inspection and copying at the FCC Docket Branch (Room 230), 1919 M Street NW., Washington, D.C. The text of the order may also be purchased by calling ITS at (202) 857–3800.

The results of the Commission's predesignation investigation indicate that on December 30, 1994, Sobel and another land mobile licensee in the Los Angeles area, James A. Kay, Jr. (''Kay''), executed a so-called Radio System Management and Marketing Agreement (''Agreement'') involving several of Sobel's stations, all of which provide service to subscribers. The Agreement, as amended, expressly covers the following stations: Stations KNBT299, WNYE761, WNYR424, WPFF529, WNXL471, WPAD685, KRU576, WPCN239, WPCZ354, WPCG780, WNWB334, WNZS492, WPDB603, WPFH460, and WPCA891. The Agreement contemplates, among other things, that if the stations have not already been built, Kay will construct them at Kay's expense; Kay will serve as the exclusive supplier of equipment and labor to maintain each of the stations; Kay will be the exclusive marketing agent for the sales of service to the public and/or persons eligible to receive service from each of the stations; Kay will serve as the sole manager of each of the stations; Kay will compensate all employees, agents, and independent contractors and pay all insurance, taxes and other costs arising out of the employment of workers at each of the stations; Kay will maintain all financial records and contracts associated with the operations of each of the stations; and Kay will bear all responsibility for paying utility, telephone, site rental, radio equipment, and legal expenses associated with the operations of each of the stations. In consideration for these services, the Agreement provides that Kay will receive the first $600 of gross revenues per month from the operation of each of the stations, and half of all remaining gross revenues per month from the operation of each of the stations. The Agreement runs for 10 years and renews automatically (unless Kay elects otherwise) for five 10 year periods (for a total of 50 years). The Agreement also grants to Kay, in consideration for $100, an irrevocable 10 year option to purchase any or all of the covered stations, including the assignment of each associated FCC license, for $500 per station upon demand by Kay. The Agreement requires Sobel to maintain exclusive ownership of the subject stations during the term of the Agreement, free of all liens and encumbrances, ''until and unless said license(s) are assigned to'' Kay.

In determining whether *de facto* control of a non-broadcast license or facility has been transferred in violation of § 310(d) of the Communications Act, the Commission and the courts have traditionally relied upon a six-part test announced in *Intermountain Microwave*, 24 RR 983 (1963). When the *Intermountain* factors are applied to the Agreement between Sobel and Kay, a substantial and material question arises as to whether Sobel has willfully and/or repeatedly engaged in unauthorized transfers of control of his stations to Kay, in violation of § 310(d) of the Communications Act of 1934, as amended. Sobel and Kay executed the Agreement a mere two weeks after the Commission formally placed Kay's basic qualifications to remain a licensee in issue. *Order to Show Cause, Hearing Designation Order, and Notice of Opportunity for Hearing for Forfeiture*, 10 FCC Rcd 2062 (1994)(requiring Kay to show cause why his licenses should not be revoked). The nature and timing of Sobel's arrangement with Kay raise serious questions concerning Sobel's compliance with § 310(d) of the Act and, as a consequence, Sobel's basic qualifications to be and remain a Commission licensee.

The Commission designated specific applications for hearing and directed Sobel to show cause why his licenses should not be revoked, in a consolidated proceeding before an FCC Administrative Law Judge at a time and place to be specified in a subsequent Order, upon the following issues: (a) To determine whether Marc Sobel and/or Marc Sobel d/b/a Air Wave Communications have willfully and/or repeatedly violated § 310(d) of the Communications Act of 1934, as amended, by engaging in unauthorized transfers of control of their respective stations to James A. Kay, Jr.; (b) To determine, in light of the evidence adduced pursuant to the foregoing issue, whether Marc Sobel and/or Marc Sobel d/b/a Air Wave Communications are qualified to be and remain Commission licensees; (c) To determine whether the above-captioned applications filed by Marc Sobel and/or Marc Sobel d/b/a Air Wave Communications should be granted; and (d) To determine whether the above-captioned licenses held by Marc Sobel and/or Marc Sobel d/b/a Air Wave Communications should be revoked. The Commission also directed the ALJ to determine, pursuant to § 503(b)(2)(B) of the Communications Act of 1934, as amended, whether an Order of Forfeiture shall be issued against Marc Sobel and/or Marc Sobel d/b/a Air Wave Communications in an amount not to exceed $100,000 for each violation or each day of a continuing violation, except that the amount assessed for any continuing violation shall not exceed a total of $1,000,000 for any single act or failure to act, for having willfully and/or repeatedly violated § 310(d) of the Communications Act of 1934, as amended. The Commission also placed the burden of proceeding with the introduction of evidence and the burden of proof with respect to the issues (a), (b), and (d) above shall be on the Wireless Telecommunications Bureau, and burden of proceeding with the introduction of evidence and the burden of proof with respect to the issue at (c) above on Sobel.

Federal Communications Commission.

Shirley S. Suggs,

Chief, Publications Branch.

[FR Doc. 97–12075 Filed 5–8–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting; Deletion of Agenda Item from May 7th Open Meeting

May 6, 1997.

The following item has been deleted from the list of agenda items scheduled for consideration at the May 7, 1997, Open Meeting (62 FR 24653, May 6, 1997as revised in notice published May 8, 1997) and previously listed in the Commission's Notice of May 5, 1997.

Item No., Bureau, and Subject

1—Office of General Counsel—Title: Section 257 proceeding to Identify and Eliminate Market Entry Barriers for Small Businesses (GN Docket No. 96–113).

Office of Communications Business Opportunities—Summary: The Commission will consider addressing implementation of Section 257.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–12344 Filed 5–7–97; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Approved by Office of Management and Budget

May 2, 1996.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collection pursuant to the Paperwork Reduction Act of 1995, Pub. L. 96–511. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. Not withstanding any other provisions of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Questions concerning the OMB control numbers and expiration dates should be directed to Dorothy Conway, Federal Communications Commission, (202) 418–0217.

Federal Communications Commission

OMB Control No.: 3060–0746.

Expiration Date: 3/31/97.

Title: Application for Electronic Renewal of Wireless Radio Services Authorizations.

Form No.: FCC 900.

Estimated Annual Burden: 5,852 annual hour; average 10 minutes per respondent; 32,355 respondents.

Description: The ''Generic'' renewal and application may be filed in lieu of the FCC form 313R, 402R, 405, 405A, 452R, 574R and 610R to file electronically for renewal of Wireless Radio Service Authorizations. Concurrent with renewal applicants may also request a change of licensee name (with no change in corporate structure, ownership or control), change of mailing address, change the name of their ship, add an official ship number, reinstate a Land Mobile License and notify the Commission of a change in the number of mobiles/pagers for a Land Mobile License.

OMB Control No.: 3060–0747.

Expiration Date: 12/31/99.

Title: Application for Station Authorization in the Microwave Services (Parts 74 and 101).

Form No.: FCC 415.

Estimated Annual Burden: 140,000 annual hours; 7 hours per respondent; 20,000 respondents.

Description: FCC form 415 is used to apply or to amend a pending application, for an authorization to operate a radio station in 47 CFR Part 101, Fixed Microwave Services, and 47 CFR Part 74, Subpart E, Aural Broadcast Auxiliary Stations and Subpart F, Television Broadcast Auxiliary Stations.

OMB Control No.: 3060–0751.

Expiration Date: 1/31/2000.

Title: Regulation of International Accounting Rates (CC Docket No. 90–337).

Form: N/A.

Estimated Annual Burden: 80 total annual hours; average 8 hours per respondent; 10 responses.

Description: CC Docket No. 90–337 implemented rules making it easier for U.S. carriers engaged in international telecommunications to negotiate lower accounting rates. Any carrier that interconnects an international private line to the U.S. public switched network will report on an annual basis its arrangements for the interconnection of such private lines except those private lines that terminate in countries that have been determined to offer equivalent private line resale opportunites to U.S. carriers.

OMB Control No.: 3060–0392.

Expiration Date: 1/31/2000.

Title: 47 CFR 1.1401 through 1.1416 Pole Attachment Complaint Procedures.

Form: N/A.

Estimated Annual Burden: 449 total annual hours; average 1–25 hour per respondent; 83 respondents.

Description: Pole attachment provisions are mandated by Congress pursuant to Section 224 of the Communications Act of 1934. The provisions in Section 224 were initially applicable to cable television system operators. Section 703 of the Telecommunications act of 1996 amended Section 224 and expanded the scope of the pole attachment provisions to include telecommunications carriers as well as cable television system operators.

OMB Control No.: 3060–0113.

Expiration Date: 1/31/2000.

Title: Broadcast EEO Program Report.

Form: FCC 396.

Estimated Annual Burden: 6,000 total annual hours; average 3 hours per respondent; 2,000 respondents.

Description: All AM, FM, TV, LPTV and international stations with 5 or more full-time employees must file the Equal Employment Opportunity Program Report (FCC 396) at the time of renewal of station license. The report is reviewed by FCC analysts to detemine if stations are providing equal employment opportunity to all qualified persons without regard to race, color, religion, sex or national origin.

OMB Control No.: 3060–0228.

Expiration Date: 12/31/99.

Title: 47 CFR 78.33 Special Temporary Authority (Cable Television Reply Stations).

Form No.: N/A.

Estimated Annual Burden: 140 annual hour; average 4 hours per respondent; 35 respondents.

Description: 47 CFR 78.33 permits cable television relay station (CARS) operators to file informal requests for informal requests for special temporary authority to install and operate equipment in a manner different than the way authorized in the station license. Special temporary authority may also be requested by cable operators and equipment suppliers to conduct a field survey to determine necessary data in connection with the preparation of a formal aplication for installation of a radio system as well as to conduct equipment, program service and path tests.

OMB Control No.: 3060–0310.

Expiration Date: 12/31/99.

Title: 47 CFR 76.12 Registration Statement Required.

Form No.: N/A.

Estimated Annual Burden: 150 annual hours; average .25 hour per respondent; 600 respondents.

Description: 47 CFR 76.12 requires that a registration statement be filed with the Commission before a system community unit shall be authorized to

commence operation. A system community unit is a cable television system, or portion of a cable television system, that operates or will operate within a separate and distinct community or municipal entity.

OMB Control No.: 3060–0249.

Expiration Date: 1/31/2000.

Title: Section 74.781 Station Records.

Form: N/A.

Estimated Annual Burden: 5,081 total annual hours; average .25–.75 hours per respondent; 6,556 responses.

Description: Section 74.781 requires licensees of low power television, TV translator and TV booster stations to maintain adequate records. The records are used by FCC staff in field inspections to assure that reasonable measures are taken to maintain proper station operations and to assure compliance with the Commission Rules.

OMB Control No.: 3060–0250.

Expiration Date: 1/31/2000.

Title: Rebroadcasts—Section 74.784.

Form: N/A.

Estimated Annual Burden: 2,163 total annual hours; average 1 hour per respondent; 2,163 respondents.

Description: Section 74.784 requires licensees of low power television and TV translator stations to notify the FCC when rebroadcasting programs or signals of another station and to certify that written consent has been obtained from originating station. Data used by FCC staff to ensure compliance with Section 325(a) of the Communications Act, as amended.

OMB Control No.: 3060–0474.

Expiration Date: 2/28/2000.

Title: Section 74.1263 Time of Operation.

Form: N/A.

Estimated Annual Burden: 38 total annual hours; average .5 hours per respondent; 75 respondents.

Description: Section 74.1263 requires licensees of FM translator or booster stations to notify the FCC of its intent to temporarily discontinue operations, its return to operations, and its intent to permanently discontinue operations. The data is used by FCC staff to keep records up-to-date and to make usued frequencies available to others.

OMB Control No.: 3060–0241.

Expiration Date: 2/28/2000.

Title: Section 74.633 Temporary Authorizations.

Form No.: N/A.

Estimated Annual Burden: 95 annual hour; average 1–2 hours per respondent; 90 respondents.

Description: Section 74.633 requires licenses of television auxiliary broadcast stations to submit informal requests for special temporary authority to operate station on temporary basis under certain circumstances. The data is used by FCC staff to ensure that interference will not be caused to other established stations.

OMB Control No.: 3060–0157.

Expiration Date: 2/28/2000.

Title: Section 73.99 Presunrise Service Authorization (PSRA) and Postsunset Service Authorization (PSSA).

Form No.: N/A.

Estimated Annual Burden: 50 annual hours; .25–.50 hours per respondent; 200 respondents.

Description: Section 73.99 requires licensees of AM radio broadcast stations to submit letters of intent to use presunrise or postsunset service authorizations. Data is used by FCC staff to maintain complete technical information about stations and to ensure that interference is not caused to other stations.

OMB Control No.: 3060–0240.

Expiration Date: 2/28/2000.

Title: Section 74.651 Equipment Changes.

Form: N/A.

Estimated Annual Burden: 10 total annual hours; average 1 hour per respondent; 10 responses.

Description: Section 74.651 requires licensees of TV auxiliary broadcast stations to notify the FCC in writing of equipment changes which may be made at licensee's discretion. Data used by FCC staff to maintain complete technical records regarding a licensee's facilities.

OMB Control No.: 3060–0041.

Expiration Date: 2/28/2000.

Title: Application for Authority to Operate a Broadcast Station by Remote Control.

Form: FCC 301–A.

Estimated Annual Burden: 30 total annual hours; average .25–.5 hours per respondent; 80 respondents.

Description: FCC–301–A is filed by AM radio station licensees/permittees with directional antennas to request authority to operate a station by remote control. The data is used by FCC staff to assure that the directional antenna system is stable.

OMB Control No.: 3060–0242.

Expiration Date: 2/28/2000.

Title: Section 74.604 Interference Avoidance.

Form: N/A.

Estimated Annual Burden: 2 total annual hours; average 2 hours per respondent; 1 respondent.

Description: Section 74.604 requires that the Commission be notified if a mutual agreement to avoid interference cannot be reached by licensees assigned a common channel for TV pickup, TV studio transmitter link or TV relay purposes in the same area. Data used by FCC staff to take such action as may be necessary to assure equitable distribution of available frequencies.

OMB Control No.: 3060–0568.

Expiration Date: 4/30/2000.

Title: Commercial Leased Access Rates, Terms and Conditions.

Form No.: N/A.

Estimated Annual Burden: 94,171 annual hour; average 1–10 hours per respondent; 137,970 respondents.

Description: As required by Section 612 of the Communications Act, as amended, the Commission must ensure reasonable rates, terms, and conditions for the leasing of channel capacity on cable systems by programmers unaffiliated with the cable operator. The Commission has amended its rules governing leased access, including its rules for calculating maximum leased access rates. The information required by certain of these amendments will be used in the calculation of revised rates, the provision of information to prospective leased access programmers, and the dispute resolution process.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–12076 Filed 5–8–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Report No. 2193; Petitions for Reconsideration and Clarification of Action in Rulemaking Proceedings

Petition for reconsideration has been filed in the Commission's rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of this document is available for viewing and copying in Room 239, 1919 M Street, N.W., Washington, D.C. or may be purchased from the Commission's copy contractor, ITS, Inc. (202) 857–3800. Oppositions to this petition must be filed May 27, 1997. See Section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Amendment of the Commission's Rules Regarding the 37.0–38.6 GHz and 38.6–40.0 GHz Bands. (ET Docket No. 95–183, RM–8553).

Implementation of Section 309(j) of the Communications Act—Competitive Bidding, 37.0–38.6 GHz and 38.6–40.0 GHz. (PP Docket No. 93–253).

Number of Petitions Filed: 1.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–12172 Filed 5–8–97; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1176–DR]

Arkansas; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Arkansas, (FEMA–1176–DR), dated April 14, 1997, and related determinations.

EFFECTIVE DATE: April 24, 1997.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Arkansas, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of April 14, 1997:

The counties of Cleburne, Dallas, Grant, Greene, Sharp, and Union for Individual Assistance (already designated for Public Assistance and Hazard Mitigation).

The county of Faulkner for Individual Assistance and Hazard Mitigation.

The county of Poinsett for Public Assistance (already designated for Individual Assistance and Hazard Mitigation).

The county of White for Individual Assistance, Public Assistance, and Hazard Mitigation.

The counties of Clay and Searcy for Public Assistance and Hazard Mitigation.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Lacy E. Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 97–12177 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1163–DR]

Kentucky; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the Commonwealth of Kentucky, (FEMA–1163-DR), dated March 4, 1997, and related determinations.

EFFECTIVE DATE: April 24, 1997.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the Commonwealth of Kentucky, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of March 4, 1997:

The counties of Calloway, Casey, and Graves for Hazard Mitigation (already designated for Public Assistance).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Lacy E. Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 97–12181 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1163–DR]

Kentucky; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the Commonwealth of Kentucky, (FEMA–1163-DR), dated March 4, 1997, and related determinations.

EFFECTIVE DATE: April 24, 1997.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the Commonwealth of Kentucky, is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of March 4, 1997:

Marion County for Public Assistance (already designated for Individual Assistance and Hazard Mitigation).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Lacy E. Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 97–12182 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1163–DR]

Kentucky; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Kentucky (FEMA–1163–DR), dated March 4, 1997, and related determinations.

EFFECTIVE DATE: April 18, 1997.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, effective this date and pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Mike Polny of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

This action terminates my appointment of Glenn C. Woodard as Federal Coordinating Officer for this disaster.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

James L. Witt,

Director.

[FR Doc. 97–12183 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1166–DR]

Federated States of Micronesia; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the Federated States of Micronesia (FEMA–1166–DR),

dated March 11, 1997, and related determinations.

EFFECTIVE DATE: April 21, 1997.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, effective this date and pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint William Carwile of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

This action terminates my appointment of Sally Ziolkowski as Federal Coordinating Officer for this disaster.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

Director.

[FR Doc. 97–12178 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1175–DR]

Minnesota; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State Minnesota (FEMA–1175–DR), dated April 8, 1997 and related determinations.

EFFECTIVE DATE: April 24, 1997.

FOR FURTHER INFORMATION CONTACT: Madga Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 24, 1997, the President amended the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 51521 *et seq.*), in a letter to James L. Witt, Director of the Federal Emergency Management Agency, as follows:

I have determined that the damage in certain areas of the State of Minnesota, resulting from severe flooding, severe winter storms, snowmelt, high winds, rain, and ice on March 21, 1997, and continuing, is of sufficient severity and magnitude that an adjustment to the cost share for emergency work under the Public Assistance program is warranted under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (''the Stafford Act'').

Therefore, I amend my declaration of April 8, 1997 to authorize the Federal Emergency Management Agency (FEMA) to reimburse at 100 percent Federal funding all eligible costs for debris removal and emergency protective measures (Categories A and B) under the Public Assistance program. This assistance may be provided to all counties designated under the major disaster declaration.

This letter will confirm my announcement of April 22, 1997.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

Director.

[FR Doc. 97–12176 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1174–DR]

North Dakota; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State North Dakota (FEMA–1174–DR), dated April 7, 1997, and related determinations.

EFFECTIVE DATE: April 24, 1997.

FOR FURTHER INFORMATION CONTACT: Madga Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 24, 1997, the President amended the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 51521 *et seq.*), in a letter to James L. Witt, Director of the Federal Emergency Management Agency, as follows:

I have determined that the damage in certain areas of the State of Minnesota, resulting from severe flooding, severe winter storms, snowmelt, high winds, rain, and ice on March 21, 1997, and continuing, is of sufficient severity and magnitude that an adjustment to the cost share for emergency work under the Public Assistance program is warranted under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (''the Stafford Act'').

Therefore, I amend my declaration of April 8, 1997 to authorize the Federal Emergency Management Agency (FEMA) to reimburse at 100 percent Federal funding all eligible costs for debris removal and emergency protective measures (Categories A and B) under the Public Assistance program. This assistance may be provided to all counties designated under the major disaster declaration.

This letter will confirm my announcement of April 22, 1997.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

Director.

[FR Doc. 97–12174 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1174–DR]

North Dakota; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of North Dakota, (FEMA–1174–DR), dated April 7, 1997, and related determinations.

EFFECTIVE DATE: April 23, 1997.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of North Dakota, is hereby amended to include Categories C through G under the Public Assistance program in those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of April 7, 1997:

Adams, Barnes, Benson, Billings, Burleigh, Cass, Cavalier, Dickey, Dunn, Eddy, Emmons, Foster, Grand Forks, Grant, Griggs, Hettinger, Kidder, Lamoure, Logan, McHenry, McIntosh, McKenzie, McLean, Mercer, Morton, Mountrail, Nelson, Pembina, Pierce, Ramsey, Ransom, Renville, Richland, Rolette, Sargent, Sheridan, Sioux, Slope, Stark, Steele, Stutsman, Towner, Traill, Walsh, Ward, and Wells Counties for Categories C through G under the Public Assistance program (already designated for Categories A and B under the Public Assistance program, Individual Assistance, and Hazard Mitigation).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Lacy E. Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 97–12180 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1173–DR]

South Dakota; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State South Dakota (FEMA–1173–DR), dated April 7, 1997, and related determinations.

EFFECTIVE DATE: April 24, 1997.

FOR FURTHER INFORMATION CONTACT: Madga Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 24, 1997, the President amended the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 51521 *et seq.*), in a letter to James L. Witt, Director of the Federal Emergency Management Agency, as follows:

I have determined that the damage in certain areas of the State of South Dakota, resulting, from severe flooding, severe winter storms, heavy spring rain, rapid snowmelt, high winds, and ice jams beginning on February 3, 1997, and continuing, is of sufficient severity and magnitude that an adjustment to the cost share for emergency work under the Public Assistance program is warranted under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (''the Stafford Act'').

Therefore, I amend my declaration of April 7, 1997 to authorize the Federal Emergency Management Agency (FEMA) to reimburse at 100 percent Federal funding all eligible costs for debris removal and emergency protective measures (Categories A and B) under the Public Assistance program. This assistance may be provided to all counties designated under the major disaster declaration.

This letter will confirm my announcement of April 22, 1997.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

James L. Witt,

Director.

[FR Doc. 97–12179 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

The National Board Fiscal Year 1997 Plan for Carrying Out the Emergency Food and Shelter Program (EFSP); Correction

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Correction to Notice.

SUMMARY: This document contains corrections to the Notice published Tuesday, April 1, 1997, 62 FR 15482—15516.

EFFECTIVE DATE: April 15, 1997.

FOR FURTHER INFORMATION CONTACT: Carolyn Coleman, Federal Emergency Management Agency, 500 C Street SW., Washington DC 20472, (202) 646–3107.

SUPPLEMENTARY INFORMATION:

Background

The EFSP Notice did not include the current threshold that triggers audit requirements under OMB Circular A–133, resulting from the Single Audit Act of 1996 (31 U.S.C. 7501). The Single Audit Act increased the threshold triggering audit requirements for non-Federal entities to $300,000 for those non-Federal entities' fiscal years beginning after June 30, 1996.

Need for Correction

The correction is necessary to add the new threshold above which non-Federal entities are required to meet audit requirements under the Single Audit Act and OMB Circular A–133.

Correction of Publication

Accordingly, the EFSP Notice published April 1, 1997, is corrected as follows:

1. On page 15485, in the third column, in Section 5.0, paragraph (a)(11) is revised to read:

5.0 Local Boards' Role and Responsibilities

* * * * *

(11) Local Boards are responsible for monitoring LROs that expend over $100,000 (or over $300,000 for fiscal years beginning after June 30, 1996) in a year in Federal awards and ensuring that they comply with OMB Circular A–133.

2. On page 15487, in the third column, § 6.1, paragraph (b)(3), the second paragraph is amended to read:

6.1 Independent Annual Audit Requirements

* * * * *

(b) * * *

(3) * * *

In addition to the above requirements, any LRO expending $100,000 or more (or $300,000 or more for fiscal years beginning after June 30, 1996) in a year in combined Federal awards must have an audit conducted in accordance with OMB Circular A–133, as applicable.

* * * * *

Dated: April 30, 1997.

Kay C. Goss,

Associate Director, Preparedness, Training and Exercise Directorate.

[FR Doc. 97–12189 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

Changes to the Hotel and Motel Fire Safety Act National Master List

AGENCY: United States Fire Administration, FEMA.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA or Agency) gives notice of additions and corrections/changes to, and deletions from, the national master list of places of public accommodations that meet the fire prevention and control guidelines under the Hotel and Motel Fire Safety Act.

EFFECTIVE DATE: June 9, 1997.

ADDRESSES: Comments on the master list are invited and may be addressed to the Rules Docket Clerk, Federal Emergency Management Agency, 500 C Street SW., room 840, Washington, D.C. 20472, (fax) (202) 646–4536. To be added to the National Master List, or to make any other change to the list, please see Supplementary Information below.

FOR FURTHER INFORMATION CONTACT: John Ottoson, Fire Management Programs Branch, United States Fire Administration, Federal Emergency Management Agency, National Emergency Training Center, 16825 South Seton Avenue, Emmitsburg, MD 21727, (301) 447–1272.

SUPPLEMENTARY INFORMATION: Acting under the Hotel and Motel Fire Safety Act of 1990, 15 U.S.C. 2201 note, the United States Fire Administration has worked with each State to compile a national master list of all of the places of public accommodation affecting commerce located in each State that meet the requirements of the guidelines under the Act. FEMA published the national master list in the **Federal Register** on Friday, June 21, 1996, 61 FR 32036–32256.

Parties wishing to be added to the National Master List, or to make any

other change, should contact the State office or official responsible for compiling listings of properties which comply with the Hotel and Motel Fire Safety Act. A list of State contacts was published in 61 FR 32032, also on June 21, 1996. If the published list is unavailable to you, the State Fire Marshal's office can direct you to the appropriate office. The Hotel and Motel Fire Safety Act of 1990 National Master List is now accessible electronically. The National Master List Web Site is located at: http://www.usfa/fema.gov/hotel/index.htm

Visitors to this web site will be able to search, view, download and print all or part of the National Master List by State, city, or hotel chain. The site also provides visitors with other information related to the Hotel and Motel Fire Safety Act. Instructions on gaining access to this information are available as the visitor enters the site.

Periodically FEMA will update and redistribute the national master list to incorporate additions and corrections/changes to the list, and deletions from the list, that are received from the State offices. Each update contains or may contain three categories: ''Additions;'' ''Corrections/changes;'' and ''Deletions.'' For the purposes of the updates, the three categories mean and include the following:

''Additions'' are either names of properties submitted by a State but inadvertently omitted from the initial master list or names of properties submitted by a State after publication of the initial master list;

''Corrections/changes'' are corrections to property names, addresses or telephone numbers previously published or changes to previously published information directed by the State, such as changes of address or telephone numbers, or spelling corrections; and

''Deletions'' are entries previously submitted by a State and published in the national master list or an update to the national master list, but subsequently removed from the list at the direction of the State.

Copies of the national master list and its updates may be obtained by writing to the Government Printing Office, Superintendent of Documents, Washington, DC 20402–9325. When requesting copies please refer to stock number 069–001–00049–1.

Michael B. Hirsch,

Acting General Counsel.

The update to the national master list for the month of April 1997 follows:

THE HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 NATIONAL MASTER LIST 4/16/97 UPDATE

Index	Property name	PO Box/Rt No	Street address	City	State/ZIP	Phone
ADDITIONS						
CA						
CA1495	DAVIS INN		1111 RICHARDS BLVD.	DAVIS	CA 95616	(916) 756–0910
CA1494	LAMPLIGHTER LODGE.		210 S MAIN ST.	RED BLUFF	CA 96080	(916) 527–1150
ID						
ID0182	SHILO INN		1586 N. BLUE LAKES BLVD.	TWIN FALLS	ID 83301	(208) 733–7545
MD						
MD0293	QUALITY SUITES SHADY GROVE.		3 RESEARCH COURT.	ROCKVILLE	MD 20850	(301) 840–0200
MD0292	HOLIDAY INN WASHING-TON—SILVER SPRING.		8777 GEORGIA AVE.	SILVER SPRING	MD 20910	(301) 589–0800
MI						
MI0327	SLEEP IN HOTEL		801 PETOSKEY AVENUE.	CHARLEVOIX	MI 49720	(616) 547–0300
MI0331	DAYS INN		2603 N. LINCOLN ROAD.	ESCANABA	MI 49829	(906) 789–1200
MI0333	ESCANABA SUPER 8 MOTEL.		2415 N. LINCOLN ROAD.	ESCANABA	MI 49824	(906) 786–1000
MI0335	HOLIDAY INN—GRAYLING.		2650 SOUTH I–75—BUS. LOOP.	GRAYLING	MI 49738	(517) 348–7611
MI0324	HOUGHTON SUPER 8 MOTEL.		1200 E. LAKE-SHORE DR.	HOUGHTON	MI 49931	(906) 482–2240
MI0326	SUPER 8 MOTEL—IRON MOUNTAIN.		2702 N. STE-PHENSON AVE.	IRON MOUNTAIN	MI 49801	(906) 774–3400
MI0330	JACKSON COUN-TRY HEARTH INN.		1111 BOARDMAN ROAD.	JACKSON	MI 49202	(517) 783–6404
MI0329	CLUBHOUSE INN LANSING.		2710 LAKE LAN-SING ROAD.	LANSING	MI 48912	(517) 482–0500
MI0323	QUALITY INN		3121 E. GRAND RIVER AVE.	LANSING	MI 48912	(517) 351–1440
MI0328	RAMADA INN CONVENTION CENTER.		450 S. NICOLET	MACKINAW CITY	MI 49701	(616) 436–5535
MI0325	BEST WESTERN VALLEY PLAZA INN.		5221 BAY CITY RD.	MIDLAND	MI 48642	(517) 496–2700

THE HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 NATIONAL MASTER LIST 4/16/97 UPDATE—Continued

Index	Property name	PO Box/Rt No	Street address	City	State/ZIP	Phone
MI0334	BEST WESTERN AMERICAN HERITAGE INN.		1681 GRAND RIVER AVENUE.	PORTLAND	MI 48875	(800) 528–1234
MI0332	WYNDHAM GARDEN HOTEL—DETROIT METRO AIRPORT.		8600 MERRIMAN ROAD.	ROMULUS	MI 48174	(313) 728–7900
MN						
MN0309	BLACK BEAR HOTEL AND CASINO.		1789 HWY 210	CARLTON	MN 55718	(218) 878–7400
MN0308	BEST WESTERN EDGEWATER WEST.		2211 LONDON ROAD.	DULUTH	MN 55812	(218) 728–3601
MN0305	SUPER 8 MOTEL MORRIS.		EAST HIGHWAY 28.	MORRIS	MN 56267	(800) 800–8000
MN0306	JACKPOT JCT. CASINO HOTEL/LOWER SIOUX LODGE.	RR1 BOX 420		MORTON	MN 56270	(800) 946–2274
MN0307	BEST WESTERN KELLY INN.		161 ST. ANTHONY.	ST. PAUL	MN 55103	(612) 227–8711
MS						
MS0118	HARRAH'S MARDI GRAS CASINO AND HOTEL.		1100 CASINO STRIP.	ROBINSONVILLE	MS 38664	(601) 363–7777
NC						
NC0377	DAYS INN		614 CLARK DRIVE	LINCOLNTON	NC 28092	(704) 735–827
NC0376	BEST WESTERN HOSPITALITY INN.		2800 BRENTWOOD ROAD.	RALEIGH	NC 27604	(919) 872–8600
NC0378	LA QUINTA INN & SUITES.		2211 SUMMIT PARK LAKE.	RALEIGH	NC 27622	(919) 785–0071
TX						
TX0725	LA QUINTA INN & SUITES.		4001 SCOTT'S LEGACY.	ARLINGTON	TX 76004	(800) 531–5900
TX0722	HOLIDAY INN MID TOWN.		2095 N. 11TH ST.	BEAUMONT	TX 77703	(409) 892–2222
TX0718	GREEN OAKS PARK HOTEL.		6901 WEST FREEWAY.	FORT WORTH	TX 76116	(800) 433–2174
TX0726	LA QUINTA INN & SUITES.		4900 BRYANT IRVING ROAD.	FORT WORTH	TX 76132	(817) 370–2700
TX0728	LA QUINTA INN & SUITES.		4700 NORTH FREEWAY.	FORTH WORTH	TX 76137	(817) 222–2888
TX0719	RAMADA PLAZA HOTEL FORT WORTH CONVENT. CENTER.		1701 COMMERCE ST.	FORT WORTH	TX 76102	(817) 335–7000
TX0727	LA QUINTA INN & SUITES.		15225 KATY FREEWAY.	HOUSTON	TX 77094	(409) 763–1224
TX0720	LAS COLINAS HILTON GARDEN INN.		7516 LAS COLINAS BLVD.	IRVING	TX 75063	(972) 444–8434
TX0723	PLAZA SAN ANTONIO—A MARRIOTT HOTEL.		555 S. ALAMO	SAN ANTONIO	TX 78205	(210) 229–1000
TX0721	BEST WESTERN—SAN MARCOS.		917 I–H 35 NORTH.	SAN MARCOS	TX 78666	(512) 754–7557
TX0729	LA QUINTA INN & SUITES.		2912 HIGHWAY 75 NORTH.	SHERMAN	TX 75090	(214) 867–7475
TX0724	HOLIDAY INN		1495 EAST INDUSTRIAL.	SULPHUR SPRINGS.	TX 75482	(903) 885–0562
UT						
UT0096	SLEEP INN		1051 S MAIN ST.	MOAB	UT 84532	(801) 259–4655
CORRECTIONS						
IA						

THE HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 NATIONAL MASTER LIST 4/16/97 UPDATE—Continued

Index	Property name	PO Box/Rt No	Street address	City	State/ZIP	Phone
IA0133	BEST WESTERN JESSE JAMES INN.	PO BOX 397	EXIT 76–I 80	ADAIR	IA 50002	(515) 742–5251
IA0005	BEST WESTERN STARLITE VILLAGE OF ANKENY.	PO BOX 378	133 S.E. DELAWARE.	ANKENY	IA 50021	(515) 964–1217
IA0132	BEST WESTERN LONGBRANCH HOTEL/CONVENTION CTR.		90 TWIXT TOWN ROAD N.E.	CEDAR RAPIDS	IA 52402	(319) 377–6386
IA0006	BEST WESTERN STEEPLE GATE INN.		100 W. 76th ST.	DAVENPORT	IA 52806	(319) 386–6900
IA0007	BEST WESTERN DENISON'S INN.	US 30 & 59	502 BOYER VALLEY ROAD.	DENISON	IA 51442	(712) 263–5081
IA0127	BEST WESTERN STARLITE VILLAGE.		214 WASHINGTON ST.	WATERLOO	IA 50701	(319) 235–0321
IA0135	BEST WESTERN RED FOX INN.	PO BOX 667	HWY 3 WEST	WAVERLY	IA 50677	(319) 352–5330
IA0126	BEST WESTERN QUOTE HOUSE SUITES.		1708 NORTH HIGHLAND.	WILLIAMSBURG	IA 52361	(319) 688–9777
KS						
KS0002	BEST WESTERN PRESIDENT'S INN.	BOX 458	2210 N. BUCKEYE	ABILENE	KS 67410	(913) 263–2050
KS0016	BEST WESTERN RED COACH.		2525 W. CENTRAL STREET.	ELDORADO	KS 67042	(316) 321–6900
KS0152	BEST WESTERN GARDEN PRAIRIE INN.	PO BOX 44	1400 N HWY 156	ELLSWORTH	KS 674390044	(913) 472–3116
KS0025	BEST WESTERN J-HAWK MOTEL.		515 W. KANSAS AVE.	GREENSBURG	KS 67054	(316) 723–2121
KS0134	BEST WESTERN INN.	PO BOX 169	1315 N. STATE STREET.	IOLA	KS 667490169	(316) 365–5161
KS0039	BEST WESTERN INN AND CONFERENCE CENTER.		501 SW BLVD.	KANSAS CITY	KS 66103	(913) 677–3060
KS0052	BEST WESTERN CONTINENTAL INN.	PO BOX 823	100 BLUEMONT	MANHATTAN	KS 66502	(913) 776–4771
KS0055	BEST WESTERN SURF MOTEL.		2005 CENTER STREET.	MARYSVILLE	KS 66508	(913) 562–2354
KS0056	BEST WESTERN AIRPORT RED COACH INN.		300 CENTENIAL DRIVE.	MCPHERSON	KS 67460	(316) 241–2460
KS0058	BEST WESTERN RED COACH INN.	PO BOX 872	1301 E. FIRST STREET.	NEWTON	KS 67114	(316) 283–9120
KS0126	BEST WESTERN GOLDEN PLAINS MOTEL.	RT. 1 BOX 3		OAKLEY	KS 67748	(913) 672–3254
KS0081	BEST WESTERN CANDELIGHT.		2831 SW FAIRLAWN.	TOPEKA	KS 666141596	(913) 272–9550
KS0082	BEST WESTERN MEADOW ACRES.		2950 S. TOPEKA BLVD.	TOPEKA	KS 666112193	(913) 267–1681
KS0105	BEST WESTERN WICHITA RED COACH.		915 E. 53RD ST. N..	WICHITA	KS 67219	(316) 832–9387
MD						
MD0035	BEST WESTERN HOTEL & CONFERENCE CENTER.		5625 O'DONNELL ST..	BALTIMORE	MD 21224	(410) 633–9500

THE HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 NATIONAL MASTER LIST 4/16/97 UPDATE—Continued

Index	Property name	PO Box/Rt No	Street address	City	State/ZIP	Phone
MD0007	BEST WESTERN FLAGSHIP OCEANFRONT.	.....	2600 BALTIMORE AVE.	OCEAN CITY	MD 21842	(410) 289–3384
MI						
MI0285	BEST WESTERN GREENFIELD INN.	.....	3000 ENTERPRISE DR.	ALLEN PARK	MI 48101	(313) 271–1600
MI0182	BEST WESTERN—BILL OLIVER'S.	.....	5676 E M–55, P.O. BOX 266.	CADILLAC	MI 49601	(616) 775–2458
MI0146	BEST WESTERN EXECUTIVE HOTEL & SUITES.	.....	31525 W. 12 MILE RD.	FARMINGTON HILLS.	MI 48334	(313) 553–0000
MI0007	BEST WESTERN OF HARBOR SPRINGS.	.....	8514 M–119	HARBOR SPRINGS.	MI 49740	(616) 347–9050
MI0092	BEST WESTERN COUNTRY INN.	.....	850 US 41 W.	ISHPEMING	MI 49849	(906) 485–6345
MI0319	BEST WESTERN GOVERNOR'S INN & CONF. CENTER.	.....	6133 S. PENNSYLVANIA AVE.	LANSING	MI 48911	(517) 393–5500
MI0138	BEST WESTERN MIDWAY HOTEL.	.....	7711 W. SAGINAW HWY.	LANSING	MI 48917	(517) 627–8471
MI0279	BEST WESTERN LAUREL PARK SUITES.	.....	16999 S. LAUREL PARK.	LIVONIA	MI 48154	(313) 464–0050
MI0283	BEST WESTERN—TROY-MADISON.	.....	1331 W. 14 MILE RD.	MADISON HEIGHTS.	MI 48071	(810) 583–7000
MI0284	BEST WESTERN INN.	.....	5770 E. PICKARD ST.	MT. PLEASANT	MI 48858	(517) 772–1101
MI0265	BEST WESTERN CONCORDE INN OF WATERFORD.	.....	7076 HIGHLAND RD.	WATERFORD	MI 48327	(313) 666–8555
MN						
MN0007	BEST WESTERN BRADBURY SUITES.	.....	7770 JOHNSON AVE..	BLOOMINGTON ...	MN 55435	(612) 893–9999
MN0014	BEST WESTERN THUNDERBIRD HOTEL.	.....	2201 E. 78TH ST.	BLOOMINGTON ...	MN 554251228	(612) 854–3411
MN0106	BEST WESTERN NORTHWEST INN & CONF. CTR..	.....	6900 LAKELAND AVE. N.	BROOKLYIN PARK.	MN 554251228	(612) 566–8855
MN0023	BEST WESTERN HOLLAND HOUSE & SUITES.	.....	615 HWY. 10 E. ...	DETROIT LAKES	MN 56501	(218) 847–4483
MN0033	BEST WESTERN SUPERIOR INN & SUITES.	PO BOX 456	HWY. #61 E.	GRAND MARAIS ..	MN 55604	(800) 842–8439
MN0243	BEST WESTERN GOLD PINE MOTOR INN.	RT 2 BOX 384	325 FIRE MONUMENT RD.	HINCKLEY	MN 55037	(320) 384–6112
MN0271	BEST WESTERN VICTORIAN INN.	.....	1000 HWY. 7 WEST.	HUTCHINSON	MN 55350	(320) 587–6030
MN0123	BEST WESTERN CLIFF DWELLER.	P.O. BOX 26	U.S. HWY. 61	LUTSEN	MN 556120026	(218) 663–7273
MN0240	BEST WESTERN GOLDEN VALLEY.	.....	4820 OLSON MEMORIAL HWY..	MINNEAPOLIS	MN 55422	(320) 588–0511
MN0164	BEST WESTERN ROYALE INN.	.....	207 N. FIRST ST.	MONTEVIDEO	MN 56265	(320) 269–5554

THE HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 NATIONAL MASTER LIST 4/16/97 UPDATE—Continued

Index	Property name	PO Box/Rt No	Street address	City	State/ZIP	Phone
MN0062	BEST WESTERN KELLY INN PLYMOUTH.	.....	2705 ANNAPOLIS LN.	PLYMOUTH	MN 55441	(612) 553–1600
MN0234	BEST WESTERN QUIET HOUSE SUITES.	.....	752 WITHERS HARBOR DR.	RED WING	MN 55066	(612) 388–1577
MN0194	BEST WESTERN DROVER'S INN.	.....	701 S. CONCORD ST.	SOUTH ST. PAUL	MN 55075	(612) 455–3600
MN0076	BEST WESTERN AMERICANNA INN.	.....	520 S. HWY. 10 ...	ST. CLOUD	MN 56304	(320) 253–0606
MN0205	BEST WESTERN KELLY INN.	.....	HWY. 23 AND 4TH AVE. S.	ST. CLOUD	MN 56301	(320) 253–0606
MN0208	BEST WESTERN INN OF THIEF RIVER FALLS.	.....	1060 HWY. 32 S ..	THIEF RIVER FALLS.	MN 56701	(218) 681–7555
MN0088	BEST WESTERN RIVERPORT INN & SUITES.	.....	900 BRUSKI DR ...	WINONA	MN 55987	(507) 452–0606
NC						
NC0359	BEST WESTERN MOUNTAINBROOK INN.	.....	1021 SOCO ROAD, HWY. 19.	MAGGIE VALLEY	NC 28751	(704) 926–3962
NC0313	BEST WESTERN LUXBURY HOTEL SOUTHEAST CHARLOTE.	.....	9701 E. INDEPENDENCE BLVD.	MATTHEWS	NC 28105	(704) 845–5911
NC0095	BEST WESTERN INN I–95/GOLD ROCK.	RT 1 BOX 121	.....	ROCKY MOUNT ...	NC 27809	(919) 985–1450
NC0042	BEST WESTERN CAROLINIAN.	.....	2916 MARKET ST	WILMINGTON	NC 28403	(919) 763–4653
NY						
NY0420	BEST WESTERN ALBANY AIRPORT INN.	.....	200 WOLF RD	ALBANY	NY 122051197	(518) 458–1000
NY0489	BEST WESTERN—BATAVIA INN.	.....	8204 PARK RD	BATAVIA	NY 14020	(716) 343–1000
NY0057	BEST WESTERN—BINGHAMTON REGENCY.	PO BOX 2337 ..	ONE SARBO SQUARE.	BINGHAMTON	NY 13901	(607) 722–7575
NY0575	BEST WESTERN—CLIFTON PARK.	.....	RTE. 146 AND PLANK RD.	CLIFTON PARK ...	NY 12065	(518) 371–1811
NY0573	BEST WESTERN INN OF COLBLESKILL.	PO BOX 189	CAMPUS DRIVE EXTENSION.	COLBESKILL	NY 12043	(518) 234–4321
NY0586	HOMESTEAD INN	.....	749 WEST MAIN STREET.	ENDICOTT	NY 13760	(607) 754–1533
NY346	BEST WESTERN—PALISADE MOTEL.	.....	RT. 218 & 9 W	HIGHLAND FALLS	NY 10928	(914) 446–9400
NY0054	BEST WESTERN OF LAKE GEORGE.	.....	EXIT 21 AT I–87 ...	LAKE GEORGE	NY 12845	(518) 668–5701
NY0053	BEST WESTERN LITTLE FALLS MOTOR INN.	.....	20 ALBANY ST	LITTLE FALLS	NY 13365	(313) 823–4954
NY0052	BEST WESTERN MONTICELLO.	.....	21 RACEWAY RD. & ROUTE 17B.	MONTICELLO	NY 12701	(914) 796–4000
NY0628	SEAPORT INN	.....	33 PECK SLIP	NEW YORK	NY 10038	(800) 468–3569
NY0050	BEST WESTERN CAPTAINS QUARTERS HOTEL.	PO BOX 1011 ..	27 E. FIRST ST. ...	OSWEGO	NY 13126	(315) 342–4040
NY0298	BEST WESTERN—LODGE ON THE GREEN.	PO BOX 150	RT. 15 & 17 BOX 150.	PAINTED POST ...	NY 14870	(607) 962–2456

THE HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 NATIONAL MASTER LIST 4/16/97 UPDATE—Continued

Index	Property name	PO Box/Rt No	Street address	City	State/ZIP	Phone
NY0347	BEST WESTERN—PARAMONT HOTEL.		RTE 17W. COOLEY RD OFF TANZMAN R.	PARKSVILLE	NY 12768	(914) 292–6700
NY0519	BEST WESTERN INN OF RIVERHEAD.		30 E. MORICHES RD.	RIVERHEAD	NY 11901	(516) 727–6200
NY0574	BEST WESTERN PLAYMORE FARMS.		3291 SOUTH BROADWAY, ROUTE 9.	SARATOGA SPRINGS.	NY 12866	(518) 584–2350
NY0629	BEST WESTERN—WOODBURY.		7940 JERICHO TURNPIKE.	WOODBURY	NY 11797	(516) 921–6900
PA						
PA0078	BEST WESTERN CONCORDVILLE HOTEL.		RT. 322 & RT. 1	CONCORDVILLE	PA 19331	(215) 358–9400
PA0123	BEST WESTERN GETTYSBURG HOTEL EST 1797.		#1 LINCOLN SQUARE.	GETTYSBURG	PA 17325	(717) 337–2000
PA0140	BEST WESTERN HOTEL CROWN PARK.		765 EISENHOWER BLVD.	HARRISBURG	PA 17111	(717) 558–9500
PA0150	BEST WESTERN GENETTI MOTOR LODGE.	PO BOX 250	32ND & N. CHURCH ST.	HAZELTON	PA 18201	(717) 454–2494
PA0171	BEST WESTERN THE INN AT KING OF PRUSSIA.	RT. 202 N	127 S. GULPH RD	KING OF PRUSSIA.	PA 19406	(215) 265–4500
PA0182	BEST WESTERN EDEN RESORT INN & CONF CENTER.		222 EDEN RD	LANCASTER	PA 17601	(717) 569–6444
PA0285	BEST WESTERN PARKWAY CENTER INN.		875 GREENTREE RD.	PITTSBURGH	PA 15220	(412) 922–7070
PA0347	BEST WESTERN WAYNESBORO.		239 W. MAIN ST	WAYNESBORO	PA 17268	(717) 762–9113
PA0378	BEST WESTERN WESTGATE INN.		1415 KENNETH RD.	YORK	PA 17404	(717) 845–5671
TX						
TX0451	BEST WESTERN MALL SOUTH.		3950 RIDGEMONT DR.	ABILENE	TX 79606	(915) 695–1262
TX0460	BEST WESTERN ATRIUM INN.		7928 GESSNER DR.	AUSTIN	TX 78753	(512) 339–7311
TX0082	BEST WESTERN INN BY THE BAY.	PO BOX 310	3902 N. HWY. 35	FULTON	TX 78358	(512) 729–8351
TX0483	GREENWAY PLAZA INN & SUITES.		2929 S.W. FREEWAY.	HOUSTON	TX 77098	(713) 528–6161
TX0482	BEST WESTERN LLANO.		901 W. YOUNG	LLANO	TX 77373	(915) 247–4101
TX0151	BEST WESTERN LUBBOCK REGENCY.		6624 I–27	LUBBOCK	TX 79404	(806) 745–2208
TX0110	BEST WESTERN ROSE GARDEN INN & SUITE.	PO3353/78502	300 E. EXPWY. 83	MCALLEN	TX 78503	(210) 630–3333
TX0546	BEST WESTERN GARDEN OASIS/GARDEN BUFFET REST.		110 W. IH–20	ODESSA	TX 79761	(915) 337–3006
TX0448	BEST WESTERN CONTINENTAL INN.		9735 IH–35 N	SAN ANTONIO	TX 78233	(210) 655–3510
TX0140	BEST WESTERN LACKLAND INN & SUITES.		6815 HWY. 90 W	SAN ANTONIO	TX 78227	(512) 675–9690

THE HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 NATIONAL MASTER LIST 4/16/97 UPDATE—Continued

Index	Property name	PO Box/Rt No	Street address	City	State/ZIP	Phone
TX0220	BEST WESTERN FIESTA ISLES HOTEL.	PO–3079	5701 PADRE BLVD.	SOUTH PADRE ISLAND.	TX 78597	(210) 761–4913
TX0455	BEST WESTERN TRAIL DUST INN.	PO–789/75483	1521 SHANNON RD./IH–30 E.	SULPHUR SPRINGS.	TX 75482	(903)885–7515
TX0523	BEST WESTERN INN AT SCOTT & WHITE.		2625 S. 31ST ST	TEMPLE	TX 76504	(817)778–5511
TX0410	BEST WESTERN COUNTRY INN.	PO–350	1800 W. VEGA BLVD.	VEGA	TX 79092	(806)267–2131
TX0061	BEST WESTERN WACO MALL.		6624 HWY. 84 W	WACO	TX 76712	(817)776–3194
TX0115	BEST WESTERN PALM AIRE MOTEL AND SUITES.		415 S. INTER-NATIONAL BLVD.	WESLACO	TX 78696	(512)969–2411
VA						
VA0636	BEST WESTERN OLD COLONY INN.		615 FIRST STREET.	ALEXANDRIA	VA 22314	(703)739–2222
VA0599	BEST WESTERN HANOVER HOUSE MOTOR LODGE.	I95 & ATLEE	10296 SLIDING HILL RD.	ASHLAND	VA 23005	(804)550–2805
VA0501	BEST WESTERN CAVALIER INN.	P O BOX 5647	105 EMMET STREET.	CHARLOTTES-VILLE.	VA 2290300000	(804)296–8111
VA0033	BEST WESTERN MT VERNON.	PO BOX 7284	1613 EMMET STREET.	CHARLOTTES-VILLE.	VA 229067284	(804)296–5501
VA0640	BEST WESTERN RIVERSIDE.		2121 RIVERSIDE DR.	DANVILLE	VA 24540	(804)793–4000
VA0504	BEST WESTERN JOHNNY APPLESEED INN.		543 WARRENTON ROAD.	FREDERICKS-BURG.	VA 224060000	(540)373–0000
VA0535	BEST WESTERN THUNDERBIRD.		3000 PLANK ROAD.	FREDERICKS-BURG.	VA 224010000	(540)876–7404
VA0534	BEST WESTERN LEESBURG.		726 E. MARKET STREET.	LEESBURG	VA 220750000	(703)777–9400
VA0423	BEST WESTERN BATTLEFIELD INN.		10820 BALLS FORD ROAD.	MANASSAS	VA 22110	(703)361–8000
VA0025	BEST WESTERN TYSONS WESTPARK HOTEL.		8401 WESTPARK DRIVE.	MCLEAN	VA 221020000	(703)734–2800
VA0533	BEST WESTERN CENTER INN.	US 13	235 NORTH MILI-TARY HIGH-WAY.	NORFOLK	VA 235020000	(757)461–6600
VA0523	BEST WESTERN RADFORD INN.	P O BOX 1008	1501 TYLER AVE	RADFORD	VA 241410000	(540)639–3000
VA0555	BEST WESTERN COACHMAN INN.	PO BOX 7329	I81 US 220N EXIT 150B.	ROANOKE	VA 24019	(540)992–1234
VA0556	BEST WESTERN WYTHEVILLE INN.		355 NYE ROAD	WYTHEVILLE	VA 24382	(540)228–7300
WI						
WI0162	BEST WESTERN MIDWAY HOTEL APPLE-TON.		3033 WEST COL-LEGE AVENUE.	APPLETON	WI 54914	(414)731–4141
WI0168	MIDWAY HOTEL		2851 HENDRICK-SON DRIVE	EAU CLAIRE	WI 54701	(715)835–2242
WI0069	BEST WESTERN COURTYARD.		1225 JANESVILLE AVENUE.	FORT ATKINSON	WI 53538	(414)563–6444
WI0098	BEST WESTERN HUDSON HOUSE INN.	P.O. BOX 146	1616 CRESTVIEW DR.	HUDSON	WI 54016	(715)386–2394
WI0130	LUMBERMEN'S INN.	PO BOX 127	HIGHWAY 2	IRON RIVER	WI 54847	(715)372–4515

THE HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 NATIONAL MASTER LIST 4/16/97 UPDATE—Continued

Index	Property name	PO Box/Rt No	Street address	City	State/ZIP	Phone
WI0092	WELCOME INN–LANCASTER.	.....	420 WEST MAPLE STREET.	LANCASTER	WI 53813	(608)723–4162
WI0158	MIDWAY HOTEL ..	.....	3710 EAST WASHINGTON AVENUE.	MADISON	WI 53704	(608)244–2424
WI0226	WEST TOWNE SUITES.	.....	650 GRAND CANYON DRIVE.	MADISON	WI 53719	(608)833–4200
WI0184	MIDWAY HOTEL–HWY 10.	.....	251 NORTH MAYFAIR ROAD.	MILWAUKEE	WI 53226	(414)774–3600
WI0025	HARBORSIDE MOTOR INN.	.....	135 EAST GRAND AVENUE.	PORT WASHINGTON.	WI 53074	(414)284–9461
WI0126	QUIET HOUSE	RT. 2 BOX426 ..	.....	PRAIRIE DU CHIEN.	WI 53821	(608)326–4777
WI0102	CLARIDGE MOTOR INN.	.....	70 NORTH STEVENS STREET.	RHINELANDER	WI 54501	(715)362–7100
WI0004	VILLAGE HAUS MOTOR LODGE.	.....	201 AIRPORT RD	SHAWANO	WI 54166	(715)526–9595
WI0196	MIDWAY HOTEL ..	.....	2901 MARTIN AVENUE.	WAUSAU	WI 54401	(715)842–1616
WI0125	BEST WESTERN WOODS VIEW INN.	.....	5501 WEST NATIONAL AVENUE.	WEST MILWAUKEE.	WI 53214	(414)671–6400
WI0076	BEST WESTERN AMBASSADOR INN.	.....	610 FRONTAGE ROAD SOUTH.	WISCONSIN DELLS.	WI 53965	(608)254–4477
WI0007	RAPIDS MOTOR INN.	.....	911 HUNTINGTON AVENUE.	WISCONSIN RAPIDS.	WI 54494	(715)423–3211
WV						
WV0081	BEST WESTERN ALPINE LODGE.	PO BOX 520	RT. 32 WILLIAMS AVE.	DAVIS	WV 26260	(304)259–5245
WV0077	BEST WESTERN OF ELKINS.	PO BOX 1878 ..	RT. 250/219 S.	ELKINS	WV 26241	(304)636–7711
WV0170	BEST WESTERN MOTOR INN.	.....	4115 1ST AVE.	NITRO	WV 25143	(304)755–8341
WV0059	BEST WESTERN—. SUMMERSVILLE LAKE MOTOR LODGE.	.....	1203 S. BROAD ST.	SUMMERSVILLE ..	WV 26651	(304)872–6900
DELETIONS						
MN						
MN0302	BEST WESTERN EDGEWATER EAST.	.....	2400 LONDON RD	DULUTH	MN 55812	(218)728–3601
MN0031	BEST WESTERN GOLDEN VALLEY HOUSE.	.....	4820 OLSON MEMORIAL HWY.	GOLDEN VALLEY	MN 55422	(612)588–0511
UT						
UT0035	HOWARD JOHNSON HOTEL.	.....	122 W. SOUTH TEMPLE.	SALT LAKE CITY	UT 84101	(801) 521–0130

[FR Doc. 97–12188 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–08–U

FEDERAL EMERGENCY MANAGEMENT AGENCY

Members of Senior Executive Service Performance Review Board

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice lists the names of the members of the FEMA Senior Executive Service Performance Review Board.

EFFECTIVE DATE: January 15, 1997.

FOR FURTHER INFORMATION CONTACT: Denise R. Yachnik, Executive Coordinator, Office of Human Resources Management, 500 C Street, SW, Washington, DC 20742, 202–636–3040.

SUPPLEMENTARY INFORMATION: The names of the members of the FEMA Senior Executive Service Performance Review Board established under 5 U.S.C. 4314(c)(4) are: John L. Matticks, Donald G. Bathurst, Lynn G. Canton, James L. Taylor, Joe D. Bray, Richard W. Krimm, Bruce J. Campbell, Dianne K. Bona.

Dated: May 2, 1997.

Michael B. Hirsch,

Acting General Counsel.

[FR Doc. 97–12187 Filed 5–8–97; 8:45 am]

BILLING CODE 6718–01–P–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984.

Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, N.W., Room 962. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register.**

Agreement No.: 217–011324–010

Title: Transpacific Space Utilization Agreement

Parties:

American President Lines, Ltd.
Kawasaki Kisen Kaisha, Ltd.
A.P. Moller-Maersk Line
Mitsui O.S.K. Lines, Ltd.
Neptune Orient Lines, Ltd.
Nippon Yusen Kaisha Line
Orient Overseas Container Line, Inc.
P&O Nedlloyd Limited
Sea-Land Service, Inc.
Hapag-Lloyd Container Line GmbH
P&O Nedlloyd B.V.
Hanjin Shipping Company, Ltd.
Transportacion Maritima Mexicana, S.A. de C.V.
Yang Ming Lines
Westwood Shipping Lines
Hyundai Merchant Marine, Co., Ltd.
Evergreen America Corporation

Synopsis: The proposed modification would expand the Agreement's geographic scope to permit short-term space charters on voyages from all U.S. ports and points to ports and points in the Indian Subcontinent, rather than just from US West Coast ports and points. The proposed modification would also permit Transportacion Maritima Mexicana, S.A. de C.V. or Westwood Shipping Lines to charter space on voyages from ports or points in the Agreement's foreign geographic scope to ports and points in the U.S. with any other member or members of the Agreement.

By Order of the Federal Maritime Commission.

Dated: May 5, 1997.

Joseph C. Polking,

Secretary.

[FR Doc. 97–12141 Filed 5–8–97; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 10:00 a.m., Wednesday, May 14, 1997.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: May 7, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–12343 Filed 5–7–97; 10:54 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 742]

Implementing Hazardous Substance Training for Emergency Responders; Notice of Availability of Funds for Fiscal Year 1997

Introduction

The Centers for Disease Control and Prevention (CDC), the Nation's prevention agency, announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement to conduct a training program for emergency responders, primarily firefighters, who are exposed to hazardous materials.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering Healthy People 2000 see the section Where to Obtain Additional Information.)

Authority

This program is authorized under sections 21(a) and 22(e)(7) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 670(a) and 671(e)(7)).

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority-and/or woman-owned businesses are eligible to apply.

Note: Public Law 104–65 dated December 19, 1995, prohibits an organization described in section 501(c)(4) of the IRS Code of 1986, that engages in lobbying activities to influence the Federal Government, from receiving Federal funds.

Availability of Funds

Approximately $1,806,000 will be available in Fiscal Year 1997 to fund one cooperative agreement. This award is expected to begin on or about September 30, 1997, for a 12-month budget period within a project period of five years. Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, Section 503 of Pub. L. No. 104–208, provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1997, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208 (September 30, 1996).

Background

In 1992, the Environmental Protection Agency reported that there were 7,116 CERCLA (Comprehensive Environmental Response, Compensation and Liability Act) section 103(a) notifications to the Federal Government of release of CERCLA hazardous substances. During that same year, the Federal Government received 35,284 notifications to the Emergency Response Notification System (ERNS) data base at the Department of Transportation.

It is estimated that there are between 2–3 million emergency responders in the country. Firefighters comprise the largest group. National Fire Protection Association (NFPA) estimated there were a total of 1,073,600 firefighters in 1994 and 250,000 fire department calls related to hazardous materials.

Emergency responders are at high risk for injury and illness due to uncontrolled exposures. An assessment of the mortality experience of firefighters using information from the National Occupational Mortality Surveillance (NOMS) systems found a high risk for falls, an excess of deaths from fire-related exposures and an excess of deaths from leukemia, lymphoma, and multiple myeloma.

This agreement will expand the current occupational health and safety education efforts of the CDC by targeting emergency responders who have a responsibility for responding to and controlling hazardous emergencies. The Occupational Safety and Health Administration regulated the safety and health of employees involved in operations related to uncontrolled waste sites and in any emergency response to incidents involving hazardous substances (29 CFR 1910.120(q)(6)). Training is conducted in emergency response for the purpose of protecting nearby persons, property and the environment. This cooperative agreement will significantly strengthen the occupational public health infrastructure by integrating resources for occupational safety and health research and public health prevention programs at the State and local levels.

Purpose

The purpose of the award is to assist in the implementation of a national hazardous substance training program for emergency responders, primarily firefighters, in the area of hazardous materials emergency response. The specific objectives are:

A. Assess the need for training nationally;

B. Develop a five-year training plan to meet those needs;

C. Conduct direct training and develop faculty expertise on site; and,

D. Evaluate the training program and the impact of the training.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under A.(Recipient Activities), below, and CDC/NIOSH be responsible for conducting activities under B.(CDC Activities), below.

A. Recipient Activities

1. Develop a complete plan of action to establish a five year national training program for hazardous materials emergency responders. Include collaboration with communities to establish a network among representatives of firefighters, police, hospitals and other community emergency responders.

2. Identify and select regions and populations for training based on a list of criteria to be developed by the applicant and identification of needs by the organization.

3. Designate groups to be trained per year, including specific levels of training and amount of training and types of trainees (e.g., volunteers and career firefighters).

4. Select participants and conduct training programs for emergency responders, coordinating efforts with local, State and community agencies.

5. Develop additional curricula on special topics or hazard areas as identified in needs surveys. Course materials utilized will be those which exist and meet Federal, national and State requirements and which have been developed specifically for emergency responders under federally supported programs such as those from the National Institute of Environmental Health Sciences (NIEHS) and revised as appropriate.

6. Develop a plan to select and train faculty to conduct training classes. Audio-visual support, space, facilities, and equipment will be provided by the recipient.

7. Develop and conduct an evaluation program to test knowledge, the effectiveness of training and the impact of the training.

8. Maintain profile information on trainees (e.g., State, employer, based on existing records held by the organization.

9. Disseminate training information to appropriate groups.

B. CDC/NIOSH Activities

1. Provide technical assistance and consultation, through site visits and correspondence, in the areas of identifying needs, program development and implementation.

2. Provide scientific and technical assistance in the development of curriculum materials.

3. Provide on site technical consultation if needed during the training programs with recommendations to assist the trainers.

4. Provide training materials, such as video tapes and published documents to the recipient for duplication and distribution, when appropriate and needed.

5. Provide technical assistance in the development of an evaluation plan.

6. Assist in the dissemination of training information to appropriate personnel.

Technical Reporting Requirements

An original and two copies of the quarterly progress reports are due within 30 days after the end of each quarter and should include a summary of activities performed and any new materials developed. A progress report and financial status report is due 90 days after the end of each budget period. Final financial and performance reports are required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, CDC.

The quarterly progress reports must include, in addition to activities performed:

A. A list of training courses delivered in the quarter, their location, title of the course and number of persons trained and a general summary of activities performed in the quarter;

B. A comparison of actual accomplishments to the goals established for the period; and,

C. Reasons for lack of success if goals were not met.

The annual progress reports should include a summary of yearly activities, number and type of courses delivered, number of people trained and a profile of trainees, including gender, State, employer, type of firefighter (career or volunteer), etc.

Application Content

The entire application, including appendices, should not exceed 75 pages and the Proposal Narrative section contained therein should not exceed 30 pages. Pages should be clearly numbered and a complete index to the application and any appendices included. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, double-spaced, with unreduced type (font size 12 point) on 8½″ by 11″ paper, with at least 1″ margins, headers, and footers, and printed on one side only.

The applicant should provide a detailed description of first-year activities and briefly describe future-year objective and activities.

A. Title Page

The heading should include the title of grant program, project title, organization, name and address, project director, and telephone number.

B. Abstract

A one page, singled-spaced, typed abstract must be submitted with the application. The heading should include the title of grant program, project title, organization, name and address, project director and telephone number. This abstract should include a work plan identifying specific activities to be developed, specific activities to be completed, and a time-line for completion of these activities.

C. Narrative

The narrative of each application must:

1. State the applicant's understanding of the need or problem and the purpose of this cooperative agreement.

2. Document and describe the need for the program.

3. Document the applicant's expertise in developing materials and in providing training to emergency responders, primarily firefighters, in the area of hazardous materials exposures.

4. Document the applicant's ability to provide qualified staff, knowledge, financial, and other resources necessary to perform the applicant's responsibilities in this project, and describe the approach to be used in carrying out those responsibilities.

5. Describe clearly the objectives of the project for the five-year period, the steps to be undertaken in planning, implementing and evaluating this project, and the respective responsibilities of the applicant and any other entities for carrying out those steps.

6. Provide a proposed schedule for accomplishing each of the tasks to be carried out during the project period (include a timeline for activities) and a method for evaluating the accomplishments.

7. Describe the names and qualifications of the proposed staff and time allocated for them to accomplish program activities; the support staff available for the project; the instructors for the program; and audio-visual support, the facilities, space, and equipment available for the project. Submit biographical sketches on each (Use form CDC 2.145A).

8. Specify a proposed plan for administering this project and the name, qualifications, and time commitments of the Program Director who will be responsible for the administration of the cooperative agreement.

9. Provide a detailed budget for the first 12-months and an annual budget for the projected five year project which indicates anticipated costs for staff, instructors, equipment, facilities, training, travel, postage, supplies, etc., and all sources of funds to meet those needs. *Use Budget Form CDC 2.145A.* Provide justification for costs.

10. Provide letters of support from professional/community organizations, agencies and worker groups whose participation is essential for program success (such as firefighter groups, potential trainees, groups who will provide replacement teams, community and State agencies, other Federal agencies, etc.).

11. Submit a plan for evaluating the training program and impact of the program.

D. Budget

Provide a detailed budget which indicates anticipated costs for personnel, equipment, travel, communications, supplies, postage, and the sources of funds to meet these needs. The applicant should be precise about the program purpose of each budget item. For contracts described within the application budget, applicants should name the contractor, if known; describe the services to be performed; and provide an itemized breakdown and justification for the estimated costs of the contract; the kinds of organizations or parties to be selected; the period of performance; and the method of selection. Place the budget narrative pages showing, in detail, how funds in each object class will be sent, directly behind form CDC 2.145A. Do not put these pages in the body of the application. CDC may not approve or fund all proposed activities.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

A. Responsiveness to the objectives of the cooperative agreement including: (1) The applicant's understanding of the objectives of the proposed cooperative agreement, and (2) the relevance of the proposal to the objectives. (20%)

B. Feasibility of meeting the proposed goals of the cooperative agreement including; (1) the proposed schedule for initiating and accomplishing each of the activities of the cooperative agreement; and, (2) the proposed method for evaluating the accomplishments. (20%)

C. Strength and comprehensiveness of the training program plan which addresses the distinct characteristics and needs of the target audience and which includes the essential program elements for planning, conducting and evaluating training programs. (25%)

D. Training and experience of the Program Director and staff including: (a) Program Director with technical expertise and education in the hazardous substance field, (b) faculty with training and experience in the appropriate technical content areas, and (c) staff with experience in developing curricula in hazardous materials emergency response and studying health and safety issues in the target population. (15%)

E. The capability of accessing national firefighters who have responsibility for hazardous materials emergency response in order to ensure consistency in delivering training programs; credibility with State and local institutions, fire marshals and firefighters; the ability to bring in replacement teams for trainees; and accessibility to State and local educational institutions for target worker populations. (10%)

F. Experience in curriculum development and in delivering health and safety emergency response programs for the target population, particularly in a labor education cooperative environment and documentation of past performance and productivity. (10%)

G. Proposed Budget (Not Scored)

The extent to which the budget request is clearly explained, adequately justified, reasonable, sufficient for the proposed project activities, and consistent with the intended use of the cooperative agreement funds.

Executive Order 12372 Review

Applications are not subject to review by Executive Order 12372.

Public Health System Reporting Requirement

The program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number for this program is 93.263.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by this cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Application Submission and Deadlines

A. Application

The original and two copies of the application PHS Form 5161–1 (Revised 7/92, OMB Number 0937–0189) and the CDC 2.145A budget form must be submitted to Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers of Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Atlanta, GA 30305, on or before June 19, 1997.

1. Deadline: Applications will be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (The applicants must request a legibly dated U.S. Postal Service postmark or obtain a receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. Late Applicants: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicants.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to refer to Announcement 742. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to announcement number 742 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, Room 321, 255 East Paces Ferry Road, NE., Atlanta, GA, 30305, telephone (404) 842–6804, Internet: vxw1@cdc.gov.

Programmatic technical assistance may be obtained from Bernadine B. Kuchinski, Ph.D., Office of Extramural and Special Projects, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., MS D–40, Atlanta, GA 30333, telephone (404) 639–3342, Internet address: bbki@.cdc.gov.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC, 20402–9325, telephone (202) 512–1800.

Dated: May 5, 1997.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC)

[FR Doc. 97–12248 Filed 5–8–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee on Mental Retardation; Notice of Meeting

Agency Holding the Meeting: President's Committee on Mental Retardation.

Time and Date: Full Committee Meeting, June 16, 1997, 10:30 a.m. –5:00 p.m.

Place: Wilbur J. Cohen Building, 330 Independence Avenue, SW., Washington, D.C. 20201.

Status: Meetings are open to the public. An interpreter for the deaf will be available upon advance request. All locations are barrier free.

To Be Considered: The Committee plans to discuss critical issues concerning Federal Policy, Federal Research and Demonstration, State Policy Collaboration, Minority and Cultural Diversity and Mission and Public Awareness.

The PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs and services for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

CONTACT PERSON FOR MORE INFORMATION: Gary H. Blumenthal, 352–G Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201–0001, (202) 619–0634.

Dated: May 1, 1997.

Gary H. Blumenthal,

Executive Director, PCMR.

[FR Doc. 97–12155 Filed 5–8–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0158]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by June 9, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petitions for Affirmation of Generally Recognized As Safe (GRAS) Status—21 CFR 170.35(c)(1)—(OMB Control Number 0910–0132—Reinstatement)–

Under authority of sections 201, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 342, 348, and 371), FDA reviews petitions for affirmation as GRAS which are submitted on a voluntary basis by the food industry and other interested parties. Under section 409 of the act, the agency has the authority to regulate food additives. Section 201(s) of the act defines ''food additive'' and expressly excludes from the definitions substances GRAS for use in food.

Specifically under section 201(s) of the act, a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe either through scientific procedures or through common use in food before 1958. The act has historically been interpreted to permit food manufacturers to make their own determination that use of a substance in food is GRAS. To implement the GRAS provisions of the act, FDA has issued procedural regulations under § 170.35(c)(1) (21 CFR 170.35(c)(1)). These regulations establish a process by which a person may obtain FDA concurrence with a GRAS determination; this concurrence is referred to as ''GRAS affirmation.'' These regulation set forth the information to be submitted to FDA to obtain agency concurrence that a substance is GRAS (§ 170.35(c)(1)).

GRAS petitions are reviewed by FDA to ascertain whether the available data establish that the intended use of the substance is GRAS based upon either a history of the safe use of the substance before 1958, or upon widely available safety data (scientific procedures). The GRAS affirmation process is a voluntary one, and there is some risk that FDA may not agree with the petitioner's GRAS determination. The GRAS petition process does provide a public procedure for coordinating GRAS determinations. The process reduces the potential for public health problems when substances are marketed based upon unwarranted safety determinations and allows a food manufacturer to rely on the lawful status of a substance that has been affirmed by FDA as GRAS.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.35(c)(1)	5	1	5	2,614 (average)	13,070

There are no capital costs or operating and maintenance costs associated with this collection.

Dated: May 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12256 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0175]

BetzDearborn, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BetzDearborn, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a copolymer of the sodium salt of acrylic acid with polyethyleneglycol allyl ether for use as a boiler water additive.

DATES: Written comments on the petitioner's environmental assessment by June 9, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Paulette M. Gaynor, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3079.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7A4541) has been filed by BetzDearborn, Inc., 4636 Somerton Rd., Trevose, PA 19053. The petition proposes to amend the food additive regulations in § 173.310 *Boiler water additives* (21 CFR 173.310) to provide for the safe use of a copolymer of acrylic acid and polyethyleneglycol allyl ether for use as a boiler water additive.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before (*insert date 30 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments. 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. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: April 16, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–12255 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0028]

International Conference on Harmonisation; Guideline on Stability Testing for New Dosage Forms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guideline entitled ''Stability Testing for New Dosage Forms.'' The guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guideline addresses the generation of stability information for new dosage forms for submission to FDA by the owner of the original application. The guideline is an annex to the ICH guideline entitled ''Stability Testing of New Drug Substances and Products.''

DATES: Effective June 9, 1997. Written comments may be submitted at any time.

ADDRESSES: Submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the guideline are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Guiragos K. Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of March 6, 1996 (61 FR 9060), FDA published a draft tripartite guideline entitled ''Stability Testing for New Dosage Forms.'' The notice gave interested persons an opportunity to submit comments by June 4, 1996.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies at the ICH meeting held on November 5, 1996.

In the **Federal Register** of September 22, 1994 (59 FR 48754), FDA published a guideline entitled ''Stability Testing of New Drug Substances and Products.'' The guideline addresses the generation of stability information for submission to FDA in new drug applications for new molecular entities and associated drug products. For biotechnological/biological products, see ''Quality of Biotechnological/Biological Products: Stability Testing of Biotechnological/Biological Products'' (60 FR 43501, August 21, 1995).

This guideline is an annex to that guideline and addresses the generation of stability information for new dosage forms for submission to FDA by the owner of the original application, after the original submission for new drug substances and products.

This guideline represents the agency's current thinking on stability testing for new dosage forms. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

As with all of FDA's guidelines, the public is encouraged to submit written comments with new data or other new information pertinent to this guideline. The comments in the docket will be periodically reviewed and, where appropriate, the guideline will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guideline. 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. The guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guideline is available on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cder/guidance.htm).

The text of the guideline follows:

Stability Testing for New Dosage Forms

1. General

This document is an annex to the ICH Harmonized Tripartite Guideline on Stability Testing of New Drug Substances and Products and addresses the recommendations on what should be submitted regarding stability of new dosage forms by the owner of the original application, after the original submission for new drug substances and products.

2. New Dosage Forms

A new dosage form is defined as a drug product which is a different pharmaceutical product type, but contains the same active substance as included in the existing drug product approved by the pertinent regulatory authority.

Such pharmaceutical product types include products of different administration route (e.g., oral to parenteral), new specific functionality/delivery systems (e.g., immediate release tablet to modified release tablet) and different dosage forms of the same administration route (e.g., capsule to tablet, solution to suspension).

Stability protocols for new dosage forms should follow the guidance in the parent stability guideline in principle. However, a reduced stability database at submission time (e.g., 6 months accelerated and 6 months long-term data from ongoing studies) may be acceptable in certain justified cases.

Dated: May 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12157 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0155]

Report on Food and Drug Administration Nutrition Labeling Information Study—December 1996, Raw Fruit/Vegetables and Raw Fish; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Food and Drug Administration Nutrition Labeling Information Study—December 1996, Raw Fruit/Vegetables and Raw Fish.'' This report summarizes survey data on actions taken by food retailers to provide consumers with nutrition labeling information for raw fruit, vegetables, and fish. This report is mandated by the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

DATES: Comments may be submitted at any time.

ADDRESSES: Submit written comments and requests for single copies of the report to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments and requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. Copies of the document will be available at cost from the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The report and received comments are available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nancy T. Crane, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5615.

SUPPLEMENTARY INFORMATION: The 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) to require, among other things, that under section 403(q)(4) of the act (21 U.S.C. 343(q)(4)), FDA do the following: (1) Identify the 20 most frequently consumed raw fruit, vegetables, and fish in the United States; (2) establish guidelines for the voluntary nutrition labeling of these raw fruit, vegetables, and fish; and (3) issue regulations that define ''substantial compliance'' with respect to the adherence by food retailers with those guidelines.

In the **Federal Register** of November 27, 1991 (56 FR 60880), FDA responded to those requirements by publishing a final rule on the nutrition labeling of raw fruit, vegetables, and fish (corrected on March 6, 1992 (57 FR 8174)). In the **Federal Register** of August 16, 1996 (61 FR 42742), FDA published another final rule that revised the guidelines and updated the nutrition labeling values for the voluntary nutrition labeling of raw fruit, vegetables, and fish. This action made the labeling under the voluntary nutrition labeling program more consistent with mandatory nutrition labeling of other foods regulated by FDA.

FDA lists the 20 most frequently consumed raw fruit, vegetables, and fish in § 101.44 (21 CFR 101.44). In § 101.45 (21 CFR 101.45), FDA set forth guidelines on how these foods are to be nutrition labeled. Under these guidelines, nutrition labeling information may be provided by food retailers in the parts of their stores where raw fruit, vegetables, and fish are sold. Information may be made available in signs, posters, brochures, notebooks, or leaflets and may be supplemented by video, live demonstration, or other media.

In § 101.43 (21 CFR 101.43), FDA defines ''substantial compliance'' to mean that at least 60 percent of the food retailers sampled in a representative survey provide nutrition labeling information (as specified in the guidelines) for at least 90 percent of the foods that they sell that are included on the listing of the most frequently consumed raw fruit, vegetables, and fish. FDA makes separate determinations of substantial compliance for raw fruit and vegetables collectively and for raw fish (§ 101.43(a)).

Section 403(q)(4)(C) of the act directed FDA to issue a report 30 months after enactment of the 1990 amendments that includes a determination of whether there is substantial compliance with the agency's implementing regulations. The act also states that if substantial compliance is achieved by food retailers, FDA is to reassess voluntary labeling compliance every 2 years. If substantial compliance is not achieved, FDA is to propose to require that nutrition information be provided by any person who offers raw fruit and vegetables or raw fish to consumers (section 403(q)(4)(D)(i) of the act).

In the **Federal Register** of May 18, 1993 (58 FR 28985), and May 5, 1995 (60 FR 22400), FDA announced the availability of reports that found that, under the standard in § 101.43, there was substantial compliance by food retailers in the provision of nutrition labeling information for raw fruit, vegetables, and fish. These determinations were based on compliance surveys that were conducted in November/December of 1992 and 1994. For both time periods, aggregate percentages (i.e., percentages over all stores sampled) for both raw fruit and vegetables and for raw fish showed that approximately three-fourths of the retail food stores surveyed provided the voluntary nutrition information.

Because substantial compliance was achieved in 1995, section 403(q)(4)(C)(ii) of the act requires that FDA reassess voluntary labeling compliance and issue a report in 1997. FDA is now announcing that this reassessment has been done. The results

of this reassessment are set forth in the report entitled ''Food and Drug Administration Nutrition Labeling Information Study—December 1996, Raw Fruit/Vegetables and Raw Fish.''

Based upon the results of this study that was conducted under contract, FDA once again concludes that substantial compliance by food retailers in providing nutrition labeling information for raw fruit and vegetables and for raw fish has been met. On a store count basis, more than 70 percent (73.0 percent for raw produce and 71.2 percent for raw fish) of the sampled stores selling raw fruit, vegetables, and fish voluntarily provided nutrition labeling information in an appropriate manner for these raw foods.

Data were also reported on an all commodity volume (ACV) basis. ACV data are weighted estimates that represent annual store sales volumes and reflect the percent of the market serviced. ACV data approximate more representatively than store counts the percent of the population exposed to the nutrition labeling information. ACV values were higher than those for sampled store counts.

For raw fruit/vegetables, stores in compliance account for 77.8 percent of the annual sales of all food stores. For raw fish, stores in compliance account for 74.0 percent of the annual sales of all food stores. A possible interpretation of these data is that about three-fourths of U.S. consumers are exposed to nutrition labeling information for raw fruit, vegetables, and fish. Because many consumers shop in more than one store, the actual level of consumer exposure is most likely to be even higher.

FDA will again survey retail stores in 1999 to determine whether substantial compliance in the provision of voluntary labeling information for raw fruit, vegetables, and raw fish continues to exist. If, at that time, substantial compliance is not met, the agency will propose to modify § 101.43 to make the program mandatory.

Dated: April 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12158 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–142]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Contained in BPD–393, Examination and Treatment for Emergency Medical Conditions and Women in Labor, 42 CFR 488.18, 489.20 and 489.24; *Document:* HCFA–R–142; *Use:* BPD–393 contains information collection requirements for hospitals that would seek to prevent them from inappropriately transferring individuals with emergency medical conditions, as mandated by Congress. HCFA will use this information to help assure compliance with this mandate. This information is not contained elsewhere in regulations. *Frequency:* On occasion; *Affected Public:* Individuals or households, Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents: 7,000; Total Annual Responses: 7,000; Total Annual Hours Requested:* 8,818,577.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's web site address at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

Dated: May 1, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–12072 Filed 5–8–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: Subcommittee F—Manpower and Training Subcommittee.

Date: June 18–20, 1997.

Time: June 18—6:30 p.m. to Adjournment, June 19, 20—8:00 a.m. to Adjournment.

Place: St. James Hotel, 950 24th Street, N.W., Washington, DC 20037.

Contact Person: Mary Bell, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, 6130 Executive Blvd. Room 611A, Bethesda, MD 20892, Telephone: 301–496–7978.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers

Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: May 6, 1997.

LaVerne Y. Springfield,

Committee Management Officer, NIH.

[FR Doc. 97–12234 Filed 5–8–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of a Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Sleep Academic Award Review.

Date: June 17, 1997.

Time: 9:00 a.m.

Place: Holiday Inn Chevy Chase, Chevy Chase, Maryland.

Contact Person: Louise P. Corman, Ph.D., Two Rockledge Center, Room 7180, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0270.

Purpose/Agenda: To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: May 5, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–12231 Filed 5–8–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Environmental Health Sciences Special Emphasis Panel (SEP) meetings:

Name of SEP: Review of Conference Grants (R13s), (Telephone Conference Call).

Date: May 12, 1997.

Time: 1:00 p.m.

Place: National Institute of Environmental Health Sciences, North Campus, Building 1 Conference Room, Research Triangle Park, NC 27709.

Contact Person: Dr. John Braun, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1446.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Genetic Toxicity Testing in Rodents.

Date: May 19, 1997.

Time: 1:00 p.m.

Place: National Institute of Environmental Health Sciences, South Campus, Building 101, Conference Room 101A, Research Triangle Park, NC 27709.

Contact Person: Dr. John Braun, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1446.

Purpose/Agenda: To review and evaluate contract proposals.

Name of SEP: Mouse Sub-chromosomal DNA Paint Probes, (Telephone Conference Call).

Date: May 22, 1997.

Time: 10:00 a.m.

Place: National Institute of Environmental Health Sciences, North Campus, Building 17, Room 1713, Research Triangle Park, NC 27709.

Contact Person: Dr. John Braun, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1446.

Purpose/Agenda: To review and evaluate contract proposals.

This notice is being published less than fifteen days prior to these meetings due to the urgent need to meet timing limitations imposed by the grant/contract review and funding cycle.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Grant applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health)

Dated: May 5, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–12232 Filed 5–8–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 United States Code Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Date: June 5, 1997.

Time: 11 am to adjournment.

Place: 6120 Executive Blvd., Rockville MD 20892, (telephone conference call).

Contact Person: Richard S. Fisher, PhD., Scientific Review Administrator, NIDCD/DEA/SRB, EPS Room 400C, 6120 Executive Boulevard, Bethesda, MD 20892–7180, 301–496–8693.

Purpose/Agenda: To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, United States Code. The applications and/or proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: May 6, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–12235 Filed 5–8–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Purpose/Agenda: Peer review of a concept statement for a proposed request for contract proposal (RFP).

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date of Meeting: May 9, 1997 (Telephone conference).

Time: 1:00 p.m.

Place of Meeting: Willco Building, 6000 Executive Blvd., Bethesda, MD 20892–7003.

Contact Person: Sean O'Rourke, 6000 Executive Blvd, Suite 409, Bethesda, MD 20892–7003, 301–443–2861.

The meeting will be closed in accordance with the provisions set forth in sec. 552(c)(9)(B), Title 5 U.S.C. The discussions could reveal confidential the specific details of future requests for contract proposals (RFPs), the disclosure of which would significantly frustrate implementation of the agency's proposed contract activities.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance, Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; National Institutes of Health)

Dated: May 6, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc, 97–12236 Filed 5–8–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting of the Biomedical Library Review Committee

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Biomedical Library Review Committee on June 19–20, 1997, convening at 8:30 a.m. in the Board Room of the National Library of Medicine, Building 38, 8600 Rockville Pike, Bethesda, Maryland.

The meeting on June 19 will be open to the public from 8:30 a.m. to approximately 11 a.m. for the discussion of administrative reports and program developments. Attendance by the public will be limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Roger W. Dahlen at 301–496–4221 two weeks before the meeting.

In accordance with provisions set forth in secs. 522b(c)(4) and 552b(c)(6), Title 5 U.S.C., and sec. 10(d) of Pub. L. 92–463, the meeting on June 19 will be closed to the pubic for the review, discussion, and evaluation of individual grant applicants from 11 a.m. to approximately 5 p.m., and on June 20 from 8:30 a.m. to adjournment. These applications and the discussion could reveal confidential trade secrets or commercial property, such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Roger W. Dahlen, Scientific Review Administrator, and Chief, Biomedical Information Support Branch, Extramural Programs, National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland 20894, telephone number: 301–496–4221, will provide summaries of the meeting, rosters of the committee members, and other information pertaining to the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.879—Medical Library Assistance, National Institutes of Health)

Dated: May 6, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–12233 Filed 5–8–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meetings and Correction of Meeting Notices

Pursuant to Public law 92–463, notice is hereby given of the following meetings of the SAMHSA Special Emphasis Panel I (SEP I) in May and June and correction of meeting notices for the SAMHSA Center for Substance Abuse Prevention (CSAP) National Advisory Council and Special Emphasis Panel I (SEP I) in May.

With regard to the SEP I meetings being announced, a summary of the meetings and a roster of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: (301) 443–4783.

Substantive program information may be obtained from the individuals named as Contact for the meetings listed below.

The meetings will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, these meetings are concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, section 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: May 28–29, 1997.

Place: Embassy Suites Hotel, Boardroom Suite 217, 1250 22nd Street, NW., Washington, D.C.

Closed: May 28, 1997, 8:30 a.m.–5:00 p.m. May 29, 1997, 8:30 a.m.–adjournment.

Panel: Center for Mental Health Services Cooperative Agreement to Evaluate Housing Approaches for Persons with Serious Mental Illness.

Contact: Walter Sloboda, Room 11C–22, Parklawn Building, Telephone: (301) 594–2197 and FAX: (301) 443–3437.

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: June 8–12, 1997.

Place: Sheraton City Center Hotel, Dupont Conference Room, 1143 New Hampshire Avenue, NW., Washington, D.C.

Closed: June 8, 1997, 6:00 p.m.–8:00 p.m., June 9–11, 1997, 8:30 a.m.–5:00 p.m., June 12, 1997, 8:30 a.m.–adjournment.

Panel: Center for Mental Health Services Cooperative Agreement for an HIV/AIDS Behavior Prevention/Intervention Model for Young Adults/Adolescents and Women.

Contact: Wendy B. Davis, Room 17–89, Parklawn Building, Telephone: (301) 443–9913 and FAX: (301): 443–3437.

Summary of Correction Notices

Public notice was given in the **Federal Register** on April 9, 1997 (Volume 62, Number 68, page 17199) that the SAMHSA Center for Substance Abuse Prevention (CSAP) National Advisory Council would be meeting on May 22, 1997 at the Marriott Residence Inn, Bethesda, Maryland. The date of this meeting has subsequently been changed to May 21–22, 1997.

The agenda of the meeting and the contact for additional information remain as announced, with the following exception. A portion of the meeting will include a presentation about the Center's procurement plans. Therefore, a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(3) and 5 U.S.C. App. 2, section 10(d).

Meeting Date(s): May 21–22, 1997.

Closed: May 21, 1997, 1:00 p.m.–2:00 p.m.

Open: May 22, 1997, 8:30 a.m.–5:00 p.m.

In addition, in the same **Federal Register**, public notice was given that the Special Emphasis Panel I (SEP I) would be meeting on May 19–21, 1997, at the Residence Inn—Bethesda, Maryland. The dates of this meeting have subsequently changed to May 20–22, 1997. The agenda and hours of the closed session of the meeting and the contact for additional information remain as announced.

Dated: May 5, 1997.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 97–12154 Filed 5–8–97; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4200–N–60]

Notice of Proposed Information, Collection for Public Comment, Historically Black Colleges and Universities Program

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of Proposed Information Collection for Public Comments.

SUMMARY: The proposed information collection requirement for the Historically Black College Program described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: July 8, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Shelia E. Jones, Department of Housing & Urban Development, 451 7th Street, SW, Room 7230, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Delores Pruden or John Simmons of the Historically Black Colleges and Universities Program, 202–708–1590 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Historically Black Colleges and Universities (HBCUs) Program.

OMB Control Number, if applicable: 2506–122.

Description of the need for the information and proposed use: Application information is needed to determine competition winners i.e. which HBCUs are the most capable of achieving the HUD HBCU Program Objective ''To Expand their role and effectiveness in addressing community development needs, including neighborhood revitalization, housing and economic development in their localities, consistent with the purposes of title I of the Housing and Community Development Act of 1974''. The application for the competition requires the completion of form HUD–40076 HBCU which includes a Standard Form (SR) 424, ''Application For Federal Assistance'' and a Standard Form 424B, Assurances—Non-construction Programs. After awards are made, grantees are required to submit quarterly reports so that: their performance can be evaluated; (2) their progress in achieving the program objective can be measured; and (3) documentation can be gathered for the preparation of reports including the annual report for the Department of Education. The quarterly reports require the submission of the SF–269A and forms HUD–441.1 and 661.1.

The existing approval granted under OMB Number 2506–122 is due to expire on September 30, 1997.

Agency form numbers, if applicable: Forms HUD–441.1, HUD–661.1 and HUD–40076HBCU.

Members of affected public: Historically Black Colleges and Universities.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: These are 104 HBCUs eligible to apply for the HUD HBCU Program. The Department estimates that each applicant will use, an average of forty (40) hours to prepare an application. Winners of the competition will be required to submit quarterly reports, a final report and perform recordkeeping. The Department estimates that each grantee will use an average of seven (7) hours per quarter to complete quarterly reports, an average of four (4) hours to complete a final report, and an average of thirty-two (32) hours to do recordkeeping. See number of respondents, frequency of response, and hours of response below.

	Number of respondents	Number of responses per respondent frequency	Total annual responses	Hours per response	Total hours
Ap[plications	104	1	104	40	4,160
Quarterly reports	16	3	48	7	336
Final report	16	1	16	4	64
Recordkeeping	16	1	.....	32	512
					5,072

Status of the proposed information collection: Extension of a previously approved collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: May 2, 1997.

Jacquie Lawing,

General Deputy Assistant Secretary.

[FR Doc. 97–12082 Filed 5–8–97; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4235–N–02]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, room 7256, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Steward B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a periods of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Property Management, Program Support Center, HHS, room 5B–41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing its as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), provides should contact the appropriate landholding agencies at the following addresses: ARMY: Mr. Jeff Holste, CECPW–FP, U.S. Army Center for Public Works, 7701 Telegraph Road, Alexandria, VA 22310–3862; (703) 428–6318; AIR FORCE: Ms. Barbara Jenkins, Air Force Real Estate Agency (Ara–MI), Bolling Air Force Base, 112 Luke Avenue, Suite 104, Building 5683, Washington DC 20332–8020; (202) 767–4184; GSA: Mr. Brian K. Polly, Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW, Washington, DC 20405; (202) 501–2059; NAVY: Mr. Charles C. Cocks, Department of the Navy, Director, Real Estate Policy Division, Naval Facilities Engineering Command, Code 241A, 200 Stovall Street, Alexandria, VA 22332–2300; (703) 325–7342; (These are not toll-free numbers).

Dated: May 1, 1997.

Jacquie M. Lawing,

General Deputy Assistant Secretary.

Title V, Federal Surplus Property Program Federal Register Report for 05/09/97

Suitable/Available Properties

Buildings (by State)

Building 8–3641
Fort Bragg
Fort Bragg 28307–
Landholding Agency: Army
Property Number: 219710025
Status: Unutilized
Comment: 960 sq. ft., aluminum trailer, needs repair, possible asbestos and leadpaint, off-site use only

Colorado

Bldg. T–6016, Fort Carson
Ft. Carson Co: El Paso Co 80913–5023
Landholding Agency: Army
Property Number: 219710136
Status: Unutilized
Comment: 2988 sq. ft., needs repair, most recent use—community center, off-site use only

Georgia

Bldg. 1009
Hunter Army Airfield
Savannah Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 219710229
Status: Excess
Comment: 2341 sq. ft., wood, needs rehab, off-site use only

Bldg. T–293
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219710230
Status: Excess
Comment: 5220 sq. ft., most recent use—admin., needs major repairs, off-site use only

Bldg. T–957
Fort Stewart
Hinesville Co: Liberty GA 31314–

Landholding Agency: Army
Property Number: 219710231
Status: Excess
Comment: 6072 sq. ft., most recent use—storage, needs major repairs, off-site use only

Bldg. T–963
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219710232
Status: Excess
Comment: 3108 sq. ft., most recent use—veh. maint. shop, needs major repairs, off-site use only

Bldg. T–1055
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219710233
Status: Excess
Comment: 3114 sq. ft., most recent use—storage, needs major repairs, off-site use only

Bldg. T–1092
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219710234
Status: Excess
Comment: 180 sq. ft., most recent use—storage, needs major repairs, off-site use only

Bldg. T–8072
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219710235
Status: Excess
Comment: 109 sq. ft., most recent use—storage, needs major repairs, off-site use only

Bldg. 19109
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219710236
Status: Excess
Comment: 600 sq. ft., most recent use—power plant, needs major repairs, off-site use only

Hawaii

Bldg. P–953
Schofield Barracks
Wahiawa HI 96786–
Landholding Agency: Army
Property Number: 219710119
Status: Unutilized
Comment: 882 sq. ft. metal, good condition, off-site use only

Bldg. P–594
Schofield Barracks
Wahiawa HI 96786–
Landholding Agency: Army
Property Number: 219710120
Status: Unutilized
Comment: 882 sq. ft. metal, good condition, off-site use only

Bldg. P–225
Fort Shafter Military Reservation
Honolulu Co: Honolulu HI 96819–
Landholding Agency: Army
Property Number: 219710121
Status: Unutilized
Comment: 330 sq. ft., most recent use—storage, requires complete cleaning, off-site use only

Maine

Reserve Ctr. Bldg. & Land
Bridgeton Memorial US Army Reserve Center
Depot Street
Bridgton Co: Cumberland ME 04009–1211
Landholding Agency: Army
Property Number: 219710122
Status: Unutilized
Comment: 4484 sq. ft., 1-story, brick on 3.65 acres

Maintenance Bldg.
Bridgeton Memorial US Army Reserve Center
Depot Street
Bridgton Co: Cumberland ME 04009–1211
Landholding Agency: Army
Property Number: 219710123
Status: Unutilized
Comment: 1325 sq. ft., 1-story, brick, most recent use—vehicle maintenance shop

Missouri

4 Bldgs.
Fort Leonard Wood
83, 85, 89 Cable Street
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Landholding Agency: Army
Property Number: 219710124
Status: Unutilized
Comment: 1236 sq. ft. each, needs repair, presence of asbestos, most recent use—family quarters

Fort Leonard Wood
38 Bldgs.
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Location: 1–16, 18, 20, 22, 24, 26–29, 31, 33–45 Depuy Street
Landholding Agency: Army
Property Number: 219710125
Status: Unutilized
Comment: 1083–1485 sq. ft. each, needs repair, presence of asbestos, most recent use—family quarters

14 Bldgs.
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Location: 1–5, 7, 22, 24, 26, 28, 30, 32, 34, 36 Diamond Street
Landholding Agency: Army
Property Number: 219710126
Status: Unutilized
Comment: 1083–1454 sq. ft. each, needs repair, presence of asbestos, most recent use—family quarters

32 Bldgs.
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Location: 1–17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 52, 54, 56, 58, 60, 62 Elwood Street
Landholding Agency: Army
Property Number: 219710127
Status: Unutilized
Comment: 1083–1454 sq. ft. each, needs repair, presence of asbestos, most recent use—family quarters

4 Bldgs.
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Location: 1, 3, 5, 7 Epps Street
Landholding Agency: Army
Property Number: 219710128
Status: Unutilized
Comment: 1083 sq. ft. each, needs repair, presence of asbestos, most recent use—family quarters

46 Bldgs.
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Location: Indiana Street
Landholding Agency: Army
Property Number: 219710129
Status: Unutilized
Comment: 1083–1454 sq. ft. each, needs repair, presence of asbestos, most recent use—family quarters

14 Bldgs.
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Location: Young Street
Landholding Agency: Army
Property Number: 219710130
Status: Unutilized
Comment: 1083 sq. ft. each, needs repair, presence of asbestos, most recent use—family quarters

Bldgs. T–2340 thru T2343
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Landholding Agency: Army
Property Number: 219710138
Status: Underutilized
Comment: 9267 sq. ft. each, most recent use—storage/general purpose

New Jersey

57 Family Housing Units
Fort Dix, Laurel Hill
Ft. Dix Co: Burlington NJ 08640–5505
Landholding Agency: Army
Property Number: 219710238
Status: Underutilized
Comment: 42 units=4604 sq. ft., 1 unit=3453 sq. ft., 9 units=3064 sq. ft., 5 units=2480 sq. ft., needs rehab, presence of asbestos/lead base paint, off-site use only

New York

Reserve Center
Sgt. H. Grover H. O'Connor USARC
303 N. Lackwarna Street
Wayland Co: Steuber NY 14572–
Landholding Agency: Army
Property Number: 219710239
Status: Unutilized
Comment: 17102 sq. ft., good condition

Motor Repair Shop
Sgt. H. Grover H. O'Connor USARC
303 N. Lackwarna Street
Wayland Co: Steuber NY 14572–
Landholding Agency: Army
Property Number: 219710240
Status: Unutilized
Comment: 1325 sq. ft., good condition

Reserve Center
PFC. Robert J. Manville USARC
1205 Lafayette Street
Ogdensburg Co: St. Lawrence NY 13669–
Landholding Agency: Army
Property Number: 219710241
Status: Unutilized
Comment: 11,540 sq. ft., good condition

Motor Repair Shop
PFC. Robert J. Manville USARC
1205 Lafayette Street
Ogdensburg Co: St. Lawrence NY 13669–
Landholding Agency: Army
Property Number: 219710242
Status: Unutilized
Comment: 2524 sq. ft., good condition

Bldg. T–96, Fort Drum
Ft. Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219710243
Status: Unutilized
Comment: 11283 sq. ft., most recent use—storage, needs rehab, off-site use only

Bldg. T–4890, Fort Drum
Ft. Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219710244
Status: Unutilized
Comment: 2395 sq. ft., most recent use—admin., needs rehab, off-site use only

North Carolina

Building A–3672
Fort Bragg
Fort Bragg Co: Cumberland NC 28307–
Landholding Agency: Army
Property Number: 219710026
Status: Unutilized
Comment: 30 sq. ft., guard shack, needs repair, possible asbestos and leadpaint, off-site use only

Oklahoma

Building T–266
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710027
Status: Unutilized
Comment: 2,419 sq. ft., possible asbestos and leadpaint, most recent use—classroom, off-site use only

Building T–267
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710028
Status: Unutilized
Comment: 2,419 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–598
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710029
Status: Unutilized
Comment: 744 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building P–1016
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710030
Status: Unutilized
Comment: 115 sq. ft., possible asbestos and leadpaint, most recent use—utility, off-site use only

Building P–1453
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710031
Status: Unutilized
Comment: 648 sq. ft., possible asbestos and leadpaint, most recent use—range/target house, off-site use only

Building T–1601
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710032
Status: Unutilized
Comment: 5,258 sq. ft., possible asbestos and leadpaint, most recent use—chapel, off-site use only

Building P–1800
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710033
Status: Unutilized
Comment: 2,545 sq. ft., possible asbestos and leadpaint, most recent use—military equipment, off-site use only

Building P–1805
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710034
Status: Unutilized
Comment: 106 sq. ft., possible asbestos and leadpaint, most recent use—utility, off-site use only

Building P–1806
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710035
Status: Unutilized
Comment: 44 sq. ft., possible asbestos and leadpaint, most recent use—utility, off-site use only

Building T–1942
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710036
Status: Unutilized
Comment: 1,549 sq. ft., possible asbestos and leadpaint, most recent use—shop office, off-site use only

Building T–1960
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710037
Status: Unutilized
Comment: 10,309 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–1961
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710038
Status: Unutilized
Comment: 7,128 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–2035
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710039
Status: Unutilized
Comment: 18,157 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–2181
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710040
Status: Unutilized
Comment: 2,805 sq. ft., possible asbestos and leadpaint, most recent use—office, off-site use only

Building T–2426
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710041
Status: Unutilized
Comment: 8,876 sq. ft., possible asbestos and leadpaint, most recent use—office/storage, off-site use only

Building T–2440
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710042
Status: Unutilized
Comment: 8,994 sq. ft., possible asbestos and lead paint, most recent use—storage, off-site use only

Building T–2451
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710043
Status: Unutilized
Comment: 9,470 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–2607
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710044
Status: Unutilized
Comment: 6,743 sq. ft., possible asbestos and leadpaint, most recent use—classroom, off-site use only

Building T–2608
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710045
Status: Unutilized
Comment: 6,737 sq. ft., possible asbestos and leadpaint, most recent use—classroom, off-site use only

Building T–2711
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710046
Status: Unutilized
Comment: 18,082 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–2952
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710047
Status: Unutilized
Comment: 4,327 sq. ft., possible asbestos and leadpaint, most recent use—motor repair shop, off-site use only

Building T–2953
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710048
Status: Unutilized
Comment: 114 sq. ft., possible asbestos and leadpaint, most recent use—storehouse, off-site use only

Building T–3002
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710049
Status: Unutilized
Comment: 9,359 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–3003
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710050
Status: Unutilized
Comment: 3,239 sq. ft., possible asbestos and leadpaint, most recent use—office/storage, off-site use only

Building T–3152
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710051
Status: Unutilized
Comment: 3,151 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–3153
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710052
Status: Unutilized
Comment: 3,151 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–3154
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710053
Status: Unutilized
Comment: 3,151 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–3155
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710054
Status: Unutilized
Comment: 3,151 sq. ft., possible asbestos and leadpaint, most recent use—repair shop, off-site use only

Building T–3156
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710055
Status: Unutilized
Comment: 9,359 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–4009
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710056
Status: Unutilized
Comment: 2,817 sq. ft., possible asbestos and leadpaint, most recent use—classroom, off-site use only

Building T–4010
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710057
Status: Unutilized
Comment: 2,815 sq. ft., possible asbestos and leadpaint, most recent use—office, off-site use only

Building T–4011
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710058
Status: Unutilized
Comment: 9,456 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–4026
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710059
Status: Unutilized
Comment: 9,597 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–4030
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710060
Status: Unutilized
Comment: 9,618 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–4068
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710061
Status: Unutilized
Comment: 2,750 sq. ft. possible asbestos and leadpaint, most recent use—office, off-site use only

Building T–4069
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710062
Status: Unutilized
Comment: 2,750 sq. ft., possible asbestos and leadpaint, most recent use—office, off-site use only

Building T–4070
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710063
Status: Unutilized
Comment: 2,750 sq. ft., possible asbestos and leadpaint, most recent use—office, off-site use only

Building T–4468
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710064
Status: Unutilized
Comment: 2,262 sq. ft., possible asbestos and leadpaint, most recent use—barracks, off-site use only

Building T–4488
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710065
Status: Unutilized
Comment: 2,974 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building P–5042
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710066
Status: Unutilized
Comment: 119 sq. ft., possible asbestos and leadpaint, most recent use—heatplant, off-site use only

Building T–5093
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710067
Status: Unutilized
Comment: 9,361 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–5098
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710068
Status: Unutilized
Comment: 3,117 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–5099
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710069
Status: Unutilized
Comment: 9,279 sq. ft., possible asbestos and leadpaint, most recent use—thriftshop, off-site use only

Building T–5613
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710070
Status: Unutilized
Comment: 3,205 sq. ft., possible asbestos and leadpaint, most recent use—storage, off-site use only

Building T–6227
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710071
Status: Unutilized
Comment: 720 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6234
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710072
Status: Unutilized

Comment: 816 sq. ft., possible asbestos and leadpaint, most recent use—range/target house, off-site use only

Building T–6235
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710073
Status: Unutilized
Comment: 512 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6236
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710074
Status: Unutilized
Comment: 512 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6403
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710075
Status: Unutilized
Comment: 512 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6404
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710076
Status: Unutilized
Comment: 512 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6405
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710077
Status: Unutilized
Comment: 720 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6407
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710078
Status: Unutilized
Comment: 240 sq. ft., possible asbestos and leadpaint, most recent use—range/target house, off-site use only

Building T–6408
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710079
Status: Unutilized
Comment: 64 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6409
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710080
Status: Unutilized
Comment: 816 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6425
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710081
Status: Unutilized
Comment: 512 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building T–6427
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710082
Status: Unutilized
Comment: 720 sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

Building S–6431
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710083
Status: Unutilized
Comment: 848 sq. ft., possible asbestos and leadpaint, most recent use—training shelter, off-site use only

10 Buildings
Fort Sill
Lawton Co: Comanche OK 73503–5100
Location: T–6432, T–6435, T–6436, T–6437, T–6438, S–6439, S–6440, T–6442, S–6444, T–6445
Landholding Agency: Army
Property Number: 219710084
Status: Unutilized
Comment: various sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

10 Buildings
Fort Sill
Lawton Co: Comanche OK 73503–5100
Location: T–6446, T–6447, P–6449, S–6452, T–6452, S–6453, T–6455, P–6460, P–6463, S–6450
Landholding Agency: Army
Property Number: 219710085
Status: Unutilized
Comment: various sq. ft., possible asbestos and leadpaint, most recent use—range support, off-site use only

4 Buildings
Fort Sill
Lawton Co: Comanche OK 73503–5100
Location: T–6465, T–6466, T–6467, T–6468
Landholding Agency: Army
Property Number: 219710086
Status: Unutilized
Comment: various sq. ft., possible asbestos and leadpaint, most recent use—range support, off site use only

Building P–6539
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 219710087
Status: Unutilized
Comment: 1,483 sq. ft., possible asbestos and leadpaint, most recent use—office, off-site use only

Reserve Training
James T. Coker Reserve Center
1500 N First Street
Durant Co: Bryan, OK
Landholding Agency: Army
Property Number: 219710245
Status: Unutilized
Comment: 14086 sq. ft., good conndition

Maintenance Shop
James T. Coker Reserve Center
1500 N First Street
Durant Co: Bryan OK
Landholding Agency: Army
Property Number: 219710246
Status: Unutilized
Comment: needs repair.

Texas

Building 4630
Fort Hood
Fort Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 219710088
Status: Unutilized
Comment: 21,833 sq. ft., most recent use—Admin., off-site use only

Washington

11 Buildings
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: #EO103–EO106, EO306, EO315–EO316, EO343–EO344, EO353–EO354
Landholding Agency: Army
Property Number: 219710143
Status: Unutilized
Comment: 2360 sq. ft., possible asbestos/lead paint, most recent use—officer's quarters, off-site use only

Bldgs. EO109, EO350
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710144
Status: Unutilized
Comment: 1165 sq. ft., possible asbestos/lead paint, most recent use—dayroom, off-site use only

Bldgs. EO120, EO321, EO338
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710145
Status: Unutilized
Comment: 3810 sq. ft., possible asbestos/lead paint, most recent use—officer's quarters, off-site use only

5 Bldgs.
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: #EO127, EO136, EO302, EO204, EO330
Landholding Agency: Army
Property Number: 219710146
Status: Unutilized
Comment: 2284 sq. ft., possible asbestos/lead paint, most recent use—offices, off-site use only

Bldg. EO136
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710147
Status: Unutilized
Comment: 3885 sq. ft., possible asbestos/lead paint, most recent use—officer's quarters, off-site use only

Bldgs. EO158, EO303
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–

Landholding Agency: Army
Property Number: 219710148
Status: Unutilized
Comment: 1675 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldgs. EO202
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710149
Status: Unutilized
Comment: 992 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. EO312
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710150
Status: Unutilized
Comment: 3885 sq. ft., possible asbestos/lead paint, most recent use—officer's quarters, off-site use only

Bldg. EO322
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710151
Status: Unutilized
Comment: 2250 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. EO325
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710152
Status: Unutilized
Comment: 3336 sq. ft., possible asbestos/lead paint, most recent use—officer's quarters, off-site use only

Bldg. EO329
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710153
Status: Unutilized
Comment: 1843 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. EO334
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710154
Status: Unutilized
Comment: 3779 sq. ft., possible asbestos/lead paint, most recent use—recreation, off-site use only

Bldg. EO335
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710155
Status: Unutilized
Comment: 2207 sq. ft., possible asbestos/lead paint, most recent use—dining facility, off-site use only

Bldg. EO347
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710156
Status: Unutilized
Comment: 1800 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. EO349, EO110
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710157
Status: Unutilized
Comment: 1296 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

4 Bldgs.
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: #EO351, EO308, EO207, EO108
Landholding Agency: Army
Property Number: 219710158
Status: Unutilized
Comment: 1144 sq. ft., possible asbestos/lead paint, most recent use—day room, off-site use only

Bldgs. EO352, EO307
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710159
Status: Unutilized
Comment: 992 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. EO355
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219710160
Status: Unutilized
Comment: 2360 sq. ft., possible asbestos/lead paint, most recent use—training facility, off-site use only

Land (by State)

New Hampshire

Land—7.97
Industrial Park
Belmont Co: Belnap NH
Landholding Agency: Army
Property Number: 219710118
Status: Unutilized
Comment: 7.97 acres, severe sloping

Ohio

Receiver Site
Bethany Relay Station
Wayne Co: Butler OH 45040–
Landholding Agency: GSA
Property Number: 549720001
Status: Surplus
Comment: 29 acres with concrete bldg. (1560 sq. ft.)
GSA Number: 1–GR–OH–0726C

Unsuitable Properties

Buildings (by State)

Alabama

Bldg. 426, Maxwell AFB
Montgomery Co: Montgomery AL 36114–3112
Landholding Agency: Air Force
Property Number: 189720027
Status: Unutilized
Comment: Secured Area, Extensive deterioration

California

Bldg. 00530
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720007
Status: Unutilized
Comment: Secured Area, Extensive deterioration

Bldg. 00835
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720008
Status: Unutilized
Comment: Secured Area, Extensive deterioration

Bldg. 00879
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720009
Status: Unutilized
Comment: Secured Area, Extensive deterioration

Bldg. 1028
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720010
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 01630
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720011
Status; Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 01797
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720012
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 01830
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720013
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 01852
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720014
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 06449

Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720015
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 10003
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720016
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 10252
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720017
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 10745
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720018
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 11345
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720019
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 13219
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720020
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 13600
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720021
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 14019
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720022
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 14026
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720023
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 16162
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720024
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. 16191
Vandenberg AFB
Vandenberg AFB Co: Santa Barbara CA 93437–
Landholding Agency: Air Force
Property Number: 189720025
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Florida

Facility No. 90520
Cape Canaveral AS
Cape Canaveral Co: Brevard FL 32925–
Landholding Agency: Air Force
Property Number: 189720038
Status: Underutilized
Reason: Secured Area

Bldg. 312, Patrick AFB Co: Brevard FL 32925–
Landholding Agency: Air Force
Property Number: 189720039
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Georgia

Bldg. T–1054
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219710237
Status: Excess
Reason: Extensive deterioration

Maryland

Lower Waldorf Field Site
Waldorf Co: Charles MD 20603–
Landholding Agency: GSA
Property Number: 549720002
Status: Excess
Reason: Extensive deterioration
GSA Number: 4–N–MD–587A

Montana

Bldg. 23
Great Falls ANG Station
Great Falls Co: Cascade MT 59404–
Landholding Agency: Air Force
Property Number: 189720030
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material, Secured Area

Bldg. 24
Great Falls ANG Station
Great Falls Co: Cascade MT 59404–
Landholding Agency: Air Force
Property Number: 189720031
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material, Secured Area

Bldg. 28
Great Falls ANG Station
Great Falls Co: Cascade MT 59404–
Landholding Agency: Air Force
Property Number: 189720032
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material, Secured Area

Bldg. 35
Great Falls ANG Station
Great Falls Co: Cascade MT 59404–
Landholding Agency: Air Force
Property Number: 189720033
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material, Secured Area

Bldg. 228
Malmstrom AFB
Malmstrom AFB Co: Cascade MT 59402–
Landholding Agency: Air Force
Property Number: 189720034
Status: Excess
Reason: Secured Area

Bldg. 1090
Malmstrom AFB
Malmstrom AFB Co: Cascade MT 59402–
Landholding Agency: Air Force
Property Number: 189720035
Status: Excess
Reason: Secured Area

Bldg. 1091
Malmstrom AFB
Malmstrom AFB Co: Cascade MT 59402–
Landholding Agency: Air Force
Property Number: 189720036
Status: Excess
Reason: Secured Area

Bldg. 360
Malmstrom AFB
Malmstrom AFB Co: Cascade MT 59402–
Landholding Agency: Air Force
Property Number: 189720037
Status: Excess
Reason: Secured Area

Nebraska

Bldg. 606
NE Air National Guard
Lincoln Co: Lancaster NE 68524–1888
Landholding Agency: Air Force
Property Number: 189720028
Status: Underutilized
Reason: Floodway, Secured Area

Bldg. 675
NE Air National Guard
Lincoln Co: Lancaster NE 68524–1888
Landholding Agency: Air Force
Property Number: 189720029
Status: Underutilized
Reason: Floodway, Secured Area

New York

Bldg. 740
Niagara Falls Air Force Reserve
Niagara Falls Co: Niagara NY 14304–5001
Landholding Agency: Air Force
Property Number: 189720026
Status: Underutilized
Reason: Within airport runway clear zone, Floodway, Secured Area

North Carolina

Bldg. M240, Camp Lejeune
Camp Lejeune Co: Onslow NC 28542–0004
Landholding Agency: Navy
Property Number: 779720024
Status: Unutilized

Reason: Secured Area

Wyoming

Bldgs. 2565–2571
F.E. Warren AFB
Cheyenne Co: Laramie WY 82005–5000
Landholding Agency: Air Force
Property Number: 189720001
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. 2564, 2572
F.E. Warren AFB
Cheyenne Co: Laramie WY 82005–5000
Landholding Agency: Air Force
Property Number: 189720002
Status: Unutilized
Reason: Secured Area, Extensive deterioration

9 Bldgs.
F.E. Warrren AFB
2982–2986, 2989, 2991, 2994–2995
Cheyenne Co: Laramie WY 82005–5000
Landholding Agency: Air Force
Property Number: 189720003
Status: Unutilized
Reason: Secured Area, Extensive deterioration

6 Bldgs.
F.E. Warrren AFB
2768, 2772, 2773, 2993, 2980, 2988
Cheyenne Co: Laramie WY 82005–5000
Landholding Agency: Air Force
Property Number: 189720004
Status: Unutilized
Reason: Secured Area, Extensive deterioration

8 Bldgs.
F.E. Warrren AFB
2784, 2762–2764, 2769, 2775, 2777, 2981
Cheyenne Co: Laramie WY 82005–5000
Landholding Agency: Air Force
Property Number: 189720005
Status: Unutilized
Reason: Secured Area, Extensive deterioration

8 Bldgs.
F.E. Warren AFB
2785–2786, 2770–2771, 2774, 2776, 2990, 2992
Cheyenne Co: Laramie WY 82005–5000
Landholding Agency: Air Force
Property Number: 189720006
Status: Unutilized
Reason: Secured Area, Extensive deterioration

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BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–030–07–1120–00: GP7–0178]

Notice of Meeting of Southeastern Oregon Resource Advisory Council

AGENCY: Vale District, Bureau of Land Management, Interior.

ACTION: Meeting of Southeastern Oregon Resource Advisory Council, Rangeland Health Standards and Guides subgroup: teleconference, May 27, 1997.

SUMMARY: A meeting of the Southeastern Oregon Resource Advisory Council's Rangeland Health Standards and Guides subgroup will be held by teleconference on May 27, 1997 from 8:00 to 10:00 p.m. (PDT). The teleconference is open to the public; access may be obtained at the BLM Office, BLM, 100 Oregon Street, Vale, Oregon.

The Subcommittee will discuss standards and guidelines for livestock grazing on public lands.

FOR FURTHER INFORMATION CONTACT: Jonne Hower, Bureau of Land Management, Vale District, 100 Oregon Street, Vale, Oregon 97918 (Telephone (541) 473–3144.

Dated: May 2, 1997.

Lynn P. Findley,

ADM Ops/Field Support.

[FR Doc. 97–12064 Filed 5–8–97; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–070–97–1990–00]

Resource Advisory Council Meeting, Butte, Montana

AGENCY: Butte District Office, Bureau of Land Management, D.O.I.

ACTION: Notice of Butte District Resource Advisory Council Meeting, Butte, Montana.

SUMMARY: The Council will convene at 10 a.m. Thursday, June 12, 1997. Issues that will be discussed include community based planning, review of abandoned mine priority list for the District, and the Muddy Creek Allotment.

The meeting will be held at the Dillon Resource Area Office, 1005 Selway Drive, Dillon, Montana.

The meeting is open to the public and written comments may be given to the Council. Oral comments may be presented to the Council at 3 p.m. The time allotted for oral comment may be limited, depending on the number of persons wishing to be heard. Individuals who plan to attend and need further information about the meeting, or need special assistance, such as sign language or other reasonable accommodations, should contact the Butte District, 106 North Parkmont (P.O. Box 3388, Butte, Montana 59702–3388; telephone 406–494–5059.

FOR FURTHER INFORMATION CONTACT: Jim Owings at the above address or telephone number.

Dated: May 2, 1997.

James R. Owings,

District Manager.

[FR Doc. 97–12065 Filed 5–8–97; 8:45 am]

BILLING CODE 4310–DN–P–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–930–1430–01; COC–39555]

Public Land Order No. 7259; Transfer of Jurisdiction of Reserved Federal Mineral Interest to the National Park Service; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws 442.25 acres of reserved Federal mineral interest and permanently transfers administrative jurisdiction to the National Park Service for management as a part of the Florissant Fossil Beds National Monument. The reserved Federal mineral interest is within the boundary of the Monument. This action will give the Park Service full management responsibility of the Monument and the transferred minerals will be managed under regulations appropriate to a national monument.

EFFECTIVE DATE: May 9, 1997.

FOR FURTHER INFORMATION CONTACT: Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215–7076, 303–239–3706.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows.

1. Subject to valid existing rights, the administrative jurisdiction of the following described reserved Federal mineral interest located within the Florissant Fossil Beds National Monument is hereby transferred to the National Park Service:

Sixth Principal Meridian

T. 13 S., R. 70 W.,
Sec. 18, lot 2;
Sec. 19, NW¼NE¼;
Sec. 30, NE¼, NE¼SW¼, and N½SE¼.
T. 13 S., R. 71 W.,
Sec. 23. S½NE¼.

The areas described aggregate 442.25 acres in Teller County.

2. The reserved Federal mineral interest described in paragraph 1 is to be managed as a part of the Florissant

Fossil Beds National Monument. The Monument is closed to operation of the public land laws, including the mining, mineral leasing, and other mineral entry laws.

Dated: April 25, 1997.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 97–12066 Filed 5–8–97; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–930–1430–01; N–61415]

Notice of Proposed Withdrawal and Opportunity for Public Meeting; Nevada; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Correction.

SUMMARY: This action corrects an error in the land description published as FR Doc. 97–10276 in the **Federal Register,** 62 FR 19601, April 22, 1997, for a proposed United States Geological Survey withdrawal.

On page 19601, column 2, line 6 from the bottom, which reads ''T. 15 S., R. 20 E.,'' is hereby corrected to read ''T. 15 N., R. 20 E.,''.

Dated: April 29, 1997.

William K. Stowers,

Lands Team Lead.

[FR Doc. 97–12070 Filed 5–8–97; 8:45 am]

BILLING CODE 4310–HC–M

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Interim Renewal Contracts for Friant Division Contractors

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given for the negotiation of interim renewal contracts with 14 of the Friant Division contractors, Central Valley Project, California, who are parties to long-term water service contracts, which were recently declared invalid by the United States District Court, effective March 1, 1998. The total annual quantity of water allocated pursuant to these contracts is in excess of 1.3 million acre-feet. These contracts will be replaced with interim renewal contracts negotiated pursuant to the Central Valley Project Improvement Act, Title XXXIV of Pub. L. 102–575.

FOR FURTHER INFORMATION CONTACT: Jon Anderson, Supervisory Repayment Specialist, Bureau of Reclamation, South-Central California Area Office, 2666 North Grove Industrial Drive, Suite 106, Fresno, California 93727–1551; telephone 209–487–5041.

Dated: May 5, 1997.

Robert F. Stackhouse,

Regional Resources Manager, Mid-Pacific Region.

[FR Doc. 97–12142 Filed 5–8–97; 8:45 am]

BILLING CODE 4310–94–M

DEPARTMENT OF JUSTICE

Response to Comments to Department of Justice Proposed Reforms to Affirmative Action in Federal Procurement

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: On May 23, 1996, the Department of Justice published its Proposed Reforms to Affirmative Action in Federal Procurement. 61 FR 26042. The Department reviewed over 1,000 comments. This report discusses the observations and concerns most frequently expressed, and describes the changes to the proposal that were made in response to those comments. In addition, the Federal Acquisition Regulatory Council is today publishing for comment proposed amendments to the Federal Acquisition Regulation that will implement the contracting mechanisms described in the Justice Department proposal.

FOR FURTHER INFORMATION CONTACT: Mark Gross, Civil Rights Division, P.O. Box 66078, Washington, D.C. 20035–6078, telefax (202) 514–8490.

Introduction

On May 23, 1996, the Department of Justice published its Proposed Reforms to Affirmative Action in Federal Procurement. 61 FR 26042. These reforms will ensure that the use of affirmative action in federal procurement complies with the strict scrutiny standard discussed in the Supreme Court's decision in *Adarand Constructors, Inc.* v. *Pena,* 115 S. Ct. 2097 (1995).

The Justice Department received more than 1,000 individual responses to the proposal; many of those contained a number of different and lengthy comments. We greatly appreciate the time and effort so many individuals, companies, private organizations, and government personnel from cities, states, and federal agencies, took to respond to the proposal. The comments raised many of the difficult issues that were considered during the preparation of the proposal, as well as many new ones.

This report will not summarize all the comments that were received, but rather, will discuss those observations and concerns most frequently expressed. The report will identify the changes we have made to the reform proposal both in response to the comments and as a result of our continuing work on the proposal, and those issues that remain under consideration.

The Federal Acquisition Regulatory Council is publishing today the proposed amendments to the Federal Acquisition Regulation (FAR) necessary to implement the proposed reforms, including procedures to implement Section 7102 of the Federal Acquisition Streamlining Act (FASA) and to further implement 10 U.S.C. 2323. These statutes permit federal agencies to allow competitive advantages, including price and evaluation credits, in awards involving small businesses owned and controlled by socially and economically disadvantaged persons (SDBs). The regulation explains how consideration of social and economic disadvantage will be made in the contracting process. The Small Business Administration (SBA) will be publishing regulations that describe the new process by which firms can be determined to be SDBs.

I. Eligibility and Certification

A. Determination of Social and Economic Disadvantage

Many of the comments expressed concern that the proposal could permit each federal agency to determine whether firms are owned and operated by individuals who are socially and economically disadvantaged. The primary concern was inconsistent decisions by different agencies, leading to forum shopping, where firms would search to find the agency with the most lenient standards. While that possibility is less of a concern for persons who belong to minority groups statutorily presumed to be socially and economically disadvantaged,[1] the

[1] Both FASA and 10 U.S.C. 2323 (which, in language similar to that in FASA, permits the Department of Defense, NASA, and the Coast Guard to use less than full and open competition in order to aid SDBs) incorporate by explicit reference the definition of social and economic disadvantage contained in Section 8(d) of the Small Business Act. Pursuant to Section 8(d), members of designated groups are presumed to be both socially and economically disadvantaged; those presumptions are rebuttable. By contrast, under the separate program established under Section 8(a) of the Small Business Act (the 8(a) program), members of identified groups are rebuttably presumed to be

concern expressed in quite a few comments was that individual agency determinations could lead to inconsistent results when persons who are not members of ''presumed groups'' seek to be determined to be socially and economically disadvantaged. The comments almost universally suggested that determination of social and economic disadvantage be made exclusively by the SBA, which already makes similar determinations under the 8(a) program.

The proposal stated that while agencies could perform this function themselves, it also stated that an agency might wish to assign this responsibility to SBA. Consistency is a critical feature, and the SBA is in the best position to ensure consistent application of standards on social and economic disadvantage. As a result, the SBA has been assigned responsibility for developing procedures and standards that will govern federal determinations of social and economic disadvantage, and will be assigned to do determinations of social and economic disadvantage. A system will be developed that will ensure that SBA has resources to support this effort.

B. Certification of Ownership and Control

A number of comments also questioned the proposal's decision to rely on private, state and local organizations to make certifications that a firm is owned and controlled by socially and economically disadvantaged individuals. Those comments urged the government to permit SBA to make that certification, noting that this approach would be more efficient for SDBs. As stated in the original proposal, however, there already is an exhaustive system of private, state and local certifiers of ownership and control in place, and creation of a federal structure to perform this process seems unnecessary and wasteful.

C. Re-certifications

A number of comments stated that it was unnecessarily expensive to require SDBs to provide updated certifications of ownership and control every three years. The comments urged the government to permit SDBs simply to update their certifications and to keep the certification for a longer period, perhaps five years.

The interval between certifications will remain at three years. The effort to meet strict scrutiny requires that the benefits of affirmative action go only to those individuals and firms that truly qualify for competitive advantages. One way is to ensure that firms that are determined to be SDBs continue to be eligible for that status. While annual updates will help that process, many firms undergo significant changes within three years of operation. Recertification of ownership and control every three years will help to ensure the accuracy of the list of eligible SDBs, and thereby help to ensure that the government's programs meet the standards of strict scrutiny. Every effort has been made to balance the potential impact of the certification process and the need to ensure the validity of the certification.

D. Use of the Preponderance of the Evidence Standard for Social and Economic Disadvantage of Individuals Who Do Not Qualify for a Presumption of Disadvantage

As explained in the proposal, under FASA and 10 U.S.C. 2323 members of designated minority groups seeking to participate in SDB programs fall within the statutorily mandated presumption of social and economic disadvantage established in Section 8(d) of the Small Business Act. Individuals who do not fall within the statutory presumption can qualify for SDB status by proving that the individuals who own and control the firm are socially and economically disadvantaged. Under current SBA practice for certifying individuals under the 8(a) program, those individuals who are not members of presumed groups must prove social and economic disadvantage by clear and convincing evidence. The proposal would change that standard of proof to a preponderance of the evidence.

Many comments urged us not to change the standard of proof. Generally, the comments asserted that lowering the standard could permit companies owned by individuals who are not truly socially and economically disadvantaged to qualify as SDBs and to win contracts that should go to legitimate SDBs. Those comments stated that the relatively small number of federal procurement contracts that now go to firms owned by minorities pursuant to affirmative action initiatives should not be reduced by awards going to non-deserving firms owned by non-minorities.

There is significant legal support for the use of the preponderance of the evidence when an agency is determining what is essentially a question of civil law. The Supreme Court has held that the preponderance of the evidence standard is appropriate for most inquiries made in civil litigation, including questions of discrimination. *Price Waterhouse* v. *Hopkins*, 490 U.S. 228, 252–255, 261 (1989). See also *Herman & MacLean* v. *Huddleston*, 459 U.S. 375, 389–390 (1983), in which the Court indicated that the clear and convincing evidence standard should be limited to those civil questions in which ''particularly important individual interests or rights are at stake,'' and cited as examples termination of parental rights, involuntary civil commitment, and deportation. The SBA's inquiry as to social and economic disadvantage is most comparable to the discrimination inquiry in *Price Waterhouse*, which was subject to the preponderance of the evidence standard.

Furthermore, changing the standard of proof should not permit persons who are not truly socially and economically disadvantaged to receive determinations of eligibility they do not deserve. The burden of proof to show that one is socially and economically disadvantaged remains with the applicant. Careful scrutiny of applications under proper standards will result in rejection of undeserving applicants that fail to prove to SBA that they are actually socially and economically disadvantaged. The SBA will review these applications rigorously to ensure that only truly deserving candidates are determined to be SDBs.

Finally, some comments cautioned that if more non-minority firms became SDBs as a result of the lower standard of proof, reporting all SDB contracts as part of the utilization of minority firms will over-state the number of contracts actually awarded to minority-owned firms. In the event that occurs, the General Services Administration (GSA) and other governmental agencies will explore methods to ensure that only contracts that are awarded to minority-owned firms are reported as such when the utilization figure is compiled and compared with the benchmark.

E. Timing of Certifications

At least one inquiry asked whether an SDB needed to have its formal determination of eligibility before it could respond to a solicitation as an SDB, or whether it would be sufficient if the SDB had secured its determination of eligibility by the time the contract actually was awarded. A middle ground will be adopted.

Requiring all SDBs to have final determinations of eligibility in hand before being able to respond in any way to a solicitation might encourage firms to seek eligibility on the assumption

socially disadvantaged, but must establish that they are economically disadvantaged.

that they might want to use it at some point in the fiscal year. It is clear that, at least at the beginning of this program, there will be a large number of firms seeking to be eligible SDBs, and it is important that people not be encouraged to seek that status if they are unsure whether they would ever have occasion to use it.

The proposed regulation amending the FAR states that the contracting officer will specify in the solicitation the date by which each SDB must have official determination of eligibility. That date will be early enough in the process to allow offerors a reasonable opportunity, consistent with the needs of the procurement, to obtain a determination of SDB status before the contract award process is completed. The award of a contract will not be delayed to permit a firm to secure SDB status after the date specified by the contracting officer.

II. Benchmark Limits

A. Use of SMOBE Data

The proposal states that the system will rely primarily on Census data to determine the capacity and availability of minority-owned firms. A number of comments stated that the Census Department's SMOBE (Survey of Minority-Owned Business Enterprise) data are incomplete. The comments stated that SMOBE may not count certain types of corporations and has other reporting problems. A number of comments stated that the government should focus on those firms that are ''ready, willing and able'' to participate in government contracting when determining whether present methods of contracting unfairly exclude minority-owned firms, and that SMOBE or other similar data may not accurately describe the universe of such firms.

The Commerce Department has addressed a number of ways to fill in information not contained in SMOBE, and is refining those data. The Commerce Department has also been working to determine the appropriate database, or combination of databases, to measure the availability and capacity of existing minority-owned firms for purposes of establishing the benchmark figure for minority capacity.

B. Use of Two-Digit SIC Codes

The proposal stated that benchmarks would be established in each two-digit Standard Industrial Classification (SIC) code. A number of comments asserted that two-digit SIC codes were too broad to be used for this purpose. Some comments stated that the use of two-digit SIC codes runs the risk of yielding an erroneous vision of a particular industry. For example, one comment stated that where minority firms in one four-digit SIC code within the larger two-digit classification were very successful, the government might be receiving an erroneous impression of the state of minority contracting in other activities within that two-digit SIC code and assume incorrectly that minority firms in those activities were successful.

The proposal used two-digit SIC codes for several reasons. First, available Census data would not support capacity estimates at the four-digit level. Second, were the necessary data available, it would be extremely burdensome to implement benchmarks for all the four-digit SICs in which federal contracting takes place.

However, a Department of Commerce analysis using the Federal Procurement Data System indicates that 40 four-digit SIC codes accounted for approximately 80% of dollars awarded under prime contracts above $25,000 in FY 1995. Thus, a suitably expanded Survey of Minority-Owned Business Enterprises could support future use of four-digit SIC codes in these industrial activities.

C. Areas With Little Minority Availability and Capacity

Several comments stated that, by tying benchmarks to the existing availability and capacity of minority-owned firms, the government could be continuing to exclude minority-owned firms from industrial areas in which they have had little success.

While the benchmark will be based in large part on the existing capacity and availability of minority-owned firms, consideration will also be given to the extent to which the effects of racial discrimination have impeded the ability of minority individuals to become entrepreneurs, and the ability of minority-owned firms to grow. The consideration of the effects of discrimination, as applied in these and other circumstances, may increase the benchmark beyond the estimates of the present existence of minority-owned firms, particularly in those areas in which there is little minority activity. The Commerce Department is still working to develop the statistical assessment of these effects of racial discrimination.

D. Exclusion of Small Firms From the Benchmarks

The proposal stated that we were considering, when establishing the benchmarks, excluding those firms that are simply too small to have competed for and won federal contracts. Several comments stated that excluding such small firms would freeze the effects of discrimination on those firms, as discrimination has limited the ability of many minority firms to grow and compete for federal contracts.

This comment may be addressed in three ways. In particular industries, it may be appropriate to forego any adjustments in recognition that discrimination has suppressed firm size. In others, the phenomenon may be addressed by the assessment of the effects of racial discrimination on minority business development. And, finally, as a practical matter, the Commerce Department, during its analysis of benchmarks, has identified industrial areas in which very small firms have won contracts, and so there may not be a reason to exclude any firms when the benchmarks are calculated in some SIC codes. It is not clear, at this time, whether there will be SIC codes in which federal contracts or subcontracts are always so large that an exclusion of small firms is appropriate. That determination will be made as final benchmarks are established in all SIC codes.

E. Benchmarks Should Consider Discrimination by the Private Sector

A number of comments urged consideration of the fact that discrimination has limited participation by minority-owned firms in the private sector. Those comments stated that considering curtailing or eliminating affirmative action when federal contracting has reached or exceeded those benchmarks ignores the broad discrimination occurring in the private sector.

The effects of private discrimination will be reflected in the assessment of the extent to which discrimination has impeded the development and growth of minority-owned firms. This factor will be critical when the assessment is made in any SIC code to curtail or even eliminate the use of price or evaluation credits. While affirmative action in federal procurement is not a means to make up for opportunities minority-owned firms may have lost in the private sector, it is intended to ensure that federal procurement is a means for minority-owned firms to secure full and fair treatment, which may well translate into more success for those firms in private commercial efforts.

F. Evidence of the Effects of Discrimination

The proposal stated that a statistical calculation representing the effect discrimination has had on suppressing minority business development and capacity would be made, and that

calculation would be factored into benchmarks. The Department of Commerce continues to work to develop this calculation.

Regardless of the outcome of that statistical effort, the effects of discrimination will be considered when utilization exceeds the benchmark and it is necessary to determine whether race-conscious measures in a particular SIC code should be curtailed or eliminated. Before race-conscious action is decreased, consideration will be given to the effects discrimination has had on minority business development in that industrial area, and the need to consider race to address those effects.

III. Interaction of Benchmarks and Mechanisms

A. Reservation of Contracts

The proposal stated that the authority to reserve contracts for bidding by SDBs would not be invoked for at least two years after implementation of the proposed system. The purpose of that waiting period was to allow evidence to accumulate regarding the effectiveness of the new system. The proposal contemplated that after two years the system would be evaluated to consider whether reservation of contracts might be appropriate if the system clearly was unable to remedy persistent and substantial underutilization of minority firms in particular industries resulting from past or present discrimination.

Numerous comments suggested that this two-year evaluation period was too inflexible. While, as stated in the proposal, we believe that the new system should make reservation of contracts unnecessary, we also believe a modification of the proposal is appropriate. The determination whether to consider reservation of contracts in any industry should turn not on the lapse of any particular period of time, but on the amount and strength of the evidence regarding the effectiveness of the new system in that industry. Thus, where the Department of Commerce, in consultation with the Department of Justice, the General Services Administration, and the Small Business Administration, finds substantial and persuasive evidence of (1) a persistent and significant underutilization of minority firms in a particular industry, attributable to past or present discrimination, and (2) a demonstrated incapacity to alleviate the problem by using the proposed system, then the agencies may be authorized to reserve contracts. This is a rigorous standard, and contracts will not be reserved until it is met.[2]

B. Counting 8(a) Contracts Toward the Benchmark Limits

A number of comments asserted that the government should not include contracts awarded pursuant to the SBA's 8(a) program when determining the amount of money that has been awarded to minority-owned firms in each SIC code. The reason, many asserted, was that the 8(a) program is not based on racial considerations, but rather is a race-neutral business development program. Therefore, the comments stated, race should not be considered to have been a factor in the award of those contracts. The comments also stated that, if achievement of a benchmark is an indication that there is less of a need for affirmative action programs, we should not count 8(a) contracts because those developing firms are not fully competitive, and the award of an 8(a) contract is not an indication that the minority-owned firm would fare as well in open competition.

First, while the 8(a) program is a business development program, the race of the owner of a firm is a factor in the manner in which a firm may become certified as eligible for an 8(a) contract. Therefore, 8(a) is not an entirely ''race-neutral'' program. Second, and more importantly, these comments may reflect a misunderstanding of the assessment that will be made at the end of each fiscal year. As explained in the proposal, the benchmark figure will represent the extent to which the government would expect contract dollars in particular industrial activities to be awarded to minority-owned firms in the absence of discrimination or its effects. The reason to measure the extent to which minority-owned firms have received federal contracts is to determine whether race-conscious programs, like price or evaluation credits, continue to be needed to ensure that firms owned by minorities have a fair opportunity to compete for and win federal contracts.

This assessment must count *all* contracts awarded to minority-owned firms, whether through race-conscious programs or through free and open competition. Only by determining the extent of minority participation in contracting, and then by determining whether that participation has been achieved through full and open competition, race-conscious action programs, or by a combination of the two, can we determine whether race-conscious programs continue to be needed in that SIC code. Therefore, when a contract is awarded to a minority-owned firm through the 8(a) program, it must be counted towards the benchmark. It must be counted simply because the firm that was awarded the contract is owned and operated by a minority individual or individuals.

This does not mean, however, that the fact that the contract was awarded pursuant to the 8(a) program is irrelevant to the question whether the use of race-conscious action in a particular SIC code should continue, be curtailed, or even be eliminated. If the amount of federal contract money awarded to minority-owned firms in a particular SIC code exceeds the benchmark, the determination of the extent to which race-conscious measures may be permissible in the next year will consider how the awards were made. If the benchmark is significantly exceeded in an SIC code, but a large percentage of minority contracts would not have been awarded to minority-owned firms without the use of 8(a) and/or price or evaluation credits, that might indicate that the use of price credits, or even of the 8(a) program, should be cut back, but not eliminated.

Accordingly, the fact that an award made to a minority-owned firm pursuant to 8(a) is counted towards the benchmark does not ignore the purposes of the 8(a) program. The proposal contemplates continued use of the 8(a) program as an effective means to develop small socially and economically disadvantaged businesses.

C. Counting Subcontracts Awarded Pursuant to a Prime Contractor's Subcontracting Plan Toward the Benchmark

Other comments raised a similar point; subcontracts awarded to minority-owned firms should not count toward the benchmarks if they were awarded pursuant to the subcontracting plan that Section 8(d) of the Small Business Act requires of prime contractors. The comments stated that they should not be counted because race is not a factor in the award of the subcontract. For the same reasons that contracts awarded to minority-owned firms pursuant to 8(a) must be counted toward the benchmark, subcontracts to minority-owned firms—whether awarded through race-based measures or direct competition—must be counted as well.

[2] This discussion does not apply to the 8(a) program, which, as described in the proposal, has unique indicia of narrow tailoring.

D. When Achievement of the Benchmark in an SIC Code Will Result in Curtailment or Elimination of Race-Conscious Action in that SIC Code

A number of comments requested clarification of precisely when achievement of a benchmark would result in curtailment or elimination of affirmative action measures. Some of these comments suggested a misunderstanding of the proposal.

Achievement of a benchmark in a particular SIC code does not automatically mean that race-conscious programs, or the use of 8(a) contracts, will be eliminated in that SIC code. The purpose of comparing utilization of minority-owned firms to the benchmark is to ascertain when the effects of discrimination have been overcome and minority-owned firms can compete equally without the use of race-conscious programs. Full utilization of minority-owned firms in an SIC code may well depend on continued use of race-conscious programs like price or evaluation credits. Where utilization exceeds the benchmark, the Office of Federal Procurement Policy (OFPP) may authorize the reduction or elimination of the level of price or evaluation credits, but only after analysis has projected the effect of such action.

E. Ensuring That Prime Contractors Actually Use SDB Subcontractors

A few comments asserted that many non-minority prime contractors commit to use SDBs as subcontractors in order to be awarded a prime contract, but do not actually use the SDBs, or use SDBs to a lesser extent than proposed.

The proposal addresses this problem in a number of ways. First, the extent of an evaluation credit given to a prime contractor increases as the commitment to SDBs becomes more firm. Prime contractors who present written, enforceable subcontracting commitments to specific SDBs will receive more consideration in an evaluation context than those who simply promise to find SDBs as subcontractors during the course of the contract. The more enforceable the commitment to SDBs, the higher the evaluation credit. Second, the extent to which a prime contractor has honored a commitment to subcontract to SDBs may be a factor when the prime contractor bids on a subsequent contract.

Some comments stated that it would be very difficult for prime contractors to assign an SIC code to subcontracting opportunities at the bidding stage. The proposal has a provision that will significantly ease the administrative burden of reporting subcontracting. The prime contractor may report subcontracts based on the predominant SIC code of the subcontractor. The subcontracting firm need only report to the prime contractor the SIC code in which it does most of its work, and the prime may then report that SIC code for purposes of reporting subcontracting.

Several comments stated that it would be a hardship for prime contractors to help secure determinations of eligibility for those SDBs it will use as subcontractors. These comments may reflect a misunderstanding of the proposal. No prime contractor is responsible for issuing determinations of eligibility, or for helping to establish the eligibility of an SDB it proposes to use as a subcontractor. That is the responsibility of the SDB. In order to receive a price or evaluation credit based on subcontracting, however, the prime contractor must demonstrate that its commitment is to eligible SDBs. The prime, therefore, while not involved in the process of determining or securing determinations of eligibility for SDBs, must ensure that when it submits a bid that seeks a price or evaluation credit based on subcontracting to SDBs, the firms it identifies as SDBs have been determined eligible.

Finally, a number of comments urged the government to use mentor-protégé programs aggressively. The proposal mentions mentor-protégé programs as one of the outreach and technical assistance programs the government seeks to use to increase participation of SDBs in federal contracting. Mentor-protégé programs have been an effective way of increasing participation of minority-owned firms in federal contracting, and we are hopeful that such programs will continue.

F. Joint Ventures

A number of comments stated that joint ventures of non-minority and minority-owned firms provide the minority-owned firm an opportunity to secure a share of federal contracts. Under the proposed amendments to the FAR, joint ventures will be eligible for price credits.

G. Contracts for Commercial Items

Several comments noted that it would be very difficult to assess or evaluate subcontracting opportunities under contracts for commercial items. While there are difficulties, commercial items are covered.

IV. Miscellaneous Comments

A. Funding of the 7(j) Program

Many comments expressed a concern that while the proposal relies significantly on the SBA's 7(j) program that provides technical and management assistance to qualifying individuals, Congress has not funded that program. That concern is legitimate, and the Administration is exploring measures to keep the program viable.

B. Women-Owned Firms

A number of comments expressed concern that the government appeared to give no consideration in this proposal to firms owned and operated by women, despite the fact that many women entrepreneurs had endured the effects of discrimination similar to that suffered by minorities.

Some portions of the proposal, such as the lowering of the standard of proof for non-minority firms as SDBs to preponderance of the evidence, could affect women-owned firms. Plainly, the portions of the proposal that address the manner in which race-conscious measures are permissible do not address women-owned firms not owned by minorities. The proposal concentrates on firms owned and operated by minorities because the regulation will implement Section 7102 of FASA and 10 U.S.C. 2323, and those statutes do not authorize affirmative action for women. Section 7102 permits the federal government to take affirmative action, including granting price and evaluation credits, for ''small business concerns owned and controlled by socially and economically disadvantaged individuals * * *.'' That provision refers to subsection (d)(3)(C) of Section 8 of the Small Business Act (15 U.S.C. 637), which in turn defines social disadvantage in terms of ''racial or ethnic prejudice or cultural bias.'' Women are not so designated, and therefore these portions of the proposal are limited to implementing affirmative action for the minority groups designated under FASA.

While women-owned firms, per se, are not eligible for the price and evaluation credit program enacted by FASA or 10 U.S.C. 2323, there are other avenues by which the federal government tries to ensure that women-owned firms have an equal opportunity to compete for and win federal contract dollars. The Small Business Act requires agencies to set annual goals for participation in contracting by women-owned firms. Women-owned firms may be certified under the 8(a) program by demonstrating to the SBA that the firm is owned and operated by a woman or women, and that the individual women who operate the firm have suffered social and economic disadvantage similar to that suffered by members of minority groups. The *Adarand* decision

applies strict scrutiny to actions of the federal government that use race. Actions taken with respect to gender, however, are scrutinized by a lesser standard of review, and thus the same requirements we propose to ensure that race-conscious programs are narrowly tailored should not necessarily also apply to programs for women.

C. Compelling Interest for the Use of Race-Conscious Measures

A few comments questioned the federal government's ability to use race-conscious action in procurement. Those comments stated that there was an insufficient record of discrimination by the government in procurement to support race-conscious activity.

When the proposal was published in the **Federal Register**, it was accompanied by an appendix titled ''The Compelling Interest for Affirmative Action in Federal Procurement: A Preliminary Survey.'' 61 FR 26050. That report documented the effects public and private discrimination has had on business formation and development, and the way discrimination has hindered the ability of minority-owned firms to compete for and win federal contracts. The report demonstrated that race-conscious means are still necessary to ensure that minority-owned firms have the ability to compete fairly for federal procurement dollars.

Subsequently, the Urban Institute published ''Do Minority-Owned Businesses Get A Fair Share Of Government Contracts,'' its survey of the results of numerous state and local disparity studies. The Urban Institute found generally that ''minority-owned businesses receive far fewer government contract dollars than would be expected based on their availability,'' and made extensive findings similar to those published in the **Federal Register**. The appendix to the procurement reform proposal, and the Urban Institute's study, demonstrated that a compelling interest warranting race-conscious efforts in federal procurement remains.

Mark L. Gross,

Deputy Chief, Appellate Section, Civil Rights Division.

[FR Doc. 97–12190 Filed 5–8–97; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF JUSTICE

Antritrust Divsion

United States v. Jeff Mulkey, et al., Civ No. 97–234 MA; Response of the United States to Public Comments Concerning the Proposed Consent Decree

Pursuant to Section 2(d) of the Antritrust Procedures and Penalties Act, 15 U.S.C. § 16(d), the United States publishes below the written comments received on the proposed Consent Decree in *United States* v. *Jeff Mulkey, et al.*, Civil Action No. 97–234 (MA), United States District Court for Oregon, together with its response thereto.

Copies of the written comments and the response are available for inspection and copying in Room 3235 of the Antitrust Division, United States Department of Justice, Tenth Street and Constitution Avenue, N.W., Washington, D.C. 20530 (telephone 202/514/2481) and for inspection at the Office of the Clerk of the United States District Court for the District of Oregon, United States Courthouse, Madison & Broadway, Portland, Oregon.

Rebecca P. Dick,

Deputy Director of Operations.

In the United States District Court for the District of Oregon

State of Oregon, *ex rel..*, Attorney General Hardy Myers State of Washington, *ex rel.*, Attorney General Christine O. Gregorie, State of California, *ex rel.*, Attorney General Daniel Lungren, United States of America, Plaintiffs, v. Jeff Mulkey, Jerry Hampel, Todd Whaley, Brad Pettinger, Joseph Speir, Thomas Timmer, Richard Sheldon, Dennis Sturgell, Allan Gann and Russell Smotherman, Defendants. Civil Action No. CV 97 234–MA United States' Response to Public Comments Filed: May, 1997.

I. Background

On February 11, 1997 the United States jointly filed with the states or Oregon, California and Washington a complaint to prevent and restrain the defendants from violating Section One of the Sherman Act (15 U.S.C. § 1). At the same time, a Stipulation was filed in which the parties agreed that the Consent Decree, lodged with the Court in conjunction with the filing of the Stipulation, may be filed and entered by the Court at any time after the expiration of the sixty (60) day period for public comment provided by the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16 (b)–(h). The sixty day public comment period terminated on April 25, 1997.

Under the Antitrust Procedures and Penalties Act notices were published in the **Federal Register** and the Portland Oregonian directing anyone who wished to comment on the Consent Decree to send their comments to the United States Department of Justice Antitrust Division's San Francisco Office. The Antitrust Division has received comments from the following:

1. Peter G. Heckes—Oysterville, Washington.
2. T.J. Lindbloom—Roseburg, Oregon.
3. Lyle Hartzell—Westlake, Oregon.
4. Dorothy Nicholson—Florence, Oregon.
5. Rita J. Sellers—Reedsport, Oregon.
6. Katy Ellis—Roseburg, Oregon.
7. Debbie Coffman—Eugene, Oregon.
8. Travis Wolf—Florence, Oregon.
9. Bill Bradbury—Bandon, Oregon.
10. Jim Edson—South Beach, Oregon.
11. Nick Furman—Coos Bay, Oregon.

The United States Department of Justice's Antitrust Division has carefully reviewed the comments from the above individuals and has prepared this response to address issues raised in those comments.

II. Response to Public Comments

The Comments fall into two principal categories: (1) There was insufficient evidence to support the allegations in the Complaint; and (2) it was not fair for the plaintiffs to name only the defendants in this matter since there were hundreds of other fishermen who participated in the alleged tie-up and this type of conduct has long been commonplace in the industry. The comments criticize the actions and behavior of the plaintiffs in bringing this case. None of the comments discuss the terms or impacts of the decree and, thus, do not discuss whether entry of the Consent Decree is in the public interest. Collectively, they indicate that commercial crab fishermen have violated the antitrust laws for more than just the charged 1995–96 season. In short, they support, rather than attack, a finding that entry of the Consent Decree is in the public interest.

The comments reflect in part a misunderstanding of the antitrust laws and the limited exemptions granted fishermen from the antitrust laws by the Fishermen's Collective Marketing Act (''FCMA'') (15 U.S.C. §§ 521–522). As pointed out in the Competitive Impact Statement filed in this matter, the FCMA provides protection from the antitrust laws only if fishermen jointly make marketing decisions as members of a fish marketing association formed pursuant to the terms of the FCMA. The FCMA does not protect fishermen who are not members of a fish marketing association and it does not protect fish marketing association members who

enter into marketing agreements with non-members.

The comments also demonstrate a lack of appreciation for the reasons we as a nation have adopted and enforce antitrust laws. When sellers work collectively, they can raise their prices to artificially high levels. Above-market prices inevitably reduce overall production, restricting the nation's output of goods and services; on a more personal level, they can directly harm individual consumers. These harms are sufficiently serious that price agreements among sellers are usually punished criminally. Our economic strength, which ultimately benefits us all, results in no small measure from our consistent refusal to tolerate price-fixing in any sector of the economy.

The Complaint alleges and the plaintiffs were prepared to prove at trial that the defendants entered into agreements to market crab and either were not members of a fish marketing association that had authority to market their crab or, if they were members of such an association, entered into agreements with non-members to market crab. In addition, they used threats, coercion and intimidation to enforce the agreements. Such agreements and conduct are not protected by the FCMA and are violations of Section One of the Sherman Act. As noted, the United States Department of Justice normally prosecutes conduct of this type criminally. The United States chose not to proceed criminally in this matter because some of the defendants mistakenly believed that their conduct was not a violation of the Sherman Act.

The United States joined this action in order to give notice that the defendants' alleged conduct is not permitted under federal law. The United States attempted to deter such conduct in the early 1980's when it filed civil actions and obtained entry of Consent Decrees against two northwest fish marketing associations in *United States* v. *All Coast Fisherman's Marketing Association, Inc.*, Civ. #82–233 (Oregon 1982) and *United States* v. *Del Norte Fishermen's Marketing Association, Inc.*, Civ. #82–3355 (N.D. Calif. 1984). Under the terms of those Consent Decrees the defendant associations held meetings in Crescent City, California and Charleston, Oregon, attended by their members and other interested fishermen, at which attorneys explained the applicability of federal antitrust laws to the marketing of seafood by commercial fishermen.

The United States hopes that by bringing this action against individual fishermen, it will succeed in accomplishing what those actions sought to accomplish—deterring illegal conduct in the future. The Consent Decree provides the defendants, as well as all the other fishermen that may have participated in illegal marketing agreements with them, with a guide as to what is not permissible under the Sherman Act. It is hoped that in the future any defendants and other fishermen who wish to jointly market their crab will take steps to determine how they can do so legally.

III. Conclusion

The conduct alleged in the Complaint violates the Sherman Act. The Consent Decree was proposed and agreed to in order to deter such conduct in the future and ensure compliance with the law. It helps to ensure price competition among commercial crab fishermen. None of the comments have addressed the terms of the Consent Decree or demonstrated that its entry is not in the public interest. Thus, entry of the Consent Decree is in the public interest.

Dated: May , 1997.

Respectfully Submitted,

Christopher S. Crook,

Richard B. Cohen,

Attorneys, Antitrust Division, U.S. Department of Justice.

March 16, 1997.

Mr. Christopher Crook, Acting Chief, U.S. Department of Justice Anti-Trust Division, Box 36046, 450 Golden Gate Ave., San Francisco, CA 94102.

Dear Mr. Cook: As one who's involvement in Oregon's crab industry dates back to 1975 when I first set foot on a crab boat as a college student working to cover tuition costs, I find both the official ''spin'' and accompanying media coverage of the anti-trust investigation and pending cases quite disturbing. If a person were to take all that has been written and reported on the subject at face value, it would lead them to believe that those targeted individuals are the commercial fishing industry's equivalent of ''mafioso's'' and close relatives of the Gotti family.

To imply that twelve individuals ''illegally conspired'', ''coerced'', ''intimidated'' and ''threatened'', using ''strong-armed tactics'' and ''violence'' to ''fix prices'' and hold the entire West Coast crab industry hostage, is grossly unfair and fails to take into consideration that the historical nature of the fishery and dynamics involved. To conclude that these twelve individuals alone had enough influence to keep upwards of 1000 fishermen and their vessels tied to the dock in fear of reprisal is simply ludicrous.

In short, the ''tie-up'' at the start of the 1995/96 crab season (legal or otherwise from an anti-trust standpoint) was a direct result of excessive frozen inventories and prevailing market conditions, and not the conspiratorial actions of anyone, fisherman or otherwise. Right or wrong, the process of crabbers collectively establishing an ''asking price'' prior to setting their gear, with buyers responding accordingly, has been going on for decades and actually helps to bring a certain amount of stability and order to a situation that can by nature, be intensely chaotic. Once fishing has commenced, stock abundance and consumer demand ultimately determine whether the starting price will hold, increase, or even drop as it has in some years.

Crabbers coast wide have always held these pre-season meetings publicly and in broad daylight, with no attempt to ''plot secretly'' as Webster's definition of conspiracy and the accusations associated with this case would suggest. On the contrary, all one has to do is go back and read the early December issues of any of the coastal newspapers during times of ''soft'' markets, to find reported accounts of meetings, conference calls, price impasses, and yes, even strikes. One can only wonder why, after all these years, is this process suddenly deemed worthy of the scrutiny and attention it has recently received, to the detriment of the entire industry.

In conclusion, let me say that violent acts associated with any activity should be vigorously investigated and prosecuted accordingly. It's unfortunate that in this case, it is the anti-trust laws that are being vigorously applied to a situation that resulted from an entire industry's lack of a clear understanding of those laws as they related to their collective activity.

Sincerely,

Nick Furman,

P.O. Box 403, Coos Bay, OR 97420.

Note: Newspaper and magazine article notices have not been reprinted here, however they may be inspected in Room 3229, Department of Justice, Washington, DC and at the Office of the Clerk of the United States District Court for the District of Oregon.

March 21, 1997.

Jim Edson, P.O. Box 518, South Beach, OR 97366.

Christopher S. Crook, U.S. Department of Justice, 450 Golden Gate Ave, Box 36046, San Francisco, CA 94102.

Dear Mr. Cook: I am outraged at what is happening to the crabbing industry. Thanks to the Justice Departments, we crab fishermen will no longer be able to negotiate a fair price for crab. The charges that were brought against the infamous 12 fisherman were very unnecessary and the fact that they were threatened and intimidated into paying for something they did not do is criminal. The Oregon Dept. of Justice has handled this investigation in a very despicable manner and we want these charges dropped against all these men.

The Attorney Generals Office recently investigated the crab industry on charges of price fixing and coercion. Apparently, they found that 12 out of over 400 crab fishermen were involved.

Actually, all 400+ fishermen were equally guilty of all trying to negotiate a fair price.

Now, the AG's Office is allowing the 12 villains to pick up the tab for their botched inquiry.

Since the A.G. doesn't have a clue to who the bad guys are, it might be wise to diagnose the problem. Maybe there are no bad guys, just problems.

Fortunately for all of us, 2 of the villains, Scott and Charlie have enough wherewithal and fortitude to challenge these bogus charges.

There is something very wrong in a system that would punish qualities such as honesty, integrity, and hard work, All qualities I have personally observed in Charlie Schuttpelz and Scott Hartzell.

Jim Edson,

Commercial Fisherman, South Beach, OR, 541–867–3107.

Bill Bradbury, P.O. Box 1499, Bandon, Oregon 97411, 541–347–9377.

Mr. Christopher S. Crook, Acting Chief, U.S. Department of Justice Anti-trust Division, Box 36046, 450 Golden Gate Ave, San Francisco, CA 94102.

Re: Consent Decree regarding Commercial Crab Fleet

Dear Mr. Crook: From 1980 until 1995, I represented the South Coast of Oregon in the Oregon Legislature, serving as a State Representative and State Senator. During my tenure I became quite familiar with the operations and challenges of the commercial fishing industry of Oregon.

When I learned that 12 crab fishermen had been selected to bear responsibility for the delay in the 1995–96 crab season, I was outraged.

My outrage stems from the following. First, the practice of delaying the season until a price is established between the fishermen and the processors has been going on for over 30 years. Second, during the delay, the processors were either not buying crab or they offered a price below the fishermen's cost. The facts of this case could easily be interpreted as a ''lock out'' by the processors, not a ''tie up'' by the fishermen. Third, over 95% of the vessels on the coast did not go fishing; to select out 12 people for doing what 300 other fishermen also did seems grossly unfair.

The state may characterize the ones selected as the leaders, however, more prominent leaders, especially in Newport where a coast wide meeting was organized and held, were not named in this case. The only common characteristic of the fishermen selected is that they catch a lot of crab.

I request that you question closely the advisability of entry of a consent decree that is unfairly selective of the defendants, is widely perceived as unfair and that ignores the liability of the processors in creating the situation in which the fishermen found themselves.

My best,

Bill Bradbury.

March 19, 1997.

Christopher S. Crook, Acting Chief, U.S. Department of Justice Antitrust Div., San Francisco, Ca 94102.

Dear Sir: In regard to the ten crab fishermen who have been charged by the Oregon Attorney General's Office with price fixing and who have agreed to pay a $9,100 fine and sign a consent decree. As you may know, Oregon's anti-trust laws are more stringent than Washington, California and the Federal Government's. There is a bill before the senate sponsored by Rep. Terry Thompson, Newport (HB 2659) that would exempt Fishermen's marketing and trade association's from Oregon's anti-trust laws. This would put Oregon in line with Washington, California and the Federal Government. If this passes and the Oregon Attorney General has stated he will not oppose it, than the charges brought against the crab fishermen would not be illegal and all charges should be dropped.

I am sending a copy of notes from the chairman of the Oregon Crab Commodity Commission about his meetings and discussions in 1994 with the Oregon Assistant Attorney General Andrew Aubertine. It looks as if he was just waiting for an opportunity to bring charges against the top producers in the industry. Most if not all of the crabbers charged are members of marketing associations. Please give this your serious consideration.

Sincerely,

Travis Wolf,

88359 Hwy 101 N, Florence, Or 97439.

Nick Furman's Notes Regarding Meetings with Aubertine

Summary of Initial Contact/meeting With A. Aubertine—AG's Office Oct.–Nov. 1994

10/12/94—Received call from Port Orford-area crabber with question—Can/how can fishermen legally negotiate/establish ex-vessel price with processors in a timely and orderly fashion prior to the start of the season? Responded that I would check with an attorney available to ODCC through AG's office, and get back with an answer.

10/13—Was discussing an assessment-related collections issue with Dan Rosenhouse (AG's office) on behalf of the ODCC, and posed the fisherman's question to him. Dan said he wasn't comfortable providing an answer on that type of issue, but he would contact a colleague in Salem who might be better versed with that aspect of the law.

10/17—Received a call from Andy Aubertine from the AG's office. Stated that he wanted to set up meeting in Salem to discuss issue further. Asked about the ODCC's role in preseason price process. Explained role as a Commodity Commission, stating that we produced an informational market summary and disseminated to the industry. No additional role in process.

10/25—Aubertine called again, saying that ''Dept. of Justice was on-board, and that they had a 'game plan'.'' Wanted to meet on 11/3 in Salem with his superiors.

10/26—Aubertine called to confirm meeting and informed me to bring ODCC documents (i.e. minutes, market reports).

10/31—Aubertine called again and scheduled the meeting for the 2nd.

11/2—Salem: Met with Aubertine and subordinate at 3 pm. in his office. Immediately made to feel uncomfortable by his demeanor and authoritative style. Was obviously on a ''fishing expedition'' and had no interest in responding to my initial question. Asked a lot of questions about the industry in an attempt to play ''catch-up''. Was curious about the role of Eureka FMA and had never heard about All Coast FMA. Summarized law by saying that only legal way to establish price was ''one on one'' between fisherman and processor. Didn't know the process of establishing a legal entity such as an association, and wasn't in a position to offer free legal advise. Couldn't help industry with problem and suggested that fishermen hire a lawyer to answer question in more detail. Stated that Ag's role was that of enforcement. Indicated that he would summarize our conversation in writing, for a fee, if he received a written request. Time is billed at $78/hr and $28/hr for an attorney and assistant, accordingly.

Summary: Decided that any further contact with this individual would be pointless and a waste of the Commission's money. Had no authority to go any further with this issue.

March 12, 1997.

Debbie Coffman, 35807 Willama Vista, Eugene, OR 97455, (541) 746–4760.

Christopher Crook, U.S. Department of Justice, Box 36046, San Francisco, CA 94102.

Dear Mr. Crook: I am writing to you in regard to the unconstitutional treatment that has been imposed on 12 coastal fishermen. I have read numerous articles and letters that have been directed toward the Attorney General's Office. I am sickened at how corrupt our government has become and even more disheartened that Hardy Meyers has not stood up and supported the fishermen that have been threatened, coerced, and intimidated by the Justice Department.

Andrew Aubertine has violated these fishermen's rights. Farmers and fishermen are among the hardest working people in the business community. Their products are so perishable, marketing them has to be done in advance, not when they have a boat load of crab, and a unpredictable market. Their largest threat is ''Mother Nature''. Storms and unpredictable weather were their worst nightmare until the Attorney Generals Office decided to take down the crab industry.

How is it that they have selected these ''12'' fishermen? Who are the fishermen that originally called in this complaint? Are they honorable men worthy of trust? Has their background been investigated? Out of hundreds and hundreds of fishermen, what criteria did they use to select the 12 fishermen that have been targeted? Ability to pay is what I have heard. The men that have paid the settlement of $9,100. Paid because they were afraid that litigation would cost them their livelihood and devastate their families. They only settled because they were threaten to do so by the A.G.'s Office. They were not guilty of anything. They were not even charged. They were railroaded, pure and simple.

I have lived in a coastal community for years, so I can speak from experience when I say that fishermen are the most honest hardworking people in America. Every time that they head out to sea, they risk their lives. I believe if this injustice is not stopped, the State of Oregon will be subject to a huge class action lawsuit from the whole fishing fleet for damages to the whole crabbing industry.

These fishermen's civil rights have been violated and as a concerned citizen I ask you to please look into this investigation. I believe the Justice Department is guilty of numerous violations, threats, coercion, intimidation, and the most terrifying is *extortion!*

Sincerely,

Debbie Coffman.

March 13, 1997.

Christopher S. Crook, U.S. Department of Justice, Box 36046, San Francisco, CA 94102.

re: crab fisherman

Dear Mr. Crook: The Attorney General didn't know which end the crab snaps until he attacked innocent Crab fishermen. Now he can expect to get pinched himself for his unprofessional conduct, threats, coercion, intimidation, and extortion. Their office doesn't have a clue to how the industry operates and can't grasp the fact that supply and demand controls the market, NOT THE ATTORNEY GENERAL! He is leaving a trail of more innocent victims up and down the coast suffering from harassment and threats in order for the department to settle their trumped up cases. Our tax dollars in action being wasted.

In 1994 Aubertine was asked by the Crab Commission, ''How can fishermen legally negotiate a price for crab?'' Aubertine stated, ''I am in the enforcement division.'' Instead of working with the crab commission and the fishermen, Aubertine decided to take down the whole crabbing industry. He claims the fishermen he has charged with price fixing, had hurt the economy and damaged the consumer in Oregon, Washington, and California, quite a feat for 12 independent crab fishermen out of 1,367 from all three states. The time in question, 1995/96 season, crab was plentiful and very reasonable to the consumer, there were millions of pounds of crab in cold storage.

How can the Attorney General decide when and at what risk these fishermen should take, endangering their lives to harvest crab. It is their right to tie up their boats when ever, and for what ever reason they choose. If they choose not to join associations, like the A.G.'s office is coercing them to do, it is there right. Never should association's have more rights than an individual.

It is time for the Attorney General Office to admit the witch hunt is over and get back to work.

I would like to see all these charges dropped against these fishermen as the Justice Department has violated these fishermen's civil rights as well as denying them due process of the law and used extortion, threats, and intimidation to coerce them to settle when they claim innocence.

Sincerely,

Katy Ellis

P.O. Box 87, Roseburg, OR 97470.

Chrispopher Crook, Acting Chief, San Francisco Office, Anti-trust Division, Department of Justice, San Francisco, CA 94102.

Dear Sir: I am writing to you concerning the alleged price fixing by The West Coast Commercial Crab Fishermen. My interest has risen daily from reading the many public editorials and watchdogs newspaper accounts. Somehow I don't think the Oregon Attorney General's Office is doing justice, the more information I receive.

First of all I would like to know how the Fishermen were price fixing crab at $1.25#, when their fellow West Coast Crabbers were getting the same price or more during the time frame in question. Please check these facts for yourself, Central California Dec. 1995 crab price was $1.50#, Puget Sound Washington Dec. 1995 price was $1.25, British Columbia late fall 1995 price was $1.40 U.S. and Washington tribal price Dec. 1995 was $1.25#.

The only thing I could find illegal so far from the alleged boycott, was the apparent sabotage of a delivery truck in Brookings, Or. If this incident really happened then someone should have been criminally charged. As far as I know no one has been.

Now the Oregon Department of Justice is saying this investigation has cost hundreds of thousands of dollars. I ask myself is this taxpayers money well spent. After just reading that Lawrence Singleton struck again and O.J. Simpson purchased a mansion in Florida perhaps there is more injustice than justice in our legal system.

The message that I am getting from the newspaper articles is that perhaps Oregon Assistant Attorney General Andrew Aubertine would have fit better in another era. Seem's to me that I have read about his type before, during the Roman's persecution of the Christians and the 17th century witch hunts.

In closing I would like to ask that the U.S. Department of Justice immediately dismiss this case, and then see that Andrew Aubertine is reprimanded for his vindictive investigation of independent fishermen.

The current price paid to the fishermen for dungeness crab is $2.50 a pound. I don't think it takes a rocket scientist to figure out that supply and demand control the market.

Sincerely,

Dorothy Nicholson,

1525 West 20th, Florence, OR 97439, Ph. 541–997–3149.

March 6, 1997.

Christopher Crook, Acting Chief, San Francisco Office, Anti-trust Division, Department of Justice, San Francisco, CA 94102.

Dear Sir: The charges of price fixing by the commercial Crabbers seems to me to be an uncalled for attack on a few hard working fishermen.

There are 1363 fisherman in Ore., Cal., and Washington. Why have only 12 of these men been singled out and accused? Could 12 men have possibly stopped all of these fisherman from taking their boats out during the 1995–96 crabbing season? I think not.

Ten of these men have agreed to pay the fines imposed on them in order to avoid further harassment by the Attorney Generals office. Scott Hartzell and Charley Schuttpelz have refused to pay off and admit guilt for something they are not guilty of.

Almost every year in my memory, the fishermen and the processors have haggled over what a fair price for crabs should be. After a few days a price is set by the processors and the Crabbers go out to risk life and limb to bring in the crabs, and hopefully made a decent living at it.

Why should these fisherman have to pay fines to pay the expenses incurred in a lawsuit that never should have been started?

Perhaps the people in the Attorney Generals office that stared this investigation should have to dig into their own pocket and pay for their own mistakes. Unfortunately, it will be paid for by we, the taxpayers.

Sincerely,

Rita J. Sellars,

908 Fir Ave., Reedsport, Ore. 97467.

March 1, 1997.

Christopher Crook, Acting Chief Anti-trust Div., U.S. Depart. Of Justice, San Francisco, California.

Dear Sir: The Oregon Department of Justice led by Assistant Attorney General Andrew Aubertine has conducted a witch hunt investigation of crabbers. Apparently once he started he felt he could not stop until he made some pay for his investigation. He has coerced and intimidated the fisherman he has interviewed. The statements that have come out of the Oregon Attorney Generals office by spokeswoman Jan Margosian have always said more fishermen may be charged. With this hanging over their heads and leading questions some fishermen have been coerced into saying what Mr. Aubertine and his other investigators wanted to hear. The Oregon Department of Justice has made a mountain out of a molehill. This whole miscarriage of justice by an over-zealous assistant attorney general should be dropped. The ten fishermen who have signed the consent decree and paid the fines, did so not because they had done anything wrong but because of the huge attorney fee's they would be faced with.

Sincerely,

Lyle Hartzell

05821 Canary Rd, Westlake, Or 97493.

February 19, 1997.

Box 27, Oysterville, WA, 98641.

Cristopher S. Crook, Acting Chief, San Francisco Office, U.S. Dept. of Justice, Antitrust Div., Box 36046, Golden Gate Ave., San Francisco, Calif., 94202.

Dear Mr. Crook: It has been very disturbing to follow the escapades of Assistant Attorney General Aubertine in his attempts to terrorize the west coast crab fleet by trying to hang price fixing charges on key members of the industry. If you were to examine the men he singled out, you would find that they are mainly guilty of being able to pay these outrageous fines—with income other than that of crab fishing, which has been dismal this season.

It is obvious the A.G.'s office did not want these cases to go to trial. Could it be lack of evidence? Immediately after these fines were levied it was made abundantly clear that to fight these charges could be very, very expensive. If found guilty, not only would the fishermen have to pay the fines, their lawyers, but also the expenses of the A.G.'s office. This could easily amount to over ten

times the cost of the fine. Even with a better than a 50% chance of winning the case, the odds were so stacked against the fishermen most of them simply signed off. With such a skewered system of justice who could predict what might happen.

Although I haven't crabbed for several years, I have been involved in the commercial fishing industry all my life. To ask a fisherman not to talk about the price they expect to receive for their catch is like asking freshmen highschool girls not to talk about boys. Fishermen talking about price is a normal, natural American thing to do.

Violence, intimidation and destruction of property to achieve price goals is a different matter. Seems to me if any of this could be proven real criminal charges should be filed—not phoney fines with no realistic way of challenging them.

I contend that Mr. Aubertine, being fairly young, politically ambitious and not too bright, spent a lot of state money on his price fixing investigation in hopes of furthering his political career. When the investigation came up short of hard evidence he took the easy way out. He tried to recoup the money he had wasted by singling out members of the industry by their ability to pay rather than other reasons. He did it in such a way they had no chance to defend themselves.

The solution is simple. If Mr. Aubertine has real evidence of price fixing he should come forward with this evidence and file charges. If he doesn't have this evidence he should accept the responsibility of wasting the state's money and face the consequences. This would include public apology to the men he wronged and immediate disbarment proceedings.

Sincerely,

Peter G. Heckes,

Heckes Oyster Co.

Oregon Crabbers Fight To Stay Afloat

The two Oregon Crab Fishermen that have been charged with price fixing must be mighty powerful forces to have done what they are accused of. I have read the articles and editorials that have been published, and have spoken with each of these fishermen.

It would appear from everything I have heard and seen that the Department of Justice has used threats, coercion, and intimidation to get these hard working, self employed fishermen to sign statements saying that they are guilty when in fact they are not. Most of these individuals simply could not afford to fight the Attorney General on matters they didn't understand. Faced with fines of over $100,000.00 and loss of their commercial fishing license (their very livelihood) they simply caved in to the pressure, payed the $9,000.00 ''settlement'' and went back to work.

It sure is odd that the Department of Justice alleges that meetings were held to organize and enforce the conspiracy to fix prices at $1.25 per pound when in fact they went fishing for $1.15 per pound, (which all the major fish plants were offering). If this is price fixing then it sure went the wrong way! It would seem that the rule of supply and demand set the prices. I should remind everyone that since the dawn of time fishermen have had to negotiate the best price they can for their product.

The State Attorney General Office said the lawsuit was filed after several months of negotiations failed to produce a settlement. What it should have said is they failed to produce a settlement after the threats, intimidation and coercion didn't work. The Assistant Attorney General, Andrew E. Aubertine, told these fishermen that they would pay for this investigation, and the ones who pay last will pay the most! I for one was unaware that this was the way our elected officials conducted investigations. Now, you tell me, who is guilty of coercion, threats, extortion, and intimidation. Is it the hard working fishermen, or the overzealous A.G.?

T.J. Lindbloom,

Roseburg, Oregon, 541–673–6047.

[FR Doc. 97–11939 Filed 5–8–97; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

May 6, 1997.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (P.L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor, Departmental Clearance Officer, Theresa M. O'Malley ({202} 219–5096 ext. 143). Individuals who use a telecommunications device for the deaf (TTY/TDD) may call {202} 219–4720 between 1:00 p.m. and 4:00 p.m. Eastern time, Monday through Friday.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment Standards Administration, Office of Management and Budget, Room 10235, Washington, DC 20503 (202) 395–7316, within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment Standards Administration.

Title: Airline Vacancy Listing.

OMB Number: 1214–0004 (extension).

Frequency: Semi-Annually.

Affected Public: Business or other for-profit.

Number of Respondents: 223.

Estimated Time Per Respondent: 15 minutes.

Total Burden Hours: 310.

Total Annualized capital/startup costs: 0.

Total annual costs (operating/maintaining systems or purchasing services): 0.

Description: The Airline Deregulation Act requires the Secretary of Labor to establish a program to implement the first-right-of-hire provision of the legislation (29 CFR part 22 0) to ensure that furloughed, protected employees may exercise their Statutory rights. This Act provides a mechanism for the monitoring hiring activity in the airline industry. Section 43(d)(2) of the regulations provides that covered air carriers shall report their permanent job vacancies as they occur, to a central job center, for the preparation of a comprehensive list of jobs in the industry that is distributed to all State Employment Agencies.

Agency: Employment Standards Administration.

Title: Notice of Final Payment or Suspension of Compensation Benefits.

OMB Number: 1215–0024 (extension).

Frequency: On occasion.

Affected Public: Business or other for-profit.

Number of Responses: 28,000.

Estimated Time Per Respondent: 15 minutes.

Total Burden Hours: 7,000.

Total Annualized capital/startup costs: 0.

Total annual costs (operating/maintaining systems or purchasing services): $7,000.

Description: This report is used by insurance carriers and self-insured employers to report the payment of benefits under the Longshore and Harbor Workers' Compensation Act.

Agency: Employment Standards Administration.

Title: Request for Earnings Information.

OMB Number: 1215–0112 (extension).

Frequency: On occasion.

Affected Public: Individuals or households.

Number of Respondents: 1,900.

Estimated Time Per Respondent: 15 minutes.

Total Burden Hours: 475.

Total Annualize capital/startup costs: 0.

Total annual costs (operating/maintaining systems or purchasing services): $7,000.

Description: This report gathers information regarding an employee's average weekly wage. This information is needed for determination of compensation benefits in accordance with Section 10 of the Longshore and Harbor Worker's Compensation Act.

Theresa M. O'Malley,

Departmental Clearance Officer.

[FR Doc. 97–12166 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Office of the Secretary

Bureau of International Labor Affairs; Public Hearings on Forced Labor in Burma

This document is a notice of public hearings to be held by the Department of Labor for the purpose of gathering information regarding the use of forced labor in Burma. The hearing will be held on June 27, 1997, at the Department of Labor, 200 Constitution Avenue, NW, N–3437 D, Washington, DC 20210, beginning at 9:00 a.m. The hearing will be open to the public. The Department of Labor is now accepting requests to provide oral or written testimony at the hearing from all interested parties. Each presentation will be limited to ten minutes. The Department is not able to provide financial assistance to those wishing to travel to attend the hearing. Those unable to attend the hearing are invited to submit written testimony. Parties interested in testifying at the hearing on forced labor in Burma should call Joan Mackin Barrett (202) 219–7471, ext. 105, to be put on the roster.

On March 27, 1997, the Governing Body of the International Labor Organization (ILO) established, pursuant to Article 26 of the ILO Constitution, a Constitution, a Commission of Inquiry to investigate a complaint by worker delegates to the 1996 ILO Conference about the existence of forced labor in Burma. The complaint alleges that the Government of Burma has repeatedly failed to abolish legislation which allows for the use of forced labor, and, far from ensuring that forced labor is eliminated in practice, that the Government has been actively engaged in its promotion. Specific allegations include the forced recruitment and abuse of porters by the military, as well as the use of forced laborers on railway, road, construction, and other infrastructure projects. The complaint charges that the SLORC government is directly responsible for an endemic abuse affecting hundreds of thousands of workers who are subjected to the most extreme forms of exploitation, including all too frequently loss of life.

The Commission of Inquiry is the ILO's most formal, prestigious, public and extensive procedure for the supervision of international labor standards. The ILO Constitution requires member States to provide to Commissions of Inquiry all relevant information in their possession. Thus, information obtained at the hearing will be provided to the ILO's Commission of Inquiry on Forced Labor in Burma. Testimony should be confined to the topic of forced labor in Burma.

DATES: The hearing is scheduled for Friday, June 27, 1997. The deadline for being placed on the roster for oral testimony is 5:00 p.m. on Friday June 20, 1997. Presenters will be required to submit five (5) written copies of their oral testimony to the Office of International Organizations, Bureau of International Labor Affairs, by 5:00 p.m., Wednesday, June 25, 1997. The record will be kept open for additional written testimony until 5:00 p.m., Monday, July 7, 1997.

ADDRESSES: The hearing will be held at the Department of Labor Auditorium, 200 Constitution Avenue, NW, Washington, DC. Written testimony should be addressed to the Office of International Organizations, Bureau of International Labor Affairs, Room S–5311, U.S. Department of Labor, Washington, DC 20210; fax (202) 219–9074.

FOR FURTHER INFORMATION CONTACT: Joan Mackin Barrett, Office of International Organizations, Bureau of International Labor Affairs, Room S–5311, U.S. Department of Labor, Washington, D.C., 20210; telephone: (202) 219–6241, ext. 105; fax: (202) 219–9074. Persons with disabilities who need special accommodations should contact Joan Mackin Barrett by Monday, June 23, 1997.

All written or oral comments submitted pursuant to the public hearing will be made part of the U.S. submission to the ILO referred to above and will be available for public inspection.

Signed at Washington, DC, this 2nd day of May 1997.

Andrew J. Samet,

Acting Deputy Under Secretary, International Affairs.

[FR Doc. 97–12230 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–28–M

DEPARTMENT OF LABOR

Labor Advisory Committee for Trade Negotiations and Trade Policy; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463 as amended), notice is hereby give of a meeting of the Steering Subcommittee of the Labor Advisory Committee for Trade Negotiations and Trade Policy.

Date, time and place: May 28, 1997, 10:00 a.m., U.S. Department of Labor, Room S–1011, 200 Constitution Ave., NW., Washington, DC 20210.

Purpose: The meeting will include a review and discussion of current issues which influence U.S. trade policy. Potential U.S. negotiating objectives and bargaining positions in current and anticipated trade negotiations will be discussed. Pursuant to section 9(B) of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(9)(B) it has been determined that the meeting will be concerned with matters the disclosure of which would seriously compromise the Government's negotiating objectives or bargaining positions. Accordingly, the meeting will be closed to the public.

For further information, contact: Jorge Perez-Lopez, Director, Office of International Economic Affairs; Phone: (202) 219–7597).

Signed at Washington, DC this 2nd day of May 1997.

Andrew J. Samet,

Acting Deputy Under Secretary International Affairs.

[FR Doc. 97–12229 Filed 5–8 –97; 8:45 am]

BILLING CODE 4510–28–M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents

summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of April, 1997.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–33,233; The Earthgrains Co., Indianapolis, IN

TA–W–33,259; Owens Brockway, Waco, TX

TA–W–33,102; Riverwood International Corp., Plant #72, Kankakee, IL

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

TA–W–33,148; ITT Canon Commercial Div., Santa Ana, CA

TA–W–33,277; Lucas Aftermarket Operations, Troy, MI

TA–W–33,139; Random House Value Publishing, Inc., Avenel, NJ

TA–W–33,157; Envisions, Inc., (Formerly Engineering Visions, Inc.) Harlingen, TN

TA–W–33,228; ANR Pipeline, Chickasha, OK

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–33,281; Sillcocks Plastics International & Sillcocks Miller Co., Berkeley Heights, NJ

Production at the subject firm is being transfered to a successor firm located in the United States. Separations of workers at the subject firm are caused by the transfer of production to the successor firm.

TA–W–33,347; Northern Engraving Corp., Sparta, WI

Production at the subject plant is being transfered to other production facilities located domestically. Separations of workers at Sparta, WI plant are the result of the domestic transfer.

TA–W–33,238; Arrow Automotive Industries, Inc., Santa Maria, CA

The subject firm ceased all of its production at the Santa Maria, CA plant and transferred it to other company plants within the United States.

TA–W–33,169; Lorraine Linens, Inc., Hialeah Gardens Div., Deerfield Beach, FL

TA–W–33,264; Jefferson Smurfit Corp., Industrial Packaging Div., Monroe, MI

TA–W–33,235; Hutchens Industries, Mountain Grove, MO

TA–W–33,321; Philips Lighting Co., Philips Elmet Div., Lewiston, ME

TA–W–33,404; Devoe & Raynolds Co., Louisville, KY

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–33,279; Johnson Controls, Inc., Ann Arbor Plant, Milwaukee, WI

Sales of power seat tracks for auto seats at the Ann Arbor plant of Johnson Controls increased in FY 96 compared to FY 95. Also, employment increased in FY 96 compared to FY 95.

TA–W–33,270; Binney and Smith, Inc., Winfield, KS

The parent company of Binney and Smith, Inc., made a corporate decision to transfer its production of crayons, markers, tempera paints and acrylic paints from its Winfield, KS facility to other domestic facilities.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name & location for each determination references the impact date for all workers for such determination.

TA–W–33,302; Westpoint Management (Jay Lynn) Westpoint, PA: February 27, 1996.

TA–W–33,225; Goodyear Tire and Rubber Co., Gadsden, AL: February 4, 1996.

TA–W–33,298; Great Western Malting Co., Vancouver, WA: February 3, 1996.

TA–W–33,234; Garan Manufacturing Corp., Haleyville, AL: January 12, 1996.

TA–W–33,145; Milltown Manufacturing Co., Red Boiling Spring, TN: January 17, 1996.

TA–W–33,243; SCA Molnlycke, Palmer, MA: February 11, 1996.

TA–W–33,261; Texas Instruments, Inc., Personal Productivity Products, Mobile Computing Business, Temple, TX: February 18, 1996.

TA–W–33,332 & A; Hazelhurst Textile, Hazelhurst, GA Homerville Textile Corp., Homerville, GA: March 5, 1996.

TA–W–33,304; Woodbridge Corp., Whitmore Lake, MI: February 25, 1996.

TA–W–33,340; Palermo Fashions, Inc., Hoboken, NJ: March 13, 1996.

TA–W–33,249; Triam Industries of Arizona, Tucson, AZ: February 10, 1996.

TA–W–33,372; Superior Solutions, Inc., El Paso, TX: March 18, 1996.

TA–W–33,293; Zenith Electronic Corp., N. Kostner Ave., Chicago, IL: March 5, 1996.

TA–W–33,369; Leigh Knits, Inc., Bean Station, TN: March 14, 1996. Ta–W–33,110; Sherwood, Davis and Geck, Danbury, CT: November 12, 1995.

TA–W–33,122; Grace Apparel, Galax, VA: January 10, 1996.

TA–W–33,280 & A, B; Guilford of Maine, Newport, ME, Guilford, ME (Oak Street) and Eastport, ME; February 13, 1996.

TA–W–33,278; Johnson and Johnson Medical, Inc., Arlington, TX: February 17, 1996.

TA–W–33,360; Thomson Consumer Electronics, Inc., Indianapolis, IN: March 17, 1996.

TA–W–33,333; Ranco North America Quality Control Department, Brownsville, TX: March 7, 1996.

TA–W–33,295; RMK, Solebury, PA: January 24, 1996. Attleboro,

TA–W–33,188; Carborundum Corp., Boron Nitride Div., Amhurst, NY: January 4, 1996.

TA–W–33,296; American West Trading Co., Dresden, TN: February 19, 1996.

TA–W–33,200 & A; Yokom Knitting Co., Pottstown, PA and Linden Knitwear, Mohrsville, PA: February 3, 1996.

TA–W–33,383; Osram Sylvania, Inc., Danvers, MA: March 18, 1996.

TA–W–33,356; Glasscraft, A Div. of V.V.P. America, Inc., Hickory, NC: March 13, 1996.

TA–W–33,165 & A Sunbeam Corp., Personal Care and Comfort Products Div., McMinnville, TN and Oster Professional Products Div., McMinnville, TN: January 22, 1996.

TA–W–33,395; Sans Souci Lingerie, PoplarBluff, MO: March 26, 1996.

TA–W–33,120; Philips Lighting Co., Fairmont, WV: January 6, 1996.

TA–W–33,210 & A; Singer Furniture Co., Lenior, NC: and Chocowinity, NC: February 4, 1996.

Also, pursuant to Title V of the North American Free Trade Agreement

Implementation Act (P.L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with Section 250(a) Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of April 1997.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of Section 250 of the Trade Act must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increase sin imports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers' separations. there was no shift in production from the subject firm to Canada or Mexico during the relevant period.

NAFTA–TAA–01582; Tugalo River Boxer Co., Toccoa, GA

NAFTA–TAA–01561; Northern Engraving Corp., Sparta, WI

NAFTA–TAA–01589; BOC Gases, Bethlehem, PA

NAFTA–TAA–01602; BASF Corp., Renesselaer, NY

NAFTA–TAA–01497; Lorraine Linens, Inc., Hialeah Gardens Div., Deerfield Beach, FL

NAFTA–TAA–01531; Johnson Controls, Inc., Ann Arbor Plant, Ann Arbor, MI

NAFTA–TAA–01500; Binney and Smith, Inc., Winfield, KS

NAFTA–TAA–01611; Arrow Automotive Industries, Santa Maria, CA

NAFTA–TAA–01450; CMI Industries, Inc., A.K.A. Clinton Mills, Lydia Plant, Clinton, SC

NAFTA–TAA–01522; Thomson Consumer Electronics, Inc., Audio and Communications Div., Syracuse, NY

NAFTA–TAA–01375; International Medication Systems, Ltd, South El Monte, CA

NAFTA–TAA–01554; Deluxe Corp., Deluxe Check Printers, New Berlin, WI

NAFTA–TAA–01505; Starter Corp., Century, FL

NAFTA–TAA–01535; Jefferson Smurfit Corp., Industrial Packaging Div., Monroe, MI

NAFTA–TAA–01520; Hutchens Industries, Mountain Grove, MO

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

NAFTA–TAA–01468; Envisions, Inc. (Formerly Engineering Visions, Inc), Harlingen, TX

NAFTA–TAA–01581; Nick-O Sewing Supply Co., Moscow, TN

NAFTA–TAA–01594; Administrative & Technical Services, Inc., Data Entry Services, Beloit, WI

The investigation revealed that the workers of the subject firm did not produce an article within the meaning of Section 250(a) of the Trade Act, as amended.

NAFTA–TAA–01462; Kunz Custom Upholstery, Montpelier, ID

A significant number or proportion of the workers in such workers' firm or an appropriate subdivision (including workers in any agricultural firm or appropriate subdivision) have not become totally or partially separated from employment.

NAFTA–TAA–01586; Kai Jay Pants Co., Nesquehoning, PA

Sales or production did not decline during the relevant period for certification.

Affirmative Determinations NAFTA–TAA

The following certifications have been issued; the date following the company name & location for each determination references the impact date for all workers for such determination.

NAFTA–TAA–01511; Sunbeam Corp., Professional Products Div., McMinnville, TN: February 10, 1996.

NAFTA–TAA–01433; Portac, Inc., Tacoma, WA: January 16, 1996.

NAFTA–TAA–01469; Medite Corp., Lumber Div., White City, OR: January 24, 1996.

NAFTA–TAA–01546; Louis Gallet, Inc., Uniontown, PA: March 3, 1996.

NAFTA–TAA–01481; Crewe Garment Co., Inc., Crewe, VA: February 5, 1996.

NAFTA–TAA–01515; Standard Products Co., Campbell Plastics Div., Schenectady, NY: February 7, 1996.

NAFTA–TAA–01504; Goodyear Tire and Rubber Co., Gadsden, AL: February 4, 1996.

NAFTA–TAA–01482 & A; Singer Furniture Co., Lenoir, NC and Chocowinity, NC: February 19, 1996.

NAFTA–TAA–01585; Superior Solutions, Inc., El Paso, TX: March 18, 1996.

NAFTA–TAA–01453; Carolina Knits, Inc., statesville, NC: January 27, 1996.

NAFTA–TAA–01576; Leigh Knits, Inc., Bean Station, TN: March 14, 1996.

NAFTA–TAA–01536; Anchor Glass Container Corp., Glass Containers Plant No. 18, Houston, TX: March 4, 1996.

NAFTA–TAA–01573; Thomson Consumer Electronics, Inc., Indianapolis, IN: March 19, 1996.

NAFTA–TAA–01583; V.V.P. America, Inc., Glasscraft Div., Hickory, NC: February 21, 1996.

NAFTA–TAA–01421; Sherwood, Davis, and Geck, Danbury, CT: November 12, 1995.

NAFTA–TAA–01593 & A; Al Tech Specialty Steel Corp., Dunkirk, NY and Watervliet, NY: March 22, 1996.

NAFTA–TAA–01607; The Colber Corp., Newark, NJ: April 8, 1996.

NAFTA–TAA–01580; Rubbermaid Cleaning and Maintenance Products, Sparks, NV: March 17, 1996.

NAFTA–TAA–01543; Anchor Glass Container, Connellsville, PA: March 4, 1996.

NAFTA–TAA–01566; Anchor Glass Container, Dayville, CT: March 13, 1996.

NAFTA–TAA–01610; Anchor Glass Container/Owens Brockways, Antioch, CA: March 18, 1996.

NAFTA–TAA–01551; Micom Communication Corp., A Northern Telecom (NORTEL) Co., Simi Valley, CA: February 11, 1996.

NAFTA–TAA–01457; Kahn Lucas Lancaster, Ferrells Garment Div., Middlesex, NC: January 21, 1996.

NAFTA–TAA–01503; SCA Molnlycke, Palmer, MA: February 11, 1996.

I hereby certify that the aforementioned determinations were issued during the month of April, 1997. Copies of these determinations are available for inspection in Room C–4318, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours

or will be mailed to persons who write to the above address.

Dated: April 30, 1997.

Russell T. Kile,

Program Manager, Policy & Reemployment Services Office of Trade Adjustment Assistance.

[FR Doc. 97–12225 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,127]

Character Suburbanwear, Incorporated, New York, New York; Notice of Revised Determination on Reconsideration

On March 27, 1997, the Department issued a Negative Determination Regarding Eligibility to Apply Worker Adjustment Assistance, applicable to all workers of Character Suburbanwear, Incorporated, located in New York, New York. The notice was published in the **Federal Register** on April 15, 1997 (62 FR 18361).

By the letter dated April 2, 1997, the union representative requested administrative reconsideration of the Department's findings.

The initial denial of TAA for the workers of Character Suburbanwear, Incorporated for Trade Adjustment Assistance was based on the fact that the workers were engaged in the merchandising of imported women's apparel and did not produce an article.

New findings on reconsideration show that the workers produced samples of ladies' sportswear. The workers sewed, cut and finished the samples. Other findings show that company will be closing at the end of April or May 1997.

U.S. aggregate imports of women's and girls' skirts increased absolutely in 1995 compared with the same period in 1994 and in the twelve months through September 1996 compared with the same period in 1995. Imports/shipments for women's skirts; blouses and shirts; and coats and jackets was over 120% 1994 and 1995.

Conclusion

After careful consideration of the new facts obtained on reconsideration, it is concluded that the workers of Character Suburbanwear, Incorporated, New York, New York were adversely affected by increased imports of articles like or directly competitive with ladies' sportswear contributed importantly to the declines in sales or production and to the total or partial separations of workers of Character Suburbanwear, Incorporated, New York, New York. In accordance with the provisions of the Act, I make the following certification:

All workers of Character Suburbanwear, Incorporated, New York, New York who became totally or partially separated from employment on or after January 7, 1996 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC this 18th day of April 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12218 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–32,009]

Chevron Overseas Petroleum, Inc., San Ramon, California; Notice of Negative Determination on Reconsideration on Remand

The United States Court of International Trade (USCIT) granted the Secretary of Labor's motion for a voluntary remand for further investigation in *Nelson* v. *Secretary of Labor,* No. 94–10–00630.

The Department's initial denial for the workers of Chevron Overseas Petroleum, Inc. (COPI), San Ramon, California, issued on March 25, 1996 and published in the **Federal Register** on April 9, 1996 (61 FR 45,711), was based on the fact that criterion (3) of the group eligibility requirements of Section 222 of the Trade Act of 1974, as amended, was not met.

The petitioners request for reconsideration resulted in a negative determination regarding the application which was issued on June 4, 1996 and published in the **Federal Register** on June 19, 1996 (61 FR 31,165). The Department's findings affirmed that the workers were not assigned to a domestic operating company producing oil and gas in the United States.

The petitioners identified the effected worker group as the New Ventures Business Unit of Chevron Overseas Petroleum, a division of Chevron U.S.A., Inc. During the initial TAA petition investigation the company reported that Chevron Overseas Petroleum is a division of Chevron U.S.A., Inc., which in turn is a wholly-owned subsidiary of Chevron Corporation.

On remand, the Department contacted the company official to clarify the link between the work performed by employees of the New Ventures Business Unit at the Chevron Overseas Petroleum division location in San Ramon and Chevron's domestic production of oil and gas. Findings show that the New Ventures Business Unit of COPI is a services based organization; technical staff dominate the employees of New Ventures Business Unit. Employees provide drilling, earth science, engineering and information technology support and services to COPI's overseas based Business Units. They provide no services for Chevron Corporation's domestic upstream affiliate.

Other findings on remand show that the customers of the New Ventures Business Unit of COPI are COPI's Business Units overseas. None of the work performed by employees of New Ventures Business Unit of COPI in San Ramon supported Chevron's domestic production of oil and gas.

Conclusion

After reconsideration on remand, I affirm the original notice of negative determination of eligibility to apply for adjustment assistance for workers and former workers of Chevron Overseas Petroleum, Inc., San Ramon, California.

Signed at Washington, D.C. this 1st day of May 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12222 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–32,557; TA–W–32,557D]

Cluett, Peabody and Company, Incorporated Atlanta, GA and Cluett, Peabody and Company, Incorporated New York, NY; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on August 9, 1996, applicable to all workers of Cluett, Peabody and Company, Incorporated located in Atlanta, Georgia, Albertsville, Alabama, Enterprise, Alabama and Austell, Georgia. The notice was published in

the **Federal Register** on September 9, 1996 (61 FR 48504).

At the request of the company, the Department reviewed the certification for workers of the subject firm. The workers were engaged in employment related to the production of men's dress and sport shirts. The findings show that workers separations have occurred at Cluett, Peabody and Company New York, New York locations. The workers provided management and support services for the manufacturing facilities of Cluett, Peabody and Company which are under existing certification.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports.

The amended notice applicable to TA–W–32,557 is hereby issued as follows:

All workers of Cluett, Peabody and Company, Incorporated, Atlanta, Georgia (TA–W–32,557) and New York, New York (TA–W–32,557D), who became totally or partially separated from employment on or after September 12, 1996, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C. this 28th day of April 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12223 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Program Manager of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not late than May 19, 1997.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than May 19, 1997.

The petitions filed in this case are available for inspection at the Office of the Program Manager, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 21st day of April 1997.

Russell T. Kile,

Program Manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

APPENDIX

[Petitions Instituted on 04/21/97]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
33,421	Exide Batteries (Wrks)	Frankfort, IN	04/11/97	Batteries.
33,422	REMA Bakeware (Wrks)	Salina, KS	04/07/97	Bakeware Items.
33,423	Mid Coast Marine (BBF)	Coos Bay, OR	04/07/97	Fishing and Commercial Ships.
33,424	Wellington Sears (Wrks)	Tarboro, NC	04/02/97	Fabrics.
33,425	Anchor Bay Corp (Comp)	Denver, CO	04/07/97	Crude Oil & Natural Gas.
33,426	Suckle Corp (IUE)	Scranton, PA	04/04/97	Metal Computer Frames & Components.
33,427	JH Collectibles (Wrks)	Pigeon Forge, TN	03/22/97	Selling Ladies' Ready Made Clothing.
33,428	Findlay Refractories Co (Wrks)	Washington, PA	04/02/97	Refractory Brick Blocks.
33,429	East Manufacturing Corp (IBT)	New Castle, PA	04/08/97	Flat Bed Trailers.
33,430	Bijur Lubricating Corp (UE)	Bennington, VT	03/27/97	Lubricating Equipment.
33,431	Nissan Motor Corp (Wrks)	Gardena, CA	03/21/97	Auto Marketing & Distribution.
33,432	Jos J. Pietrafesa Co (Wrks)	Sturgis, KY	03/24/97	Men's & Ladies' Trousers.
33,433	Northern Forest Products (Wrks)	Noxon, MT	04/11/97	Wooden Window Frames.
33,434	Margret Grace Millinery (Wrks)	Macungie, PA	04/08/97	Bridal Veils and Brides' Maids Hats.
33,435	Pioneer Electronic Tech (Wrks)	Pomona, CA	04/11/97	Television Speaker & Cabinet Assembly.

[FR Doc. 97–12226 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33, 194I]

Hasbro Manufacturing Services a/k/a Hasbro, Inc./Pant Ease Arcade, New York; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on March 11, 1997, applicable to all workers of Hasbro Manufacturing Services located in Arcade, New York. The notice was published in the **Federal Register** on March 31, 1997 (62 FR 15199).

At the request of the company, the Department reviewed the certification for workers of the subject firm. The workers were engaged in employment related to the production of infant and toddler's bibs and washcloths. The current worker certification for Hasbro Manufacturing Services, Arcade, New York, established an impact date of February 1, 1997. According to company officials, worker separations began at the Arcade production facility in July 1996, with the plant closing on October 17, 1996. Other findings show that Hasbro's Arcade location is also known as Hasbro, Inc./Pant Ease. Based on this information, the Department is amending the worker certification to reflect that Hasbro Manufacturing Services is also known as Hasbro, Inc./Pant Ease, and is changing the impact date for worker separations at the subject firm's Arcade production facility to February 7, 1996.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports.

The amended notice applicable to TA–W–33,194 is hereby issued as follows:

All workers of Hasbro Manufacturing Services, also known as Hasbro, Inc./Pant Ease, Arcade, New York, who became totally or partially separated from employment on or after February 7, 1996, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C. this 22nd day of April 1997.

Russell T. Kile,

Program Manager, Policy and and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12217 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–32,611; TA–W–32,611A]

J.M. Huber Corporation Oil and Gas Division Houston, Texas; J.M. Huber Corporation Oil and Gas Division Borger, Texas; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on August 21, 1996, applicable to all workers of J.M. Huber Corporation, Oil and Gas Division located in Houston, Texas. The notice was published in the **Federal Register** on September 13, 1996 (61 FR 48504).

At the request of the company, the Department reviewed the certification for workers of the subject firm. New findings show that worker separations have occurred at J.M. Huber Corporation, Oil and Gas Division, Borger, Texas. The workers are engaged in employment related to the production of crude oil and natural gas.

The intent of the Department's certification is to include all workers of J.M. Huber Corporation adversely affected by increased imports. Accordingly, the Department is amending the certification to cover workers of the subject firm's Borger, Texas location.

The amended notice applicable to TA–W–32,611 is hereby issued as follows:

All workers of J.M. Huber Corporation, Oil and Gas Division, Houston, Texas (TA–W–32,611) and Borger, Texas (TA–W–32,611A) who became totally or partially separated from employment on or after March 9, 1996 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C. this 28th day of April, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12224 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–32,842]

Sara Lee Bodywear, McAdoo, Pennsylvania; Notice of Revised Determination on Reopening

On February 28, 1997, the Department, on its own motion, reopened its investigation for the former workers of the subject firm.

The initial investigation resulted in a negative determination issued on December 13, 1996, because the workers provided distribution and warehousing services. The workers did not produce an article within the meaning of Section 222(3) of the Trade Act of 1974. The denial notice was published in the **Federal Register** on December 31, 1996 (61 FR 69110).

The petitioners provided evidence that finishing operations were performed on women's garments (including bike shorts, capri pants and ankle pants) at the Sara Lee Bodywear facility in McAdoo, Pennsylvania.

The articles produced by the subject firm have been impacted importantly by the high penetration of imports into this market. The ratio of U.S. imports of women's and girls' slacks and shorts to domestic production was above 110 percent from 1994 through September 1996.

Conclusion

After careful consideration of the new facts obtained on reopening, it is concluded that increased imports of articles like or directly competitive with women's apparel produced by the subject firm contributed importantly to the decline in sales and to the total or partial separation of workers of the subject firm. In accordance with the provisions of the Trade Act of 1974, I make the following revised determination:

All workers of Sara Lee Bodywear, McAdoo, Pennsylvania, who became totally or partially separated from employment on or after October 7, 1995, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, D.C. this 17th day of April 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12216 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–30,617]

Shaw Pipe, Incorporated Highspire, Pennsylvania Notice of Negative Determination of Reconsideration on Remand

The United States Court of International Trade (USCIT) remanded for further investigation the Secretary of Labor's negative determination in *Former Employees of Shaw Pipe, Inc.* v. *Secretary of Labor,* No. 95–04–00482.

The Department's initial denial of the petition for employees of Shaw Pipe, Incorporated, Highspire, Pennsylvania, was issued on February 24, 1995 and published in the **Federal Register** on March 10, 1995 (60 Fed. Reg. 13,177). The denial was based on the fact that the workers provided a service and did not produce an article.

On remand, during the Department's investigation, it was determined that the work performed by employees of Shaw Pipe, Incorporated, consisted of applying concrete and polyethylene coatings to small and large diameter pipe which is ultimately used for pipeline transmission. The purpose of coating steel pipe is to prevent rust and corrosion, and thus, extend the life of the pipe. Findings on remand show that in the coating process performed by employees at the subject firm, the pipe moves along a conveyor line and the coating is applied to the pipe.

Other findings on remand show that coating the pipe does not change the end use of the pipe. Subject firm officials report the pipe used for pipeline transmission could be used without the protective coating, but it is not likely. Therefore, it can be concluded that the coating of pipe does not constitute the production of a tangible or new product.

Remand findings also show that the subject firms closed the Highspire, Pennsylvania plant because the contract with the primary customer was not renewed. The customer awarded the contract to another domestic company.

Even if the work performed at Highspire was considered the production of a new product, the workers would not be eligible to apply for Trade Adjustment Assistance because they did not meet all of the group eligibility requirements of Section 222 of the Trade Act of 1974, as amended. Although criteria (1) and (2) were met, criterion (3) was not met because the primary customer of the subject firm awarded the pipe coating contract to another domestic company. Thus, increased imports did not contribute to the separation of the workers or to Shaw Pipe's decline in sales and production.

Conclusion

After reconsideration on remand, I affirm the original notice of negative determination of eligibility to apply for adjustment assistance for workers and former workers of Shaw Pipe, Incorporated, Highspire, Pennsylvania.

Signed at Washington, D.C. this 2nd day of May 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12228 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33, 128; TA–W–33,128A]

The Stanley Works Shelbyville Plant of Hand Tools Division, Shelbyville, Tennessee; The Stanley Works Pulaski Handle Manufacturing Plant & Hand Tool Division, Pulaski, Tennessee; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on February 26, 1997, applicable to all workers of The Stanley Works, Shelbyville Plant of Hand Tools Division, Shelbyville, Tennessee. The notice was published in the **Federal Register** on March 21, 1997 (62 FR 13710).

At the request of the company, the Department reviewed the certification for workers of the subject firm. New findings show that worker separations did occur at the subject firm's Pulaski, Tennessee location in early April, 1997 and are expected to continue throughout 1997. The workers are engaged in employment related to the production of hickory wood and tubular steel handles used in the manufacture of low and mid-line hammer products. The production of handles at The Stanley Works' Pulaski, Tennessee plant contributes to the production of hammers at the Stanley Works' Shelbyville, Tennessee plant.

Accordingly, the Department is amending the certification to cover workers at the subject firms' Pulaski, Tennessee plant.

The intent of the Department's certification is to include all workers of The Stanley Works adversely affected by increased imports.

The amended notice applicable to TA–W–33,128 is hereby issued as follows:

All workers of The Stanley Works, Shelbyville Plant of Hand Tools Division, Shelbyville, Tennessee (TA–W–33,128), The Stanley Works, Pulaski Handle Manufacturing Plant & Hand Tool Division, Pulaski, Tennessee (TA–W–33,128A) who became totally or partially separated from employment on or after January 9, 1996 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC this 25th day of April, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment.

[FR Doc. 97–12219 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,107]

Systems & Electronics, Inc., West Plains, Missouri; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of March 26, 1997, the IAMAW District 9, Local Lodge 2782, requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance for workers of the subject firm. The denial notice was signed on March 14, 1997, and published in the **Federal Register** on March 31, 1997 (62 FR 15199).

The petitioner presents evidence that the Department's customer survey was incomplete.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, D.C. this 23rd day of April 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12221 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,407]

Texas LPG Storage Company, Inc.; El Paso, Texas; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on April 14, 1997, in response to a worker petition which was filed on April 14, 1997, on behalf of workers at Texas LPG Storage Company, Inc., El Paso, Texas.

A negative determination applicable to the petitioning group of workers was issued on April 10, 1997 (TA–W–33, 390). No new information is evident which would result in a reversal of the Department's previous determination. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, D.C. this 24th day of April 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12215 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–01592]

Parkway Building Systems, Inc., Poulsbo, Washington; Notice of Termination of Investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (P.L. 103–182) concerning transitional adjustment assistance, hereinafter called (NAFTA–TAA), and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 U.S.C. 2273), an investigation was initiated on March 31, 1997 in response to a petition dated March 19, 1997, on behalf of workers at Parkway Building Systems, Inc., located in Poulsbo, Washington.

This case is being terminated because the workers were separated from the subject firm more than one year prior to the date of the petition. The NAFTA Implementation Act specifies that no certification may apply to any worker whose last separation occurred more than one year before the date of the petition. Consequently further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, D.C., this 30th day of April 1997.

Russell T. Kile,

Program Manager Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–12214 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–01428; NAFTA–01428A]

The Stanley Works Shelbyville Plant of Hand Tools Division, Shelbyville, Tennessee; The Stanley Works Pulaski Handle Manufacturing Plant & Hand Tool Division, Pulaski, Tennessee; Amended Certification Regarding Eligibility To Apply for NAFTA-Transitional Adjustment Assistance

In accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974 as amended (19 U.S.C. 2273), the Department of Labor issued a Certification of Eligibility to Apply for NAFTA-Transitional Adjustment Assistance on February 26, 1997, applicable to all workers of The Stanley Works, Shelbyville Plant of Hand Tools Division, Shelbyville, Tennessee. The notice was published in the **Federal Register** on March 21, 1997 (62 FR 13711).

At the request of the company, the Department reviewed the certification for workers of the subject firm. New findings show that worker separations did occur at the subject firm's Pulaski, Tennessee location in early April, 1997 and are expected to continue throughout 1997. The workers are engaged in employment related to the production of hickory wood and tubular steel handles used in the manufacturing of low and mid-line hammer products. The production of handles at The Stanley Works' Pulaski, Tennessee plant contributes to the production of hammers at the Stanley Works' Shelbyville, Tennessee plant.

Accordingly, the Department is amending the certification to cover workers at the subject firms' Pulaski, Tennessee plant.

The intent of the Department's certification is to include all workers of The Stanley Works adversely affected by increased imports from Mexico or Canada.

The amended notice applicable to NAFTA–01428 is hereby issued as follows:

All workers of The Stanley Works, Shelbyville Plant of Hand Tools Division, Shelbyville, Tennessee (NAFTA–01428) and The Stanley Works, Pulaski Handle Manufacturing Plant & Hand Tool Division, Pulaski, Tennessee (NAFTA–01428A) who became totally or partially separated from employment on or after January 7, 1996 are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed at Washington DC this 25th day of April, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment.

[FR Doc. 97–12220 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–30–M

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 are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, 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 part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act.

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 in hereby found for not utilizing notice and public comment 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 current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions 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, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having any interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit 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, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Connecticut
- CT970001 (Feb. 14, 1997)
- CT970003 (Feb. 14, 1997)
- CT970004 (Feb. 14, 1997)
- CT970005 (Feb. 14, 1997)
- CT970006 (Feb. 14, 1997)

Massachusetts
- MA970001 (Feb. 14, 1997)
- MA970002 (Feb. 14, 1997)
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- MA970019 (Feb. 14, 1997)
- MA970020 (Feb. 14, 1997)

Maine
- ME970005 (Feb. 14, 1997)
- ME970010 (Feb. 14, 1997)
- ME970022 (Feb. 14, 1997)
- ME970037 (Feb. 14, 1997)

New Hampshire
- NH970001 (Feb. 14, 1997)
- NH970003 (Feb. 14, 1997)

New Jersey
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- NY970051 (Feb. 14, 1997)

Volume II

None

Volume III

Alabama
- AL970003 (Feb. 14, 1997)
- AL970008 (Feb. 14, 1997)
- AL970034 (Feb. 14, 1997)
- AL970044 (Feb. 14, 1997)

Florida
- FL970001 (Feb. 14, 1997)
- FL970009 (Feb. 14, 1997)
- FL970014 (Feb. 14, 1997)
- FL970015 (Feb. 14, 1997)
- FL970017 (Feb. 14, 1997)

Georgia
- GA970050 (Feb. 14, 1997)

Mississippi
- MS970047 (Feb. 14, 1997)

Volume IV

Illinois
- IL970001 (Feb. 14, 1997)
- IL970002 (Feb. 14, 1997)
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Volume V

Arkansas
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KS970006 (Feb. 14, 1997)
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TX970093 (Feb. 14, 1997)
TX970117 (Feb. 14, 1997)

Volume VI

Wyoming
WY970008 (Feb. 14, 1997)
WY970009 (Feb. 14, 1997)

Volume VII

California
CA970079 (Feb. 14, 1997)
CA970109 (Feb. 14, 1997)

General Wage Determination Publication

General Wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at (703) 487–4630.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, DC this 2nd day of May 1997.

Carl Poleskey,

Chief, Branch of Construction Wage Determinations

[FR Doc. 97–11896 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Labor Research Advisory Council; Meetings and Agenda

The Spring meetings of committees of the Labor Research Advisory Council will be held on May 20, 21, and 22. All of the meetings will be held in the Conference Center of the Postal Square Building (PSB), 2 Massachusetts Avenue, NE., Washington, D.C.

The Labor Research Advisory Council and its committees advise the Bureau of Labor Statistics with respect to technical matters associated with the Bureau's programs. Membership consists of union research directors and staff members. The schedule and agenda of the meetings are as follows:

Tuesday, May 20, 1997

9:30 a.m. Committee on Employment and Unemployment Statistics—Meeting Room 6, PSB

1. Welfare reform and employment surveys
2. Current Employment Statistics (CES) Revision update
3. Standard Occupational Classification Revision
4. North American Industry Classification Structure (NAICS) Update

1:30 p.m. Committee on Foreign Labor Statistics—Meeting Room 6

1. Report on recent developments in the Office of Productivity and Technology
2. International comparisons of labor force, employment and

unemployment: recent results and current issues

Committee on Productivity, Technology and Growth—Meeting Room 6

1. New industry productivity database: Plans for extension of coverage
2. Hours at Work Survey: Redesign of the survey
3. Changes in procedures for the 1996–2006 projections
4. Use of the labor requirements tables in job impact studies

Wednesday, May 21, 1997

9:30 a.m. Committee on Prices and Living Conditions—Meeting Room 6

1. Update on program developments

a. Producer Price Indexes

b. The Consumer Price Index

2. Other business

1:30 p.m. Committee on Wages and Industrial Relations—Meeting Room 6

1. Update on National Compensation Survey (NCS) activities
2. NCS Marketing materials
3. NCS Calibration

Thursday, May 22, 1997

10:00 a.m. Committee on Occupational Safety and Health Statistics—Meeting Room 6

1. Report on summary information from the 1995 Survey of Occupational Injuries and Illnesses
2. Report on the 1994 Bulletin—Occupational Injuries and Illnesses: Counts, Rates, and Characteristics
3. Report on the activities of the ad hoc committee on standardized coding of occupational injury and illness characteristics
4. Discussion of injury and illness followback survey requirements
5. Internet status report/demonstration

The meetings are open to the public. Persons planning to attend these meetings as observers may want to contact Wilhelmina Abner on (Area Code 202) 606–5970.

Signed at Washington, DC, this 5th day of May 1997.

Katharine G. Abraham,

Commissioner.

[FR Doc. 97–12165 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–24–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

National Advisory Committee on Occupational Safety and Health; Notice of Meeting

Notice is hereby given of the date and location of the next meeting of the National Advisory Committee on Occupational Safety and Health (NACOSH), established under section 7(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 656) to advise the Secretary of Labor and the Secretary of Health and Human Services on matters relating to the administration of the Act. NACOSH will hold a meeting on June 6, 1997, in Room N3437 A–D of the Department of Labor Building located at 200 Constitution Avenue NW, Washington, DC. The meeting is open to the public and will begin at 9:00 a.m. lasting until approximately 3:30 p.m.

Agenda items will include: a brief overview of current activities in the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH); regulatory and legislative updates; as well as reports from NACOSH workgroups on performance measurement and ergonomics.

Written data, views or comments for consideration by the committee may be submitted, preferably with 20 copies, to Joanne Goodell at the address provided below. Any such submissions received prior to the meeting will be provided to the members of the Committee and will be included in the record of the meeting. Anyone wishing to make an oral presentation should notify Ms. Goodell before the meeting. The request should state the amount of time desired, the capacity in which the person will appear, and a brief outline of the content of the presentation. Persons who request the opportunity to address the Advisory Committee may be allowed to speak to the extent time permits, at the discretion of the Chair. Individuals with disabilities who need special accommodations should contact Theresa Berry (phone: 202–219–8615, extension 106; FAX: 202–219–5986) one week before the meeting.

An official record of the meeting will be available for public inspection in the OSHA Technical Data Center (TDC) located in Room N2625 of the Department of Labor Building (202–219–7500). For additional information contact: Joanne Goodell, Directorate of Policy, Occupational Safety and Health Administration (OSHA); Room N–3641, 200 Constitution Avenue NW, Washington, DC 20210 (phone: 202–219–8021, extension 107; FAX: 202–219–4383).

Signed at Washington, DC., this 5th day of May 1997.

Gregory R. Watchman,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 97–12227 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Puerto Rico State Standards; Notice of Approval

1. Background

Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health of 1970 (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called the Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary), (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State Plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On August 30, 1977, notice was published in the **Federal Register** (42 FR 43628) of the approval of the Puerto Rico plan and the adoption of Subpart FF to Part 1952 containing the decision.

The Puerto Rico plan provides for the adoption of Federal Standards as State standards by reference. Section 29 CFR 1953.20 provides that ''where any alteration in the Federal program could have an adverse impact on the 'at least effective as' status of the State program, a program change supplement to State plan shall be required.'' In response to Federal Standards changes, the State has submitted by letter dated May 28, 1992, from Artemio Andujar-Pabon, then Acting Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to James W. Stanley, Regional Administrator, standards comparable to, and incorporated as part of the state plan, Occupational Exposure to Bloodborne Pathogens; Final Rule, 29 CFR 1910, as published in the **Federal Register** (Volume 56 FR 64004–64182) of December 6, 1991.

By letter dated December 15, 1993 from Walter M. Valdes-Roldan, then Assistant Secretary for the Puerto Rico

Occupational Safety and Health Office, to James W. Stanley, former Regional Administrator, standards comparable to, and incorporated as part of the state plan, Occupational Exposure to Lead, 29 CFR 1910, as published in the **Federal Register** (Volume 55 FR 4998–4999) of February 13, 1990; Occupational Exposure to Hazardous Chemicals in Laboratories, 29 CFR 1910, as published in the **Federal Register** (Volume 55 FR 7967) of March 6, 1990; Occupational Exposure to Formaldehyde, final rule, 29 CFR 1910, as published in the **Federal Register** (Volume 57 FR 22290–22328) of March 27, 1992; Occupational Exposure to Formaldehyde, Corrections, 29 CFR 1910, as published in the **Federal Register** (Volume 57 FR 24701) of June 10, 1992; Permit-Required Confined Spaces, 29 CFR 1910, as published in the **Federal Register** (Volume 58 FR 4462–4563) of January 14, 1993; Process Safety Management of Highly Hazardous Chemicals, Explosives, and Blasting Agents, final rule, 29 CFR 1910, as published in the **Federal Register** (Volume 57 FR 6336–6417) of February 24, 1991; Process Safety Management of Highly Hazardous Chemicals, Explosives and Blasting Agents, Corrections, 29 CFR 1910, as published in the **Federal Register** (Volume 57 FR 7847) of March 4, 1992; Occupational Exposure to Asbestos, 29 CFR 1926, as published in the **Federal Register** (Volume 55 FR 3724–3732) of February 5, 1990; Safety Standards for Stairways and Ladders used in Construction Industry, Correction, 29 CFR 1926, as published in the **Federal Register** (Volume 56 FR 2585 and Volume 56 FR 5061) of January 23, 1991 and February 7, 1991; Occupational Exposure to Asbestos, Tremolite, Antrophyllite and Actinolite; final rule, 29 CFR 1910 and 1926, as published in the **Federal Register** (Volume 57 FR 24310–24330) of June 8, 1992.

By letter dated March 15, 1994 from Walter M. Valdes-Roldan, then Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Patricia K. Clark, OSHA Regional Administrator, standards comparable to, and incorporated as part of the state plan, Occupational Exposure to Cadmium (CD), Approval of Information Collection Requirements, 29 CFR 1926, as published in the **Federal Register** (Volume 57 FR 49272) of October 30, 1992; Occupational Exposure to Cadmium, Corrections, 29 CFR 1926, as published in the **Federal Register** (Volume 58 FR 21778–21850) of April 23, 1993; Occupational Exposure to Lead in Construction, Approval of Information Collection Requirements, 29 CFR 1926, as published in the **Federal Register** (58 FR 34218) of June 24, 1993; and Incorporation of General Industry Safety and Health Standards Applicable to Construction Work, final rule and technical amendments, 29 CFR 1926, as published in the **Federal Register** (58 FR 35076–35311) of June 30, 1993; and Incorporation of General Industry Safety and Health Standards Applicable to Construction Work, Corrections, 29 CFR 1926, as published in the **Federal Register** (Volume 58 FR 40468) of July 28, 1993.

By letter dated May 20, 1994 from Walter M. Valdes-Roldan, then Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Air Contaminants, Corrections, 29 CFR 1910, as published in the **Federal Register** (Volume 57 FR 29204–29206) of July 1, 1992; Occupational Exposure to Bloodborne Pathogens, Corrections, 29 CFR 1910, as published in the **Federal Register** (Volume 57 FR 29206) of July 1, 1992; Control of Hazardous Energy Sources (Lockout/Tagout), final rule, 29 CFR 1910, as published in the **Federal Register** (Volume 58 FR 16612–16623) of March 30, 1993; and Occupational Exposure to Cadmium, Correction, 29 CFR 1910 and 1915, as published in the **Federal Register** (Volume 58 FR 21778–21850) of April 23, 1993; Occupational Exposure to Cadmium, final rule, 29 CFR 1926, as published in the **Federal Register** (Volume 57 FR 42102–42463) of September 14, 1992.

By letter dated June 13, 1994 from Walter M. Valdes-Roldan, then Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Welding, Cutting and Brazing, final rule, 29 CFR 1910, as published in the **Federal Register** (Volume 59 FR 25093–25094) of June 20, 1990; Access to Employee Exposure and Medical Records, Clarification, 29 CFR 1910, as published in the **Federal Register** (Volume 55 FR 26431–26432) of June 28, 1990; Air Contaminants, 29 CFR 1910, as published in the **Federal Register** (Volume 55 FR 52840–52841) of December 24, 1990; Occupational Exposure to Lead, as published in the **Federal Register** (Volume 56 FR 24686) of May 31, 1991; Lead Exposure in Construction; Interim final rule, 29 CFR 1926, as published in the **Federal Register** (Volume 58 FR 26590-26649) of May 4, 1993; Incorporation of General Industry Safety and Health Standards Applicable to Shipyard Employment, 29 CFR 1915, as published in the **Federal Register** (Volume 58 FR 35512–35718) of July 1, 1993.

By letter dated August 23, 1994 from Walter M. Valdes-Roldan, then Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Hazard Communication, final rule, 29 CFR 1910, 1915, 1917 and 1926, as published in the **Federal Register** (Volume 59 FR 6126–6184) of February 9, 1994; Standard for Cadmium in Shipyard Employment and Construction Work: Reprint with Corrections and Technical Amendments, final rule, 29 CFR 1915, and 1926, as published in the **Federal Register** (Volume 59 FR 146–215) of January 3, 1994.

By letter dated December 5, 1994 from Juan Morale-Ruiz, then Acting Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Personal Protective Equipment for General Industry, final rule, 29 CFR 1910, as published in the **Federal Register** (Volume 59 FR 16334–16364) of April 6, 1994; and Electric Power Generation, Transmission and Distribution, Electrical Protective Equipment, final rule, 29 CFR 1910, as published in the **Federal Register** (Volume 59 FR 4320–4476) of January 31, 1994.

By letter dated January 27, 1995 from Ameedee Emmanuelli, then Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Reporting Fatalities or Multiple Hospitalization Incidents, 29 CFR 1904, as published in the **Federal Register** (Volume 59 FR 15594–15600) of April 1, 1994; Electric Power Generation, Transmission and Distribution, Electrical Protective Equipment, final rule, Stay of Enforcement and Correction, 29 CFR 1910, as published in the **Federal Register** (Volume 59 FR 33658–33664) of June 30, 1994 and Occupational Exposure to Asbestos, final rule, 29 CFR 1910, 1915 and 1926, as published in the **Federal Register** (Volume 59 FR 40964–41158) of August 30, 1994; Confined and Enclosed Spaces and Other Dangerous Atmospheres in Shipyard Employment, final rule, 29 CFR 1915, as published in the **Federal Register** (Volume 59 FR 37816–37863) of August 30, 1994.

By letter dated May 3, 1995 from Ameedee Emmanuelli, then Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Personal Protective Equipment for General Industry, final rule, Corrections, 29 CFR 1910, as published in the **Federal Register** (Volume 59 FR 33910–33911) of July 1, 1994; Retention of DOT Markings, Placards and Labels, 29 CFR 1910, 1915, 1917, 1918, 1926 and 1928, as published in the **Federal Register** (Volume 59 FR 36695–36700) of July 19, 1994; and Safety Standards for Fall Protection in the Construction Industry, 29 CFR 1926, as published in the **Federal Register** (Volume 59 FR 40672–40753) of August 9, 1994.

By letter dated November 3, 1995 from Luis E. Kolb-Ortiz, Acting Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Hazardous Waste Operations and Emergency Response, final rule, 29 CFR 1910 and 1926, as published in the **Federal Register** (Volume 59 FR 43268–43280) of August 22, 1994; Logging Operations, final rule, 29 CFR 1910, and 1926, as published in the **Federal Register** (Volume 59 FR 51672–51748) of October 12, 1994; Logging Operations, final rule, Partial Stay of Enforcement, 29 CFR 1910, as published in the **Federal Register** (Volume 60 FR 7447–7449) as of February 8, 1995; and Permit-Required Confined Spaces, final rule, Technical Amendment to Preamble, 29 CFR 1910, as published in **Federal Register** (Volume 59 FR 55208–55209) of November 4, 1994.

By letter dated January 16, 1996 from Luis E. Kolb-Ortiz, Acting Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Occupational Exposure to Asbestos, Corrections, 29 CFR 1910, 1915, and 1926, as published in the **Federal Register** (Volume 60 FR 11194) of March 1, 1995; Safety Standards for Fall Protection in the Construction Industry, final rule, 29 CFR 1926, as published in the **Federal Register** (Volume 60 FR 5131–5132) of January 26, 1995; Occupational Exposure to Asbestos, final rule, Extension of Start-Up Dates, 29 CFR 1915, as published in the **Federal Register** (Volume 60 FR 9624–9626) of February 21, 1995; Confined and Enclosed Spaces and Other Dangerous Atmospheres in Shipyard Employment, 29 CFR 1915, as published in the **Federal Register** (Volume 60 FR 14218–14220) of March 16, 1995.

By letter dated March 21, 1996 from Luis E. Kolb-Ortiz, Acting Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable to, and incorporated as part of the state plan, Occupational Exposure to Asbestos, final rule, Extension of Start-Up dates, 29 CFR 1910, 1915 and 1926, as published in the **Federal Register** (Volume 60 FR 33343–33346) of June 28, 1995; Occupational Exposure to Asbestos, Corrections, final rule, 29 CFR 1910, 1915 and 1926, as published in the **Federal Register** (Volume 60 FR 33974–34002) of June 29, 1995; Safety standards for Fall Protection in the Construction Industry, final rule, 29 CFR 1926, as published in the **Federal Register** (Volume 60 FR 39254–39256) of August 2, 1995; Permit-Required Confined Spaces, 29 CFR 1910, as published in the **Federal Register** (Volume 60 FR 26114–26116) of May 19, 1995; Occupational Exposure to Asbestos, 29 CFR 1910 and 1926, as published in the **Federal Register** (Volume 55 FR 3724–3732) of February 5, 1990; and Safety Standards for Stairways and Ladders used in Construction Industry, Correction, 29 CFR 1926, as published in the **Federal Register** (Volume 56 FR 2585 and Volume 56 FR 5061) of January 23, 1991 and February 7, 1991.

By letter dated May 28, 1996 from Luis E. Kolb-Ortiz, Acting Assistant Secretary for the Puerto Rico Occupational Safety and Health Office, to Jose A. Carpena, OSHA Puerto Rico Area Director, standards comparable, and incorporated as part of the state plan, Occupational Exposure to Lead, final rule, Amendments, 29 CFR 1910, as published in the **Federal Register** (Volume 60 FR 52856–52859) of October 11, 1995; Occupational Standards to Asbestos in Construction, final rule, Amendments, 29 CFR 1926, as published in the **Federal Register** (Volume 60 FR 50411–50413) of September 29, 1995; and Occupational Standards to Asbestos in Maritime, Amendments, final rule, 29 CFR 1915, as published in the **Federal Register** (Volume 60 FR 50411–50413) of September 29, 1995.

These standards which are contained in the Puerto Rico Regulations, Number Two (equivalent to 1904), Number Four (equivalent to 29 CFR 1910), Number Ten (equivalent to 29 CFR 1926), Number Eleven (equivalent to 29 CFR 1928) and Number 12 (equivalent to 29 CFR 1915, 1916, 1917, 1918) , were promulgated by resolutions adopted by the Puerto Rico Department of Labor and Human Resources on December 16, 1991, August 25, 1992, May 26, 1992, October 6, 1992, April 14, 1993, September 30, 1993, December 9, 1993, March 23, 1994, June 21, 1994, September 29, 1994, January 18, 1995, May 30, 1995, November 13, 1995, December 13, 1995, February 21, 1996 and February 28, 1996, pursuant to the Puerto Rico Act Number 16 and Chapter 52 of the Puerto Rico Rules and Regulations Act of 1958.

2. Decision

OSHA has determined that the State's standards are identical to the comparable Federal standards, and therefore approves the standards.

3. Location of supplement for inspection and copying

A copy of the standard supplement, along with the approved plan, in english and spanish may be inspected and copied during normal business hours at the following locations: Occupational Safety and Health Administration, Puerto Rico Area Office, BBV Plaza, Suite 5–B, 1510 F.D. Roosevelt Avenue, Guaynabo, Puerto Rico, 00968; Puerto Rico Department of Labor and Human Resources, Prudencio Rivera Martinez Bldg., Munoz Rivera Avenue 505, Hato Rey, Puerto Rico 00918; and the Directorate of Federal-State Operations, Room N3700, 200 Constitution Avenue, N.W., Washington, D.C. 20210. For electronic copies of this **Federal Register** notice, contact OSHA's Web Page at http://www.osha.gov/.

4. Public Participation

Under 29 CFR 1953.2 (c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Puerto Rico State Plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standards are identical to the Federal standards which were promulgated in accordance with Federal law meeting requirements for public participation.

2. The standards were adopted in accordance with the procedural requirement of State Law and further participation would be unnecessary.

The decision is effective (Sec. 18 Pub. L. 91–596, 84 Stat. 1608 (29 U.S.C. 667)) April 16, 1997.

Signed at New York City, New York, this 16th day of April 1997.

Patricia K. Clark,

Regional Administrator.

[FR Doc. 97–12085 Filed 5–8–97; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 97–057]

NASA Advisory Council, Life and Microgravity Sciences and Applications Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council, Life and Microgravity Sciences and Applications Advisory Committee.

DATES: May 13, 1997, 8:30 a.m. to 3:00 p.m. and 4:30 p.m. to 5:30 p.m.; and May 14, 1997, 8:00 a.m. to 6:00 p.m. On Tuesday, May 13, the Advisory Committee will meet jointly with the NASA Advisory Council's Advisory Committee on the International Space Station.

ADDRESSES: NASA Headquarters, Room MIC 7, 300 E Street, SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Ms. Diana P. Hoyt, Code UP, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–1893.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows: May 13, 1997:

—Microgravity Research Prospects
—Life Sciences Research Prospects
—Commercial Space Product Development Prospects
—Engineering Research Prospects
—Committee Discussions on Improving the Translational Linkages between Basic and Applied Research
—Committee Discussions on Private Development of Space May 14, 1997:
—Review of Joint NASA Life and Microgravity Sciences and Applications Advisory Committee/ Advisory Committee on the International Space Station Meeting
—Status of the Office of Life and Microgravity Sciences and Applications
—International Space Station Research Utilization Update
—Exobiology Activities
—Status of Office of Space Flight Activities
—Administrator Goldin's Vision for Biology
—Subcommittee/Task Force Reports
—Discussion of Committee Findings and Recommendations

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: May 5, 1997.

Leslie M. Nolan,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 97–12213 Filed 5–8–97; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Advanced Scientific Computing; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Advanced Scientific Computing (#1185).

Date and Time: May 30, 1997, 8:30 am to 5:00 pm.

Place: National Science Foundation, 4201 Wilson Boulevard, Suite 1150, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: De. John Van Rosendale, Program Director, New Technologies Program, Suite 1122, National Foundation, 4201 Wilson Boulevard, Arlington, VA 22230 (703) 306–1962.

Purpose of Meeting: To provide recommendations and advice concerning proposals submitted to NSF for financial support.

Agenda: Panel review of the New Technologies Program proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–12098 Filed 58–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Bioengineering and Environmental Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Bioengineering and Environmental Systems (No. 1189).

Date and Time: May 29, 1997; 8:30a.m.–5:00 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 530, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Fred G. Heineken, Program Director, Biotechnology Engineering, Division of Bioengineering and Environmental Systems, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone: (703) 306–1318.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate the 1997 Group proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: May 5, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–12097 Filed 5–8–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Civil and Mechanical Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Civil and Mechanical Systems (1205).

Date & Time: May 27, 1997; 8:30 am–5:00 pm.

Place: Room 330, National Science Foundation, 4201 Wilson Blvd., Arlington, VA.

Type of Meeting: Closed.

Contact Person: Dr. Jorn Larsen-Basse, Program Director, Surface Engineering and Tribology, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1360.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Unsolicited proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: May 5, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–12093 Filed 5–8–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Computer and Information Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Advisory Committee for Computer and Information Science and Engineering—1115.

Date and Time: May 28, 1997; 8:30 a.m. to 5:00 p.m.; May 29, 1997; 8:30 a.m. to 2:30 p.m.

Place: National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230, Room 375.

Type of Meeting: Open.

Contact Person: Yvonne Summers, Office of the Assistant Director, Directorate for Computer and Information Science and Engineering, National Science Foundation, 4201 Wilson Blvd., Suite 1105, Arlington, VA 22230. Telephone: (703) 306–1900.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To advise NSF on the impact of its policies, programs and activities on the CISE community; to provide advice to the Assistant Director/CISE on issues related to long range planning, and to form ad hoc subcommittees to carry out needed studies and tasks.

Agenda

(1) Review status of CISE Reorganization Plan
(2) Review status of CISE Strategic Plan
(3) Discuss special activities, e.g., Knowledge Distributed Intelligence (KDI, Government Performance and Results Act (GPRA), Partnership For Advanced Computational Infrastructure (PACI), etc.

Dated: May 5, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–12096 Filed 5–8–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Design, Manufacture, and Industrial Innovation; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, a amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Design, Manufacture, and Industrial Innovation—(1194).

Date and Time: May 28, 1996, 7:45 a.m.–4:45 p.m.

Place: Rooms 320, and 330, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Georgia-Anne Klutke, Program Director, Operations Research and Production Systems Program, (703) 306–1330, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to the NSF for financial support.

Agenda: To review and evaluate Operations Research and Production Systems unsolicited proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters that are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: May 5, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–12095 Filed 5–8–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Design, Manufacture, and Industrial Innovation; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Design, Manufacture, and Industrial Innovation—(1194).

Date and Time: May 30, 1996, 8:00 a.m.–5:30 p.m.

Place: Rooms 320, 330, 340, 360, 365, 370, 390, and 530, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. George A. Hazelrigg, Program Director, Design and Integration Engineering Program, Dr. Jay Lee, Program Director, Materials Processes and Manufacturing Program, Dr. Ming Leu, Program Director, Manufacturing Machines and Equipment Program, (703) 306–1330, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to the NSF for financial support.

Agenda: To review and evaluate Design and Integration Engineering, Materials Processes and Manufacturing, and Manufacturing Machines and Equipment unsolicited proposals as part of the selection process for awards.

Reasons for Closing: The proposals being reviewed include information of proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters that are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: May 5, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–12099 Filed 5–8–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name of Committee: Advisory Committee for Mathematical and Physical Sciences (Code 66).

Date and Time: May 27, 1997 8:00 am–5:30 pm; May 28, 1997 8:00 am–2:00 pm.

Place: Arlington Hilton Hotel, 950 North Stafford Street, Gallery 2, Arlington, VA 22203.

Type of Meeting: Open.

Contact Person: Adriaan de Graaf, Acting Executive Officer, MPS, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230 Telephone: (703) 306–1802.

Minutes: May be obtained from the contact person listed above.

Meeting Purpose: To provide advice on future science and education opportunities; on effective and efficient strategies and mechanisms for achieving overall disciplinary and multidisciplinary balance as well as balance with respect to support for individual investigators and groups, centers, and major facilities; on facilities planning; on the integration of research and education; and on the implementation of GPRA.

Agenda

May 27, 1997

AM

Introductory Remarks
State of MPS Address

Discussion of Science Opportunities

PM

Reports from MPS Working Groups on Facilities and Instrumentation, and University Industry Partnerships

Advisory Committee Working Group Discussions

May 28, 1997

AM

Summaries of Advisory Committee Working Group Discussions

Advisory Committee Recommendations

Meeting Wrap-up/Future Business

Dated: May 5, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–12094 Filed 5–8–97; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–31085; License No. 31–28369–01 EA 97–019]

Roy Sadovsky, D.V.M. Floral Park, New York; Notice of Denial of License Renewal and Order Terminating License

I

Roy Sadovsky, D.V.M., (Licensee or Dr. Sadovsky) is the holder of Byproduct Nuclear Material License No. 31–28369–01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The License authorizes possession and use of licensed material (i.e., gold-198 seeds) for implantation in horses for the treatment of leg injuries and diseases in accordance with the conditions specified therein. Condition 10 of the License requires that licensed material be used only at the Meadowlands Race Track in East Rutherford, New Jersey, or Showplace Farm and Gaitway Farm in Millstone Township, New Jersey. The License, originally issued on December 22, 1989, was amended on January 10, 1992, and was due to expire on January 31, 1995. The license has remained in effect, however, pursuant to 10 CFR 30.36(a), based on a request made by the Licensee in an application for renewal filed on January 24, 1995.

II

On August 26, and September 5, 1996, the NRC conducted an inspection at the Licensee's office in Elmont, New York, and at the Gaitway Farm in Millstone Township, New Jersey. During the inspection, it was determined that the Licensee had continued to use licensed radioactive material consisting of gold-198 seeds at White Birch Farm, in Allentown, New Jersey, a location not authorized by the license, despite being cited for that violation in an NRC Notice of Violation (NOV) issued in January 1992, and despite informing the NRC in February 1992 that he would no longer use the material at the unauthorized location.

During the inspection, the NRC inspector determined, through review of records and interview of the Licensee, that Dr. Sadovsky continued to use gold-198 seeds at the White Birch Farm location on 15 occasions between 1992 and 1996. In addition to this finding of a deliberate violation of an NRC requirement, the August-September 1996 inspection also identified other violations of NRC requirements, each of which are documented in a related Notice of Violation and Proposed Imposition of Civil Penalty issued on this date. These violations include: (1) Failing to secure from unauthorized removal or access, licensed materials (approximately 120 millicuries of gold-198) that were stored in the Licensee's unlocked, open vehicle on September 5, 1996, as required by 10 CFR 20.1801 and 20.1802; (2) transporting licensed material in violation of 10 CFR 71.5 and the applicable requirements of the U.S. Department of Transportation regulations, including failure to use a Type A package as required by 49 CFR 173.415, failure to apply the radioactive material Yellow-II label as required by 49 CFR 172.403, and failure to describe the material on the shipping paper as required by 49 CFR 172.200; (3) failing to provide individual monitoring devices to personnel who assisted in the Licensee's use of licensed material, and to ensure the use of those devices by such personnel, when provided as required by Condition 15 of the License; and (4) conducting operations with licensed material (gold-198) in a manner that caused dose rates in an unrestricted area to exceed 2 millirem in any one hour, as prohibited by 10 CFR 20.1301(a)(2).

On September 13, 1996, the NRC issued an Order Suspending the License (Effective Immediately) and Demand for Information (DFI) to the Licensee, based on the findings of the inspection. As noted in the Order, the violations involving use of licensed material at White Birch Farm were apparently willful, in that the Licensee had been put on notice in 1992 that the license limited use of licensed material to only the locations authorized on the license, and was aware that this material was being used at Allentown, New Jersey, a location not authorized on the NRC license.

Subsequently, the NRC Office of Investigations conducted an investigation of this matter. The investigation determined that the Licensee's use of gold-198 at an unauthorized location during the period from February 22, 1992, to October 19, 1994, was deliberate, and that the use of this licensed material at this location subsequent to January 1995 was willful.

By letter dated October 15, 1996, the Licensee responded to the Order and Demand for Information. In his response, the Licensee stated, among other things, that he did not willfully use licensed material at a location not authorized by his license and that he believed that his license had been amended to include use of licensed material at White Birch Farm. The Licensee repeated his position in a letter dated January 7, 1997.

On February 26, 1997, an enforcement conference was held with the Licensee. At the enforcement conference, the Licensee again denied that he had committed a willful violation of NRC requirements, and again maintained his belief that his license had been amended to authorize work at White Birch Farm.

Notwithstanding the Licensee's assertion, the NRC has concluded that the Licensee's action of performing licensed activity at White Birch Farm, an unauthorized location, was deliberate. This conclusion is supported by the fact that the Licensee used licensed material at White Birch Farm in February and March 1992, only a short time after he was put on notice by the Notice of Violation issued in January 1992 that such use was not authorized by his License. In addition, notwithstanding the Licensee's assertion that he believed that he had then submitted a license amendment to allow use of licensed material at White Birch Farm, this request was not submitted until January 1995.

III

Based on the above, the NRC has concluded that the Licensee deliberately violated NRC requirements. Furthermore, the additional violations, which were identified during the 1996 inspection, are of significant concern in that they have the potential to impact public health and safety. In particular, the radiation level from the quantity of gold-198 that the Licensee typically used is approximately 2.5 rem per hour at 10 centimeters and, when implanted in horses, the legs of the treated horses produce radiation levels of more than 200 millirem per hour at a distance of 30 centimeters. Given these radiation levels, the failure to provide and to ensure the use of individual monitoring by a worker raises a question as to

whether workers were exposed to radiation in excess of NRC requirements. The Licensee's failure to use personnel monitoring devices also raises the question of whether the Licensee was exposed to radiation in excess of NRC requirements. Furthermore, the Licensee's failure to secure licensed material, as well as the transport of this material without proper packaging, without affixing proper labels, and without including accurate shipping papers, are of serious concern to the NRC.

The NRC must be able to rely on its Licensees to comply with NRC requirements. It is important that licensed material be used in accordance with the applicable requirements. The Licensee's deliberate, continued use of licensed material at an unauthorized location, the Licensee's failure to provide individual monitoring devices to personnel who assisted in the Licensee's use of licensed material, and the Licensee's failure to take the necessary action to correct the violation of NRC requirements previously cited in January 1992, demonstrate that the Licensee is either unwilling or unable to comply with NRC requirements. Given the safety significance of the identified violations and the deliberate nature of one of the violations, the NRC no longer has reasonable assurance that public health and safety will be protected.

Consequently, I lack the requisite reasonable assurance that the Licensee is willing and able to conduct operations under License No. 31–28369–01 in compliance with the Commission's requirements, and that the health and safety of the public will be protected. Therefore, the public health, safety and interest require that, pursuant to 10 CFR 2.103, the application for renewal of the License be denied and that the License be terminated.

IV

Accordingly, pursuant to sections 81, 161b, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.103, it is hereby ordered that the Application for renewal of License No. 31–28369–01 is denied and License No. 31–28369–01 is terminated.

V

In accordance with 10 CFR 2.103, the Licensee may request a hearing on this denial of license renewal within 20 days of the date of this denial. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and include a statement of good cause for the extension. Any request for hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406–1415.

If a hearing is requested by the Licensee, the Commission will issue an Order designating the time and place of the hearing. If a hearing is held, the issue to be considered at such hearing shall be whether, on the basis of NRC findings and violations described in Sections II and III of this Notice, denial of the application for renewal of the License should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV of this Order shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland this 1st day of May 1997.

Edward L. Jordan,

Deputy Executive Director for Regulatory Effectiveness, Program Oversight, Investigations and Enforcement.

[FR Doc. 97–12159 Filed 5–8–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[IA–97–024]

Roy Sadovsky, D.V.M. Floral Park, New York; Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)

I

Roy Sadovsky, D.V.M., (Licensee or Dr. Sadovsky) is the holder of Byproduct Nuclear Material License No. 31–28369–01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The License authorizes possession and use of licensed material (i.e., gold-198 seeds) for implantation in horses for the treatment of leg injuries and diseases in accordance with the conditions specified therein. Condition 10 of the License requires that licensed material be used only at the Meadowlands Race Track in East Rutherford,New Jersey, or Showplace Farm and Gaitway Farm in Millstone Township, New Jersey. The License, originally issued on December 22, 1989, was amended on January 10, 1992, and was due to expire on January 31, 1995. The license has remained in effect, however, pursuant to 10 CFR 30.36(a), based on a request made by the Licensee in an application for renewal filed on January 24, 1995.

II

As noted in a Notice of Denial of License Renewal and Order Terminating License issued to Dr. Sadovsky concurrently on this date, the NRC has found, based on an inspection and investigation, that Dr. Sadovsky has deliberately engaged in violations of NRC requirements, as detailed in the Notice of Denial of License Renewal And Order Terminating License. Notwithstanding the denial of Dr. Sadovsky's license renewal, given Dr. Sadovsky's deliberate failure to adhere to regulatory requirements, as well as the significance of additional violations of other requirements as set forth in the Notice of Denial of License Renewal and Order Terminating License, the NRC no longer has the necessary assurance that Dr. Sadovsky's activities, if performed under any other NRC license, would be performed safely and in accordance with requirements.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Dr. Sadovsky were permitted at this

time to be involved in NRC-licensed activities. Therefore, the public health, safety and interest require that Dr. Sadovsky be prohibited from any involvement in NRC-licensed activities for a period of one year from the date of this Order, and if he is currently involved with another licensee in NRC-licensed activities, he must immediately cease such activities, and inform the NRC of the name, address and telephone number of the employer, and provide a copy of this order to the employer. Additionally, Dr. Sadovsky is required to notify the NRC of his first employment in NRC-licensed activities following the prohibition period. Furthermore, pursuant to 10 CFR 2.202, I find that the willfulness and significance of Dr. Sadovsky's conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

III

Accordingly, pursuant to sections 81, 151b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR 30.10, Part 35, and 10 CFR 150.20, it is hereby ordered, immediately effective, that:

1. For a period of one year from the date of this Order, Roy Sadovsky, D.V.M., is prohibited from engaging in NRC-licensed activities. NRC-licensed activities are those activities that are conducted pursuant to a specific or general license issued by the NRC, including, but not limited to, those activities of Agreement State licensees conducted in areas of NRC jurisdiction pursuant to the authority granted by 10 CFR 150.20.

2. For a period of one year from the date of this Order, Dr. Sadovsky shall provide a copy of this Order to any prospective employer who engages in NRC-licensed activities (as described in Section III.1 above) prior to his acceptance of employment involving non-NRC-licensed activities with such prospective employer. The purpose of this requirement is to ensure that the employer is aware of the prohibition on Dr. Sadovsky from engaging in NRC-licensed activities.

3. The first time Dr. Sadovsky is employed in NRC-licensed activities following the one year prohibition, he shall notify the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, prior to engaging in NRC-licensed activities, including activities under an Agreement State license when activities under that license are conducted in areas of NRC jurisdiction pursuant to 10 CFR 150.20. The notice shall include the name, address, and telephone number of the NRC or Agreement State licensee and the location where licensed activities will be performed.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

IV

In accordance with 10 CFR 2.202, Dr. Sadovsky must, and any other person adversely affected by this Order may, submit an answer to this Order and may request a hearing on this Order, within 20 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, and include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Dr. Sadovsky or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, to Dr. Sadovsky if the answer or hearing request is by a person other than Dr. Sadovsky. If a person other than Dr. Sadovsky requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Dr. Sadovsky, or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Dr. Sadovsky may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland this 1st day of May 1997.

Edward L. Jordan,

Deputy Executive Director for Regulatory Effectiveness, Program Oversight, Investigations and Enforcement.

[FR Doc. 97–12160 Filed 5–8–97; 8:45 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–272 and 50–311]

Public Service Electric & Gas Company, Philadelphia Electric Company, Delmarva Power and Light Company, Atlantic City Electric Company, Salem Nuclear Generating Station, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of a license amendment for Facility Operating Licenses Nos. DPR–70 and DPR–75, issued to Public Service Electric and Gas Company (PSE&G, the licensee), for operation of the Salem Nuclear Generating Station, Units 1 and 2 (Salem Units 1 and 2).

The facility consists of two pressurized-water reactors located at the licensee's site in Salem County, New Jersey.

Environmental Assessment

Identification of Proposed Action

The proposed action would change Technical Specification (TS) 3.4.3, ''Relief Valves,'' for Salem Unit 1, and TS 3.4.5, ''Relief Valves,'' for Salem

Unit 2, to ensure that the automatic capability of the power operated relief valves (PORVs) to relieve pressure is maintained when these valves are isolated by closure of the block valves.

The proposed action is in accordance with the licensee's application for amendment dated January 31, 1997, as supplemented by letter dated March 14, 1997.

The Need for the Proposed Action

In June of 1990, the NRC issued Generic Letter (GL) 90–06 entitled ''Resolution of Generic Issue 70, 'Power-Operated Valve and Block Valve Reliability,' and Generic Issue 94 'Additional Low-Temperature Overpressurization Protection For Light-Water Reactors.'" This GL was issued to increase the reliability of the PORVs and block valves to assure that they would function as required for certain transients and accidents including Steam Generator Tube Rupture (SGTR), low temperature overpressurization protection, and plant cooldown. One of the actions required by the GL was to revise the limiting conditions for operation (LCO) of the PORVs and block valves in the TSs.

PSE&G complied by submitting a request to change the TSs, by letter NLR–N93163 dated December 8, 1993, which was incorporated in the Salem Unit 1 and 2 licenses via Amendments 150 and 130, dated April 7, 1994, respectively. The submitted request and amendments were based on the guidance provided in the GL and also later revisions that were made to the LCO under NUREG–1431, ''Standard Technical Specifications Westinghouse Plants,'' Revision 0, dated September 1992. One of the changes afforded by NUREG–1431 was to allow PORV isolation provided the PORVs are capable of manual operation based on the mitigation of a Steam Generator Tube Rupture event; whereas, the TSs recommended in GL 90–06 addressed isolation only for valves with excessive seat leakage.

In June of 1993, Westinghouse issued Nuclear Safety Advisory letter, NSAL 93–013, which addressed the Inadvertent Safety Injection (SI) Actuation at Power event and informed plants that potential nonconservative assumptions were used in evaluating the Inadvertent SI analyses. Westinghouse determined that crediting PORV operation could be a potential solution for the mitigation of this event. The spurious operation of the SI System at power is classified as a Condition II event, a fault of moderate frequency, as referenced in Salem's Updated Final Safety Analysis Report (UFSAR) Section 15.2.14. A Condition II event should result in a reactor shutdown with the plant being capable of returning to operation.

PSE&G has determined that an inadvertent SI at power could cause the pressurizer to become water-solid if the resulting injection of borated water is not terminated. In the event that the pressurizer becomes fully water-solid, timely PORV actuation successfully mitigates the event. However, without automatic operation of the PORVs, the Reactor Coolant System (RCS) pressure may increase to the lift setpoint of the pressurizer safety relief valves before the PORVs are manually opened. The Salem pressurizer safety valves are not designed to relieve water. It is postulated, therefore, that one or more of the valves could fail to completely reseat if relieving a water-solid pressurizer. A resulting unisolable loss of RCS inventory has been analyzed in Salem's UFSAR as a Condition III event.

A review of the current Salem TSs indicates that a TS revision is necessary to preclude the possibility of operating with PORVs that can only be cycled manually. PSE&G's re-analysis of the Inadvertent SI at Power performed to support resolution of NSAL 93–013, credits operator action to unblock the PORVs, if necessary. However, once unblocked it is unlikely that operator actions can be readily accomplished to manually cycle the PORVs such that the pressurizer safety valve pressure is not reached. Therefore, PSE&G submitted the proposed TS changes by letter dated January 31, 1997, to incorporate the results of PSE&G's analysis (i.e., to credit automatic operation of PORVs for an Inadvertent SI event), into the TSs.

Environmental Impacts of the Proposed Action

As indicated in Salem UFSAR Section 15.2.4, ''Spurious Operation of The Safety Injection System at Power,'' the results of this transient do not lead to fuel cladding damage and thus no fission products are released. The proposed changes to the TSs assure that post transient reactor coolant system pressure relief will continue to be controllable; thus, no change in the transient result will occur. Accordingly, no changes are being made in the types of any effluent that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. The principal alternative to the action would be to deny the request. Such action would not change any current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement related to the operation of Salem Nuclear Generating Station Units 1 and 2, dated April 1973.

Agencies and Persons Consulted

In accordance with its stated policy, on April 15, 1997, the staff consulted with the New Jersey State official, Mr. R. Pinney, of the New Jersey Department of Environmental Protection and Energy, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated January 31, 1997, and supplement dated March 14, 1997, which are available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document room located at the Salem Free Library, 112 West Broadway, Salem, New Jersey 08079.

Dated at Rockville, Maryland, this 2nd day of May 1997.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director, Project Directorate I–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 97–12148 Filed 5–8–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Application for a License To Import Nuclear Waste

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 application for an import license. Copies of the application are on file in the Nuclear Regulatory Commission's Public Document Room located at 2120 L Street, N.W., Washington, D.C.

A request for a 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 Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; and the Executive Secretary, U.S. Department of State, Washington, D.C. 20520.

The information concerning the application follows.

NRC IMPORT LICENSE APPLICATION

Name of applicant	Date of application	Date received	Application number	Description of material			Country of origin
				Material type	Total qty	End use	
ALARON Corp.	April 18, 1997 ...	April 25, 1997 ...	IW003	Contaminated Condenser tubing.	110m^3	Decontamination and recycling.	Taiwan.

Dated this 2nd day of May 1997 at Rockville, Maryland.

For the Nuclear Regulatory Commission.

Donna C. Chaney,

Acting Director, Division of Nonproliferation, Exports and Multilateral Relations, Office of International Programs.

[FR Doc. 97–12146 Filed 5–8–97; 8:45 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Joint Meeting of the ACRS Subcommittees on Materials and Metallurgy and on Severe Accidents; Notice of Meeting

The ACRS Subcommittees on Materials and Metallurgy and on Severe Accidents will hold a joint meeting on June 10, 1997, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, June 10, 1997—8:30 a.m. until the conclusion of business.

The Subcommittees will hear presentations from representatives of the NRC staff and the Nuclear Energy Institute (NEI) concerning the NRC staff approach for addressing steam generator tube integrity issues, and related matters. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittees, their consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineer named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittees, along with any of their consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittees will then hear presentations by and hold discussions with representatives of the NRC staff, NEI, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements, and the time allotted therefor can be obtained by contacting the cognizant ACRS staff engineer, Mr. Noel F. Dudley (telephone 301/415–6888) between 7:30 a.m. and 4:15 p.m. (EDT). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any potential changes to the agenda, etc., that may have occurred.

Dated: May 5, 1997.

Sam Duraiswamy,

Chief, Nuclear Reactors Branch.

[FR Doc. 97–12147 Filed 5–8–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Subcommittee Meeting on Instrumentation and Control Systems and Computers; Notice of Meeting

The ACRS Subcommittee on Instrumentation and Control Systems and Computers will hold a meeting on May 28–29, 1997, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, May 28, 1997—8:30 a.m. until the conclusion of business.

Thursday, May 29, 1997—8:30 a.m. until the conclusion of business.

The Subcommittee will review the proposed final Standard Review Plan (SRP) sections, Branch Technical Positions (BTPs), and Regulatory Guides associated with digital instrumentation and control systems. The Subcommittee will also review the staff's incorporation of insights from the National Academy of Sciences/ National Research Council

Phase 2 study report as well as the staff's safety evaluation report on the Electric Power Research Institute topical report for commercial off-the-shelf software. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineer named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the cognizant ACRS staff engineer, Mr. Michael T. Markley (telephone 301/415–6885) between 7:30 a.m. and 4:15 p.m. (EDT). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any potential changes to the agenda, etc., that may have occurred.

Dated: May 5, 1997.

Sam Duraiswamy,

Chief, Nuclear Reactors Branch.

[FR Doc. 97–12151 Filed 5–8–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Subcommittee Meeting on Human Factors; Notice of Meeting

The ACRS Subcommittee on Human Factors will hold a meeting on June 3, 1997, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, June 3, 1997—8:30 a.m. until the conclusion of business.

The Subcommittee will discuss the draft of the NRC Human Performance Program Plan and related matters. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineer named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the cognizant ACRS staff engineer, Mr. Noel F. Dudley (telephone 301/415–6888) between 7:30 a.m. and 4:15 p.m. (EDT). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any potential changes to the agenda, etc., that may have occurred.

Dated: May 5, 1997.

Sam Duraiswamy,

Chief, Nuclear Reactors Branch.

[FR Doc. 97–12152 Filed 5–8–97; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee; Open Committee Meeting

According to the provisions of section 10 of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that meetings of the Federal Prevailing Rate Advisory Committee will be held on—

Thursday, June 5, 1997
Thursday, June 19, 1997
Thursday, July 3, 1997
Thursday, July 17, 1997

The meetings will start at 10:00 a.m. and will be held in Room 5A06A, Office of Personnel Management Building, 1900 E Street, NW., Washington, DC.

The Federal Prevailing Rate Advisory Committee is composed of a Chair, five representatives from labor unions holding exclusive bargaining rights for Federal blue-collar employees, and five representatives from Federal agencies. Entitlement to membership on the Committee is provided for in 5 U.S.C. 5347.

The Committee's primary responsibility is to review the Prevailing Rate System and other matters pertinent to establishing prevailing rates under subchapter IV, chapter 53, 5 U.S.C., as amended, and from time to time advise the Office of Personnel Management.

These scheduled meetings will start in open session with both labor and management representatives attending. During the meeting either the labor members or the management members may caucus separately with the Chair to devise strategy and formulate positions. Premature disclosure of the matters discussed in these caucuses would unacceptably impair the ability of the Committee to reach a consensus on the matters being considered and would disrupt substantially the disposition of its business. Therefore, these caucuses will be closed to the public because of a determination made by the Director of the Office of Personnel Management under the provisions of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463) and 5 U.S.C. 552b(c)(9)(B). These caucuses may, depending on the issues involved, constitute a substantial portion of a meeting.

Annually, the Chair compiles a report of pay issues discussed and concluded

recommendations. These reports are available to the public, upon written request to the Committee's Secretary.

The public is invited to submit material in writing to the Chair on Federal Wage System pay matters felt to be deserving of the Committee's attention. Additional information on these meetings may be obtained by contacting the Committee's Secretary, Office of Personnel Management, Federal Prevailing Rate Advisory Committee, Room 5559, 1900 E Street, NW., Washington, DC 20415 (202) 606–1500.

Dated: May 1, 1997.

Phyllis G. Foley,

Chair, Federal Prevailing Rate Advisory Committee.

[FR Doc. 97–12090 Filed 5–8–97; 8:45 am]

BILLING CODE 6325–01–M

RAILROAD RETIREMENT BOARD

Computer Matching and Privacy Protection Act of 1988; Notice of RRB Records Used in Computer Matching

AGENCY: Railroad Retirement Board (RRB).

ACTION: Notice of records used in computer matching programs; notification to individuals who are beneficiaries under the Railroad Retirement Act.

SUMMARY: As required by the Computer Matching and Privacy Protection Act of 1988, RRB is issuing public notice of its use and intent to use, in ongoing computer matching programs, information obtained from the Social Security Administration (SSA) of the amount of wages reported to SSA and the amount of benefits paid by that agency.

The purpose of this notice is to advise individuals applying for or receiving benefits under the Railroad Retirement Act of the use made by RRB of this information obtained from SSA by means of a computer match.

ADDRESSES: Interested parties may comment on this publication by writing to Ms. Beatrice Ezerski, Secretary to the Board, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

FOR FURTHER INFORMATION CONTACT: Mr. LeRoy Blommaert, Privacy, Act Officer, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092, telephone number (312) 751–4548.

SUPPLEMENTARY INFORMATION: The Computer Matching and Privacy Protection Act of 1988, P.L. 100–503, requires a Federal agency participating in a computer matching program to publish a notice regarding the establishment of a matching program. The required notice was first published at 54 FR 26282 (June 22, 1989). A second notice was published at 57 FR 23115 (June 1, 1992) covering the second cycle; and a third notice was published at 59 FR 64441 (12–14–94) covering the third cycle. New agreements are being negotiated for continuing the matching program beyond the third cycle's initial 18-month and additional 12-month periods; hence, the need for a new notice.

Name of Participating Agencies: Social Security Administration and Railroad Retirement Board.

Purpose of the Match: The RRB will, on a daily basis, obtain from SSA a record of the wages reported to SSA for persons who have applied for benefits under the Railroad Retirement Act and a record of the amount of benefits paid by that agency to persons who are receiving or have applied for benefits under the Railroad Retirement Act. The wage information is needed to compute the amount of the tier I annuity component provided by sections 3(a), 4(a) and 4(f) of the Railroad Retirement Act (45 U.S.C. § 231b(a), 45 U.S.C. § 231c(a) and 45 U.S.C. § 231c(f). This information is available from no other source.

In addition, the RRB will receive from SSA the amount of certain social security benefits which the RRB pays on behalf of SSA. Section 7(b)(2) of the Railroad Retirement Act (45 U.S.C. § 231f(b)(2)) provides that the RRB shall make the payment of certain social security benefits. The RRB also requires this information in order to adjust the amount of any annuity due to the receipt of a social security benefit. Section 10(a) of the Railroad Retirement Act (45 U.S.C. § 231i(a)) permits the RRB to recover any overpayment from the accrual of social security benefits. This information is not available from any other source.

Finally, the RRB will receive from SSA once a year a copy of SSA's Master Benefit Record for earmarked RRB annuitants. Section 7(b)(7)) of the Railroad Retirement Act (45 U.S.C. § (b)(7) requires that SSA provide the requested information. The RRB needs this information to make the necessary cost-of-living computation quickly and accurately for those RRB annuitants who are also SSA beneficiaries.

Authority for Conducting the Match: Section 7(b)(7) of the Railroad Retirement Act (45 U.S.C. § 231f(h)(7)) provides that the Social Security Administration shall supply information necessary to administer the Railroad Retirement Act.

Categories of Records and Individuals Covered: All applicants for benefits under the Railroad Retirement Act and current beneficiaries will have a record of their wages and the amount of their social security benefits requested from the Social Security Administration.

Inclusive Dates of the Matching Program: It is estimated that these matches will commence in May 1997 and will run for the full 18 months of the agreement.

The notice we are giving here is in addition to any individual notice.

A copy of this notice will be furnished to the Office of Management and Budget and the designated committees of both houses of Congress.

Dated: May 1, 1997.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 97–12068 Filed 5–8–97; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Extension

Rule 19b–4 and Form 19b–4
SEC File No. 270–38
OMB Control No. 3235–0045

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

The information is collected pursuant to Rule 19b–4 of the Securities Exchange Act of 1934 (''Act''), entitled, ''Filings with Respect to Proposed Rule Changes by Self-Regulatory Organizations.''

Rule 19b–4, as amended by the Securities Act Amendments of 1975, requires each self-regulatory organization to file with the Commission copies of any proposed amendment to its constitution, articles of incorporation, bylaws, rules or

similar instrument or any interpretation of these instruments. The Commission is required to publish notice of such filing, and either approve the proposal or institute proceedings to determine whether the proposal should be disapproved.

The collection of information is designed to provide the Commission with the information necessary to determine whether, as required by the Act, the rule proposal is consistent with the Act and the rules thereunder. The information is used to determine whether the proposal should be approved or proceedings should be instituted to determine whether disapproval is appropriate.

The respondents to the collection of information are self-regulatory organizations, which generally are securities exchanges.

An estimated 25 respondents file approximately 20 filings per year, totaling an average burden of 17,500 burden hours.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, N.W. Washington, DC 20549.

May 1, 1997.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–12078 Filed 5–8–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–26714]

Filings Under the Public Utility Holding Company Act of 1935, As Amended (''Act'')

May 2, 1997.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by May 27, 1997, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Cinergy Corp

Cinergy Corp. (''Cinergy''), a registered holding company, located at 139 East Fourth Street, Cincinnati, Ohio 45202, has filed a declaration under sections 6(a) and 7 of the Act and rule 54 thereunder.

Cinergy proposes to issue and sell from time to time through December 31, 2002 in an aggregate principal amount at any time outstanding not to exceed $400 million of unsecured debt securities (''Debentures'') in one or more series, subject to the aggregate debt limitation on outstanding Cinergy indebtedness (''Cinergy Corp. Debt Limitation''). The Debentures: (a) Will not be convertible into any other securities of Cinergy, (b) will have maturities ranging from one to 40 years, (c) may be subject to optional and/or mandatory redemption, in whole or in part, at par or at various premiums above the principal amount thereof, and (d) may be entitled to mandatory or optional sinking fund provisions. In addition, Cinergy may have the right from time to time to defer the payment of interest on the Debentures of one or more series (which may be fixed or floating or ''multi-modal'' debentures, i.e., debentures where the interest is periodically reset, alternating between fixed and floating interest rates for each reset period), with all accrued and unpaid interest (together with interest thereon) becoming due and payable at the end of each such extension period. The Debentures will be issued under an indenture (the ''Indenture'') to be entered into between Cinergy and The Fifth Third Bank, an Ohio banking corporation, as trustee (the ''Trustee,'' including any successor trustee appointed pursuant to the Indenture), with a supplemental indenture to be executed in respect of each separate offering of one or more series of Debentures (each, a ''Supplemental Indenture'').

Cinergy proposes to issue and sell the initial series of Debentures directly to one or more purchasers in privately negotiated transactions or to one or more investment banking or underwriting firms or other entities who would resell the Debentures without registration under the Securities Act in reliance upon one or more applicable exemptions from registration thereunder. From time to time Cinergy may also issue and sell the Debentures of one or more series to the public either: (i) Through underwriters selected by negotiation or competitive bidding or (ii) through selling agents acting either as agent or as principal for resale to the public either directly or through dealers.

The maturity dates, interest rates, redemption and sinking fund provisions, if any, with respect to the Debentures of a particular series, as well as any associated placement, underwriting or selling agent fees, commissions and discounts, if any, will be established by negotiation or competitive bidding and reflected in the applicable Supplemental Indenture and Purchase Agreement or underwriting agreement setting forth such terms; provided, however, that: (1) Cinergy will not issue and sell any Debentures (a) At a price higher than 102% or lower than 98% of the applicable principal amount thereof or (b) at interest rates in excess of those generally obtainable at the time of pricing or repricing of such Debentures for securities having the same or reasonably similar maturities and having reasonably similar terms, conditions and features issued by utility companies or utility holding companies

of the same or reasonably comparable credit quality; and (2) any placement, underwriting and selling agent fees, commissions and discounts to be paid by Cinergy in connection with the issue and sale of any series of Debentures will not exceed 3.5% of the aggregate principal amount thereof.

Cinergy proposes to use the net proceeds from the issue and sale of the Debenture to repay outstanding short-term indebtedness incurred to finance Cinergy's investment in Midlands Electricity plc, a foreign utility company in which Cinergy acquired an indirect 50% ownership interest in 1996 through a joint venture transaction with GPU, Inc. Cinergy states that it also may use the proceeds to refinance Debentures outstanding from time to time. Cinergy proposes to use various interest rate risk management instruments in connection with the issuance and sale of the Debentures.

Cinergy states that: (a) Interest due on the Debentures would be paid from internally generated funds, including dividends from subsidiaries, and (b) the principal of and premium, if any, on the Debentures would be paid from the proceeds of additional series of Debentures or shares of Cinergy common stock or, on a bridge basis, from the proceeds of short-term debt issued by Cinergy.

In connection with the issuance and sale of the Debentures, Cinergy proposes to mitigate interest rate risk through the use of interest rate management instruments commonly used in today's capital markets, consisting of interest rate swaps, caps, collars, floors, options, forwards, futures and similar products designed to manage and minimize interest costs. Cinergy expects to enter into these agreements with counterparties that are highly rated financial institutions. The transactions will be for fixed periods and stated notional amounts.

Fees, commissions and annual margins in connection with any interest rate management agreements will not exceed 100 basis points in respect of the principal or notional amount of the related Debentures or interest rate management agreement. In addition, with respect to options (such as caps and collars), Cinergy may pay an option fee which would not exceed 10% of the principal amount of the Debentures covered by the option.

The Connecticut Light & Power Company (70–9045)

The Connecticut Light & Power Company (''CL&P'' or the ''Applicant''), a wholly owned electric utility subsidiary of Northeast Utilities, a registered holding company, located at 107 Selden Street, Berlin, Connecticut 06037–5457, has filed an application-declaration under sections 6(a), 7, 9(a), 10 and 12(c) of the Act and rules, 46 and 54 thereunder.

CL&P requests that (i) CL&P be allowed to organize a wholly-owned special purpose corporation to be called CL&P Receivables Corporation (''CRC'') for the sole purpose of acquiring certain of CL&P's eligible accounts receivable; (ii) CRC be allowed to issue shares of Common Stock; (iii) CL&P be allowed to acquire shares of capital stock of CRC; (iv) CL&P be allowed to make, directly and indirectly, general and initial equity contributions to CRC; and (v) CRC be allowed to pay dividends to CL&P.

CL&P has entered into a Receivables Purchase and Sale Agreement dated as of July 11, 1996, as amended (''Existing Agreement'') under which CL&P may sell (from time to time in its discretion and subject to the satisfaction of certain conditions precedent) fractional, undivided ownership interests expressed as a percentage (''Receivables Interests'') in: (i) Billed and unbilled indebtedness of customers, as booked to Accounts 142.01 and 173 under the Federal Energy Regulatory Commission Chart of Accounts (''Receivables'') and (ii) certain related assets, including any security or guaranty for any Receivables, all collection thereon, and related records and software (''Related Assets''). The purchaser[s] is either a bank and its assignees or a special purpose Delaware corporation which acquires receivables and other assets and issues commercial paper to finance these acquisitions (collectively, ''Purchaser''). Citicorp North America, Inc. will act as agent (''Agent'') for the Purchaser for transactions under the Existing Agreement.

The Existing Agreement is structured so that any sales made thereunder would be accounted for as sales under generally accepted accounting principles. In order for such sales made on or after January 1, 1997 to be so treated, they must comply with the requirements of the Statement of Financial Accounting Standards No. 125 (''FAS 125'') issued in June 1996. The formation of CRC is intended to satisfy certain of the requirements of FAS 125: (i) CRC, as purchaser and transferee, will be a ''qualifying special purpose entity'' within the meaning of FAS 125, and (ii) once transferred, CL&P will no longer have effective control over the assets, so that such transfers should be labeled ''true sales'' in the event of CL&P's bankruptcy or receivership.

The restructured accounts receivable purchase and sales program will consist of two agreements which will replace the Existing Agreement, and is intended to accomplish sales to the Purchaser in a manner substantially similar to that under the Existing Agreement. Applicant states that the addition of CRC serves merely as a vehicle to isolate the Receivables as required by FAS 125, and that the restructured purchase and sales arrangements are on essentially the same terms to CL&P as the Existing Agreement. Under the first agreement (''Company Agreement''), CL&P will sell or transfer as equity contributions from time to time all of its receivables and related assets to CRC. The purchase price will take into account historical loss statistics in CL&P's receivables pool. Under the second agreement (''CRC Agreement''), CRC will sell Receivables Interests to the Purchaser from time to time. Such Receivables Interests may be funded and repaid on a revolving basis. The purchase price for a Receivables Interest will be calculated according to a formula. Such formula will include reserves based on, among other things, a multiple of historical losses, a multiple of historical dilution (such as, e.g., adjustments due to billing errors), customer concentrations that exceed specified levels and carrying costs and other costs associated with the Agreements. The formula will also take into account the cost of servicing, which will be returned to CL&P in the form of a servicing fee.

Primarily because of the reserves, the purchase price paid by the Purchaser for Receivables Interests will be lower than the purchase price paid by CRC to CL&P for Receivables and Related Assets. CL&P states that it expects CRC to have sufficient assets to pay CL&P the full purchase price for Receivables purchased from CL&P.

CL&P anticipates that the availability of Receivable and Related Assets will vary from time to time in accordance with the energy use of its customers. Therefore, since CRC's only source of funds are its participation in the program and CL&P's capital contributions, it may not have funds available at a particular time to purchase the Receivables and Related Assets. CL&P proposes to accommodate this situation by: (i) Allowing CRC to make the purchase and owe the balance to CL&P on a deferred basis, or (ii) making a capital contribution to CRC in the form of the Receivables and Related Assets for which CRC lacks the purchase price funds at the time.[1]

[1] CL&P also states that if CRC develops a substantial cash balance, it will likely dividend the excess cash to CL&P, so that CRC will not itself retain substantial cash balances at any one time,

Continued

Under the CRC Agreement, purchases may be funded by the Purchaser's issuance of commercial paper or drawing under its bank facilities. Initially, the aggregate purchase price paid by the Purchaser for Receivables Interests is not intended to exceed $200 million.

The Agent will have the right to appoint a collection agent on behalf of the Purchaser and CRC, to administer and collect receivables and to notify the obligors of the sale of their receivables, at the Agent's option. CL&P will be appointed as the initial collection agent.

Certain obligations under the Company Agreement create limited recourse against CL&P. In order to secure these obligations, CL&P will grant to CFR a lien on, and security interest in, any rights which CL&P may have in respect of Receivables and Related Assets. The CRC Agreement creates comparable recourse obligations against CRC, and CL&P states that CRC will grant a security interest to the Purchaser in all rights in the Receivables retained by CRC, the Related Assets and certain other rights and remedies (including its rights and remedies under the Company Agreement) to secure such recourse obligations.[2]

CL&P and CRC will be obligated to reimburse the Purchaser and the Agent for various costs and expenses associated with the Company Agreement and the CRC Agreement. CRC will also be required to pay to the Agent certain fees for services in connection with such agreements.

The arrangements under the Company Agreement and the CRC Agreement are schedules to terminate on July 11, 2001. CRC may, upon at least five business days notice to the Agent, terminate in whole or reduce in part the unused portion of its purchase limit in accordance with the terms and conditions of the CRC Agreement. The CRC Agreement allows the Purchaser to assign all of its rights and obligations under the CRC Agreement (including its Receivables Interests and the obligation to fund Receivables Interests) to other person, including the providers of its bank facilities.

CL&P intends that the above-described transactions will permit it, in effect, through this intermediary device, to accelerate its receipt of cash collections from accounts receivable and thereby meet its short-term cash needs.

Allegheny Power System, Inc. (70–9041)

Allegheny Power System, Inc. (''Allegheny''), 10435 Downsville Pike, Hagerstown, Maryland 21740, a registered holding company, has filed a declaration (''Declaration'') under sections 6(a) and 7 of the Act and rule 54 thereunder.

Allegheny proposes, from time to time through December 31, 2007, to issue up to a total of 500,000 shares of its common stock (''Common Stock'') to its senior officers and senior officers of its subsidiaries as performance awards (''Awards'') under a Performance Share Plan (''Plan''). The Board of Directors (''Board'') of Allegheny has determined that it would like the flexibility to make payments to the Plan participants either in Common Stock or a combination of cash and Common Stock.

The Plan was approved by Allegheny shareholders at the annual meeting in May 1994. The Plan consists of cycles which are not less than three nor more than five years in length. The Management Review Committee (''Committee'') of the Board administraters the Plan and establishes each Plan cycle, the conditions of each Award made under the Plan, which senior officers will receive Awards, the amount of each Award, and guidelines for each Plan cycle.

Based upon the guidelines set forth in each cycle, an Award payout is calculated by multiplying the amount of case awarded by the payout ratio. The number of shares of Common Stock to be awarded is then derived by converting this payout figure into a number of shares of Common Stock at the price specified for that Plan cycle. The dividends to be paid on those shares of Common Stock are treated as having been reinvested since the beginning of the Plan cycle. The shares of Common Stock are then converted back into an amount of cash using the closing price at the end of the Plan cycle. A participant receives either Common Stock or cash and Common Stock, as determined by the Committee, after the end of the Plan cycle. The total number of shares of Common Stock eligible for issuance in each Plan cycle is not expected to exceed 40,000 shares.

The Plan will terminate December 31, 2007, unless ended sooner by the Board. The Board may terminate or amend the Plan at any time, but may not, without stockholder approval, materially increase the benefits accruing to participants or increase the total number of shares of Common Stock available for Awards.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–12077 Filed 5–8–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–38571; File No. SR–Amex–97–14]

Self-Regulatory Organizations; American Stock Exchange, Inc.; Order Granting Approval to Proposed Rule Change Relating to Trading in One Sixteenth of a Dollar

May 5, 1997.

On March 17, 1997, the American Stock Exchange, Inc. (''Amex'' or ''Exchange'') submitted to the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to permit all Amex equity securities selling at or above $0.25 to trade in sixteenths.

The proposed rule change was published for comment in the **Federal Register** on April 1, 1997.[3] No comments were received concerning the proposal. This order approves the proposal.

In 1992, the Commission approved amendments to Amex Rule 127 to provide that securities selling between $0.25 and $5 could be traded in sixteenths ($0.0625).[4] In 1995, this rule was amended to expand the securities that could be traded in sixteenths to those selling up to $10.[5] The proposed rule change would eliminate the $10 cap, thus allowing all Amex-listed equity securities priced at or above $0.25 to trade in sixteenths.[6] The

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and substantially all of the net cash realized from the collection of Receivables will be made available to CL&P.

[2] CL&P states that neither CRC's nor the Purchaser's recourse to CL&P will include any rights against CL&P should customer defaults on the Receivables result in collections attributable to the Receivables Interests sold to the Purchaser being insufficient to reimburse the Purchaser for he purchase price paid by it for the Receivables Interests and its anticipated yield. The Purchaser will bear the risk for any credit losses on the Receivables which exceed the reserves for such losses included in the Receivables Interests.

[1] 15 U.S.C. § 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 38437 (Mar. 25, 1997), 62 FR 15552 (Apr. 1, 1997).

[4] Securities Exchange Act Release No. 31118 (Aug. 28, 1992), 57 FR 40484 (Sept. 3, 1992) (approving File No. SR–Amex–91–07).

[5] Securities Exchange Act Release No. 35537 (Mar. 27, 1995), 60 FR 16894 (Apr. 3, 1995) (approving File No. SR–Amex–95–02).

[6] Standard and Poor's Depositary Receipts® (''SPDRs®'') and S&P MidCap 400 SPDRs™ will continue to trade in 1/64s ($0.0155625), and dealings

Exchange believes that trading in sixteenths will enhance competition and, thus, increase the potential for an investor's order to receive price improvement.[7]

At the March 1997 meeting of the Intermarket Trading System (''ITS'') Operating Committee, the ITS participants approved enhancements to ITS to permit trading in sixteenths for all Tape B securities.[8] The Amex has represented that these system modifications have been made and the system now is able to accommodate trading all Amex equity securities in sixteenths.[9]

The Commission finds that the proposed rule change to permit all Amex equity securities selling at or above $0.25 to trade in increments as small as one sixteenth of a dollar is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) and Section 11A.[10]

The Commission believes the quality of the market for Amex-listed securities will likely be enhanced by allowing a minimum fractional change of 1/16, rather than 1/8, for all Amex equity securities selling at or above $0.25.[11] Decreasing such trading variations should help to produce more accurate pricing of such securities and can result in tighter quotations. In addition, if the quoted markets are improved by the reduced minimum tick fluctuations, the change could result in added benefits to the market such as reduced transaction costs.[12]

Furthermore, this change in the minimum increment will complement the Commission's Order Execution Rules.[13] The rule change allows a more complete display of the buying and selling interest in Amex-listed securities. For example, the enhanced transparency will allow customer limit orders in smaller increments to be displaced, thus giving these limit orders greater visibility and allowing enhanced quote competition. The enhanced transparency will improve access to the best available prices and provide an opportunity for executions at prices that were not previously available.

Finally, the Commission believes the proposal allows increased competition among the different markets pursuant to Section 11A of the Act.[14] As noted above, ITS participants will have the capability to trade all Tape B securities in sixteenths. By ensuring that all ITS participants can quote in sixteenths, regional exchanges, over-the-counter market makers trading in Amex-listed securities, and Amex specialists will be able to compete with each other by quoting in finer increments.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[15] that the proposed rule change (SR–Amex–97–14) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–12175 Filed 5–8–97; 8:45 am]

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in Amex-listed equity securities priced below $0.25 will continue to be in 1/32s ($0.03125).

[7] The proposed rule change should affect a significant number of orders because, according to the Exchange, approximately 50% of all equity securities presently traded on the Amex sell for over $10 per share.

[8] The Consolidated Tape, operated by the Consolidated Tape Association (''CTA''), compiles last sale reports in certain listed securities from all exchange and market makers trading such securities and disseminates these reports to vendors on a consolidated basis. Amex-listed stocks and qualifying regional-listed stocks are reported on CTA Tape B.

[9] Letter from Arne G. Michaelson, Senior Vice President, Amex, to Howard L. Kramer, Senior Associate Director, SEC, dated April 25, 1997.

[10] 15 U.S.C. §§ 78f(b) and 78k–1. In approving this rule change, the Commission notes that it has considered the proposal's impact on efficiency, competition, and capital formation, consistent with Section 3 of the act. *Id.* § 78c(f).

[11] A study that analyzed the 1992 reduction in the minimum tick size for Amex-listed securities priced between $1.00 and $5.00 found that, in general, the spreads for those securities decreased significantly while trading activity and market depth was relatively unaffected. *See* Hee-Joon Ahn, Charles Q. Chao, and Hyuk Choe, *Tick Size, Spread, and Volume,* 5 J. Fin. Intermediation 2 (1996).

[12] The rule change is consistent with the recommendation of the Division of Market Regulation (''Division'') in its Market 2000 Study, in which the Division noted that the 1/8 minimum variation can cause artificially wide spreads and hinder quote competition by preventing offers to buy or sell at prices inside the prevailing quote. *See* SEC, Division of Market Regulation, *Market 2000: An Examination of Current Equity Market Developments* 18–19 (Jan. 1994).

[13] *See* Securities Exchange Act Release No. 37619A (Sept. 6, 1996), 61 FR 48290 (Sept. 12, 1996).

[14] 15 U.S.C. § 78k–1(a)(1)(C)(ii).

[15] *Id.* § 78s(b)(2).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–38566; File No. SR–NASD–97–23]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to Registration Category, Study Outline and Specification for Series 72 Examination, Government Securities Representative.

May 1, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] notice is hereby given that on April 11, 1997, the NASD Regulation, Inc. (''NASD Regulation'') filed with the Securities Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in items I, II, and III below, which Items have been prepared by NASD Regulation. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organizations Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) of the Act, NASD Regulation is herewith filing a proposed rule change to create a new category of representative registration, the Government Securities Representative (Series 72), and to conform the registration requirements of the existing Registered Options Representative (Series 42) category to take into consideration this new category. Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

Rule 1032. Categories of Representative Registration

[(d) Registered Options Representative]

[Each person associated with a member whose activities in the investment banking or securities business include the solicitation and/or sale of option contracts shall be required to be certified as a Registered Options Representative and to pass an appropriate certification examination for such or an equivalent examination acceptable to the Association. Registered Options Representatives qualified in either put or call options shall not engage in both put and call option transactions until such time as they are qualified in both such options. Members shall be required to report to

[1] 15 U.S.C. § 78s(b)(1) (1988).

the Association the names of any associated persons certified as Registered Options Representatives pursuant to an examination approved by the Association. Registered Options Representatives must also be qualified with the Association as either General Securities Representatives or as Limited Representatives—Corporate Securities; provided, however, Registered Options Representatives of members that are members of a national securities exchange which has standards of approval acceptable to the Association may be deemed to be approved by and certified with the Association, so long as such representatives are approved by an registered with such exchange.]

(d) Limited Representative—Options

(1) Each person associated with a member who is included within the definition of a representative as defined in Rule 1031 may register with the Association as a Limited Representative—Option if:

(A) such person's activities in the investment banking or securities business of the member involve the solicitation or sale or option contracts, including option contracts on government securities as that term is defined in Section 3(a)(42)(D) of the Act, for the account of a broker, dealer or public customer; and

(B) such person passes an appropriate qualification examination for Limited Representative—Options.

(2) Each person seeking to register and qualify as a Limited Representative—Options must, concurrent with or before such registration may become effective, become registered pursuant to the Rule 1032 Series, either as a Limited Representative—Corporate Securities or Limited Representative—Government Securities.

(3) A person registered as a Limited Representative—Options shall not be qualified to function in any area not prescribed by subparagraph (1)(A) hereof.

* * * * *

(g) Limited Representative—Government Securities

(1) Each person associated with a member who is included within the definition of a representative as defined in Rule 1031 may register with the Association as a Limited Representative—Government Securities if:

(A) such person's activities in the investment banking or securities business involve the solicitation, purchase or sale of ''government securities,'' as that term is defined in Section 3(a)(42) (A) through (C) of the Act, for the account of a broker, dealer or public customer, and

(B) such person passes an appropriate qualification examination for Limited Representative—Government Securities.

(2) A person registered solely as a Limited Representative—Government Securities shall not be qualified to function in any area not prescribed by subparagraph (1)(A) hereof.

(3) A person who has been performing the functions of a Limited Representative—Government Securities on or before [insert date two years before effective date of this rule change] may register as such without first meeting the requirement of subparagraph (1)(B) above unless (A) such person is currently subject to a statutory disqualified as defined in Section 3(a)(39) of the Act or (B) during the past ten years before the effective date of that requirement was the subject of a suspension or fine of $5,000 or more by the Association, the Securities and Exchange Commission, the Commodity Futures Trading Commission, state securities commission, foreign financial regulatory authority, or any other regulatory organization responsible for the investment banking or securities business.

[1112. Registration of Representatives]

[All persons associated with a member who are to function as government securities representatives who have not previously been registered shall be registered as such with the Association.

(a) Definition of Representative

Persons associated with a member, including assistant officers other than principals, who are engaged in the government securities business for the member including:

(1) underwriting, trading or sales of government securities;

(2) financial advisory or consultant services for issuers in connection with the issuance of government securities;

(3) research or investment advice, other than general economic information or advice, with respect to government securities in connection with the activities described in subparagraphs (1) and (2) above;

(4) activities other than those specifically mentioned that involve communication, directly or indirectly, with public investors in government securities in connection with the activities described in subparagraphs (1) and (2) above; are designated as representatives.

(b) Notification of Representative Status

A member shall promptly notify the Association of the assumption by an individual not previously registered with the member of representative status on the form designated by the Board of Governors accompanied by the applicable fees.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD Regulation 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. NASD Regulation 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 National Association of Securities Dealers, Inc. (''NASD'') is responsible under Section 15A(g)(3) of the Act to prescribe standards of training, experience and competence for persons associated with NASD members. Pursuant to this statutory obligation, NASD Regulation administers examinations developed by NASD Regulation and other self-regulatory organizations to establish that persons associated with NASD members have attained specified levels of competence and knowledge.

The Government Securities Act of 1986 (''1986 Act''), an amendment to the Act, required sole government securities broker-dealers to register with the SEC for the first time. The 1986 Act also granted the NASD authority to require associated persons of such firms to register with the NASD. However, the 1986 Act did not allow the NASD to apply its qualification examination standards to associated persons of government securities broker-dealers. Since January 1989, such associated persons have been required to register as Government Securities Representatives or Government Securities Principals, but have not been required to pass a qualification examination. Under a 1993 amendment to the Act, the NASD was given authority to apply its qualification standards to Government Securities Representatives and Government Securities Principals.

The proposed rule change will establish an examination qualification

requirement for government securities representatives. A person may qualify to sell government securities by passing the existing Series 7 examination or the new Series 72 examination. The proposed rule change replaces current Rule 1112, which was adopted in 1989. The proposed rule change is consistent with the format of the other NASD limited registration categories.

NASD Regulation has determined to adopt a ''grandfather'' provision for this examination requirement. Persons who have been registered with the NASD as a government securities representative for two years prior to the effective date of the rule will not have to take the examination unless they are subject to a statutory disqualification as defined in Section 3(a)(39) of the Act or in the last ten years have been subject to a suspension or fine of $5,000 or more imposed by a securities or commodities regulator. This provision is consistent with previous practice in permitting persons who have achieved a certain level of experience in a segment of the securities industry to be ''grandfathered'' if a new qualification examination is adopted for that particular industry segment.

Currently, individuals who sell OTC options on government securities are not required to pass a qualification examination. The proposed rule change also will amend Rule 1032(d) for Registered Options Representatives to establish registration and qualification requirements for such individuals, and to add the Series 72 Examination to the list of those examinations which prequalify an individual to take the Limited Representative—Options (Series 42) Examination. A person selling OTC options on government securities would be required to pass the new Series 72 examination and the existing Series 42 examination. This proposed rule change will change the language of Rule 1032(d) Registered Option Representative so that it is similar to the language used in the other registration categories in Rule 1032.

The Series 72 examination will consist of one hundred (100) questions. Candidates will have three hours to complete the examination. The passing score for the examination will be 70%.

The NASD believes that the proposed rule change is consistent with the provisions of Sections 15A(b)(6) and 15A(g)(3) of the Act in that the NASD is required to prescribe standards of training, experience and competence for persons associated with NASD members. Pursuant to this statutory obligation, the NASD develops and administers examinations to establish that persons associated with NASD members have attained specified levels of competence and knowledge.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD Regulation does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Wriftten comments were neither solicited nor received.

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 NASD 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 Fifth Street, N.W., 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. NASD–97–23 and should be submitted by May 30, 1997.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[2]

[2] 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–12079 Filed 5–8–97; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities; Submissions for OMB Review

This notice lists information collection packages that have been sent to the Office of Management and Budget (OMB) for clearance, in compliance with PL. 104–13 effective October 1, 1995, The Paperwork Reduction Act of 1995.

1. You Can Make Your Payments by Credit Cards—0960–0462. The information on Forms SSA–4588 & SSA–4589 will be used to update the individual's social security record to reflect that a payment has been made on their overpayment and to effectuate payment through the appropriate credit card company. The respondents are individuals who make payments by credit cards.

Number of Respondents: 12,000.

Frequency of Response: 1.

Average Burden Per Response: 5 minutes.

Estimated Annual Burden: 1,000 hours.

2. Third Party Liability Information Statement—0960–0323. Form SSA–8019 is used by the Social Security Administration to gather information or to make changes in existing information about third party insurance (other than Medicare or Medicaid), which could be responsible for payment for a beneficiary's medical care. The respondents are applicants and beneficiaries of social security benefits.

Number of Respondents: 65,400.

Frequency of Response: 1.

Average Burden Per Response: 5 minutes.

Estimated Annual Burden: 5,450 hours.

3. Representative Payee Report—0960–0068. Sections 205(j) and 1631(a)(2) of the Social Security Act provide for the payment of supplemental security income and social security benefits to a relative, another person or an organization when the best interests of the beneficiary will be served. Form SSA–6230 (20 CFR 404.2065) is sent to parents, stepparents and grandparents with custody of minor children receiving social security benefits. Form SSA–623 (20 CFR 404.2065 and 416.665) is sent to all other payees with or without custody of the beneficiary. Both forms are used to

determine the continuing suitability of the individual/organization to serve as representative payee.

Number of Respondents: 5,315,160.

Frequency of Response: 1.

Average Burden Per Response: 15 minutes.

Estimated Annual Burden: 1,328,790 hours.

4. Telephone Replacement Card Pilot Test—0960–NEW. The Social Security Administration will conduct a pilot study on obtaining information by telephone from individuals who need a duplicate Social Security Number (SSN) card. The information will be used to properly identify an individual prior to releasing a replacement SSN card, thus eliminating the need for the respondent to take or mail his/her identity documents to a Social Security office. The information provided, which should be known by the true Social Security number holder, will be compared to information available in our current electronic systems. The respondents are individuals in the pilot study who request a duplicate SSN replacement card by telephone.

Number of Respondents: 500,000.

Frequency of Response: 1.

Average Burden Per Response: 2 minutes.

Estimated Annual Burden: 16,667 hours.

To receive a copy of the form or clearance packages, call the SSA Reports Clearance Officer on (410) 965–4125 or write to him at the address listed below. Written comments and recommendations regarding the information collection(s) should be directed within 30 days to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses:

(OMB), Office of Management and Budget, OIRA, Attn: Laura Oliven, New Executive Office Building, Room 10230, 725 17th St., NW., Washington, D.C. 20503

(SSA), Social Security Administration, DCFAM, Attn: Nicholas E. Tagliareni, 1–A–21 Operations Bldg., 6401 Security Blvd., Baltimore, MD 21235

Dated: April 25, 1997.

Nicholas E. Tagliareni,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 97–11299 Filed 5–8–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings, Agreements Filed During the Week of May 2, 1997

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: OST–97–2409.

Date Filed: April 29, 1997.

Parties: Members of the International Air Transport Association.

Subject: COMP Telex Mail vote 868, Revise or Cancel Increases from Angola/Malawi/Tanzania/Tunisia/Uganda/China/Mongolia, Intended effective date: June 1, 1997.

Paulette V. Twine,

Chief, Documentary Services.

[FR Doc. 97–12150 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ending May 2, 1997

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et seq.). The due date for Answers, Conforming Applications, or Motions to modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–97–2407.

Date Filed: April 29, 1997.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: May 27, 1997.

Description

Application of Turkish Airlines, pursuant to 49 U.S.C. Section 41301, and Subpart Q of the Regulations, requests a foreign air carrier permit to engage in scheduled foreign air transportation of persons, property and mail between a point or points in Turkey and the U.S. coterminal points New York and Chicago, either nonstop or via intermediate points, and to engage in charter foreign air transportation of persons, property and mail.

Docket Number: OST–97–2420.

Date Filed: April 30, 1997.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: May 28, 1997.

Description

Application of Tam-Transportes Aereos Meridionais, S.A., pursuant to 49 U.S.C. Section 41302, and Subpart Q of the Regulations, applies for a foreign air carrier permit authorizing the carriage of persons, property and mail in scheduled foreign air transportation between a point or points in Brazil via intermediate points to New York/Newark, Atlanta, Miami, Orlando, Detroit, Washington/Baltimore, Houston, Chicago, Los Angeles, San Francisco and San Juan, Puerto Rico. In addition, TAM requests authority to serve the following additional U.S. points on a code share basis only: Boston, Dallas/Ft. Worth, Denver, Houston, Las Vegas, Minneapolis/St. Paul, New Orleans, Philadelphia, Seattle and Vail.

Paulette V. Twine,

Chief, Documentary Services.

[FR Doc. 97–12149 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Passenger Facility Charge (PFC) Approvals and Disapprovals

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Monthly notice of PFC Approvals and Disapprovals. In April 1997, there were eight applications approved. This notice also includes information on one application, approved in March 1997, inadvertently left off the March 1997 notice. Additionally, four approved amendments to previously approved applications are listed.

SUMMARY: The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of 49 U.S.C. 40117 (Pub. L. 103–272) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158). This notice is published pursuant to paragraph d of § 158.29.

PFC Applications Approved

Public Agency: Toledo-Lucas County Port Authority, Toledo, Ohio.

Application Number: 97–02–C–00–TOL.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $799,621.

Earliest Charge Effective Date: July 1, 1997.

Estimated Charge Expiration Date: July 1, 1998.

Class of Air Carriers Not Required to Collect PFC's: Air Taxi operators.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Toledo Express Airport.

Brief Description of Projects Approved for Collection and Use: Maintenance building expansion, Snow removal equipment, Stabilize shoulders taxiway A–1, Public terminal canopy engineering, Snow removal equipment.

Decision Date: March 31, 1997.

FOR FURTHER INFORMATION CONTACT: Leonard J. Mizerowski, Detroit Airports District Office, (313) 487–7277.

Public Agency: Columbus Airport Commission, Columbus, Georgia.

Application Number: 97–02–C–00–CSG.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $199,000.

Charge Effective Date: December 1, 1993.

Charge Expiration Date: September 1, 1995.

Class of Air Carriers Not Required to Collect PFC's: None.

Brief Description of Projects Approved for Collection and Use: Remove and replace carpeting with ceramic tile in public areas of terminal building, Remove and replace carpeting in public holdrooms of terminal building, Replace Part 107 security access control system.

Decision Date: April 4, 1997.

FOR FURTHER INFORMATION CONTACT: Daniel Gaetan, Atlanta Airports District Office, (404) 305–7146.

Public Agency: Hillsborough County Aviation Authority, Tampa, Florida.

Application Number: 97–03–C–00–TPA.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $25,540,952.

Estimated Charge Effective Date: August 1, 1999.

Estimated Charge Expiration Date: November 1, 2000.

Class of Air Carriers Not Required To Collect PFC's: On-demand air taxi/commercial operators that (1) do not enplane or deplane passengers at the terminal; and, (2) enplane less than 500 passengers per year at Tampa International Airport (TPA).

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at TPA.

Brief Description of Project Approved for Collection: Acquire land for runway approach and transition zones for runway 27, Expand and improve Federal Inspection facilities, Landside terminal building fire protection system, Reconstruct existing runway 18R/36L, Master plan and Part 150 update.

Decision Date: April 8, 1997.

FOR FURTHER INFORMATION CONTACT: C. Ed Howard, Orlando Airports District Office, (407) 812–6331.

Public Agency: County of San Luis Obispo, San Luis Obispo, California.

Application Number: 94–04–I–00–SBP.

Application Type: Impose a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $6,820,830.

Estimated Charge Effective Date: July 1, 1997.

Estimated Charge Expiration Date: July 1, 2012.

Class of Air Carriers Not Required To Collect PFC's: Unscheduled part 135 air taxi operators.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at San Luis Obispo County Airport—McChesney Field.

Brief Description of Projects Approved for Collection and Use: Terminal development and construction.

Decision Date: April 16, 1997.

FOR FURTHER INFORMATION CONTACT: Marlys Vandervelde, San Francisco Airports District Office, (415) 876–2806.

Public Agency: Jackson Hole Airport Board, Jackson, Wyoming.

Application Number: 97–03–C–00–JAC.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $225,000.

Estimated Charge Effective Date: October 1, 1997.

Estimated Charge Expiration Date: May 1, 1998.

Class of Air Carriers Not Required To Collect PFC's: None.

Brief Description of Projects Approved for Collection and Use: Access road safety improvements, Aircraft rescue and firefighting building expansion, Snow removal equipment—skid steer.

Brief Description of Disapproved Project: Airfield sweeper.

Determination: Disapproved. This project is ineligible under Program Guidance Letter 91–8.1 for foreign object debris removal. Therefore, the project does not meet the requirements of § 158.15(b).

Brief Description of Withdrawn Project: Differential global positioning system.

Determination: This project was withdrawn by the public agency by letter dated January 16, 1997. Therefore, the FAA will not rule on this project in this decision.

*Decision Date:*April 22, 1997.

FOR FURTHER INFORMATION CONTACT: Christopher Schaffer, Denver Airports District Office, (303) 342–1258.

Public Agency: City of Cleveland, Ohio.

Application Number: 97–05–C–00–CLE.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $40,868,570.

Estimated Charge Effective Date: May 1, 1997.

Estimated Charge Expiration Date: April 1, 2000.

Class of Air Carriers Not Required To Collect PFC's: Air taxi/commercial operators.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Cleveland Hopkins International Airport (CLE).

Brief Description of Projects Approved for Collection and Use: Insulate residences, Land acquisition/resident relocation, Environmental assessment/environmental impact statement, Terminal passenger flow—security enhancement study, Airport roadway system vehicular ingress-egress study, Update part 150 noise compatibility program.

Brief Description of Disapproved Project: Feasibility study of improvements to Customs and Immigration facilities.

Determination: Disapproved. The city of Cleveland failed to adequately justify this project in accordance with § 158.15(a). The FAA researched CLE's current international flights in the Official Airline Guide and found that this proposed study is not supported by the number and aircraft size of the scheduled air carriers. The FAA also looked at the Fiscal Year 1995 Air Carrier Activity Information System and found the number of international flag carrier and charter enplanements was not sufficient to warrant a study of this size.

Decision Date: April 25, 1997.

FOR FURTHER INFORMATION CONTACT: Robert L. Conrad, Detroit Airports District Office, (313) 487–7295.

Public Agency: Chattanooga Metropolitan Airport Authority, Chattanooga, Tennessee.

Application Number: 97–02–C–00–CHA.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $2,803,262.

Earliest Charge Effective Date: July 1, 2005.

Estimated Charge Expiration Date: July 1, 2010.

Class of Air Carriers Not Required To Collect PFC's: Nonscheduled air taxi/commercial operators filing FAA Form 1800–31.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Chattanooga Metropolitan Airport.

Brief Description of Projects Approved for Collection and Use: Land acquisition (10 acres), Floodgate.

Brief Description of Project Partially Approved for Collection and Use: Land acquisition (8.1 acres).

Determination: Partially approved. The public agency had requested that PFC revenue pay the entire project cost, however, the FAA determined that the public agency had already received a grant of funds from the state of Tennessee to pay 75 percent of the project costs. Therefore, the PFC approved amount was limited to the project costs not financed by the state grant.

Decision Date: April 25, 1997.

FOR FURTHER INFORMATION CONTACT: Peggy S. Kelly, Memphis Airports District Office, (901) 544–3495.

Public Agency: Country of Eagle, Eagle, Colorado.

Application Number: 97–03–C–EGE.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $8,132,130.

Earliest Charge Effective Date: September 1, 1999.

Estimated Charge Expiration Date: March 1, 2012.

Class of Air Carriers Not Required To Collect PFC's: None.

Brief Description of Project Approved for Collection and Use: Terminal building.

Decision Date: April 29, 1997.

FOR FURTHER INFORMATION CONTACT: Christopher Schaffer, Denver Airports District Office, (303) 324–1258.

Public Agency: Port of Oakland, Oakland, California.

Application Number: 97–07–C–00–OAK.

Application Type: Impose and Use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Decision: $33,011,496.

Earliest Charge Effective Date: July 1, 1997.

Estimated Charge Expiration Date: July 1, 1999.

Classes of Air Carriers Not Required To Collect PFC's: (1) Air taxi/commercial operators filing FAA Form 1800–31; and (2) commuters or small certificated air carriers filing Department of Transportation Form 298–C T1 or E1.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that each proposed class accounts for less than 1 percent of the total annual enplanements at Metropolitan Oakland International Airport.

Brief Description of Projects Approved for Collection and Use: Upgrade of airport public address and paging system, Airfield lighting and marking improvements, Conduct pilot [initial phase] noise insulation program, Baggage claim improvements in Terminals One and Two.

Brief description of Project Approved for Collection: Construct remote overnight aircraft parking apron.

Decision Date: April 30, 1997.

FOR FURTHER INFORMATION CONTACT: Marlys Vandervelde, San Francisco Airports District Office, (415) 876–2806.

AMENDMENTS TO PFC APPROVALS

Amendment No. city, state	Amendment approved date	Original approved net PFC revenue	Amended approved net PFC revenue	Original estimated charge exp. date	Amended estimated charge exp. date
92–01–C–01–DTW, Detroit, MI	02/03/97	$640,707,000	$640,707,000	06/01/09	06/01/09
94–01–C–01–YNG, Youngstown, OH	02/04/97	351,180	214,384	07/01/96	07/01/96
92–01–C–03–PLN, Pellston, MI	02/05/97	311,974	133,574	11/01/96	06/01/97
93–01–C–02–PSC, Pasco, WA	04/16/97	1,725,724	3,630,945	09/01/97	05.01.02

Issued in Washington, D.C. on May 5, 1997.

Kendall L. Ball,

Acting Manager, Passenger Facility Charge Branch.

[FR Doc. 97–12241 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

Advisory Board; Notice of Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463; 5 U.S.C. App. I) notice is hereby given of a meeting of the Advisory Board of the Saint Lawrence Seaway Development Corporation, to be held at 11:00 p.m., May 22, 1997, in room D 11 of the Ramada Hotel O'Hare, Rosemont, Illinois. The agenda for this meeting will be as follows: Opening Remarks; Consideration of Minutes of Past Meeting; Review of Programs; New Business; and Closing Remarks.

Attendance at meeting is open to the interested public but limited to the space available. With the approval of the Administrator, members of the public may present oral statements at the meeting. Persons wishing further information should contact not later than May 20, 1997, Marc C. Owen, Advisory Board Liaison, Saint Lawrence Seaway Development Corporation, 400 Seventh Street, SW., Washington, DC 20590; 202–366–0091.

Any member of the pubic may present a written statement to the Advisory Board at any time.

Issued at Washington, DC on May 5, 1997.

Marc C. Owen,

Advisory Board Liaison.

[FR Doc. 97–12140 Filed 5–8–97; 8:45 am]

BILLING CODE 4910–61–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33355]

Norfolk and Western Railway Company—Purchase Exemption—Consolidated Rail Corporation

AGENCY: Surface Transportation Board.

ACTION: Notice of exemption.

SUMMARY: Under 49 U.S.C. 10502, the Board exempts from the requirements of 49 U.S.C. 11323–25 the purchase by Norfolk and Western Railway Company (NW) from Consolidated Rail Corporation of 0.47 miles of railroad beginning at milepost 0.00, where it connects with NW, and extending to milepost 0.47, where it connects with CSX Transportation, Inc., in Detroit, MI, subject to standard labor protective conditions.

DATES: The exemption will be effective June 8, 1997. Petitions to stay must be filed by May 19, 1997. Petitions to reopen must be filed by May 29, 1997.

ADDRESSES: An original and 10 copies of all pleadings referring to STB Finance Docket No. 33355 must be filed with the Office of the Secretary, Case Control Unit, Surface Transportation Board, 1925 K Street, N.W., Washington DC 20423–0001; in addition, a copy of all pleadings must be served on petitioners' representatives: James R. Paschall, Norfolk Southern Corporation, 3 Commercial Place, Norfolk, VA 23510–2191; and John K. Enright, Consolidated Rail Corporation, 2001 Market Street, P.O. Box 41419, Philadelphia, PA 19101–1419.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 565–1600. [TDD for the hearing impaired (202) 565–1695.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. To purchase a copy of the full decision, write to, call or pick up in person from: DC NEWS & DATA, INC., 1925 K Street, N.W., Suite 210, Washington, DC 20006. Telephone: (202) 289–4357. [Assistance for the hearing impaired is available through TDD services (202) 565–1695.]

Decided: April 30, 1997.

By the Board, Chairman Morgan and Vice Chairman Owen.

Vernon A. Williams,

Secretary.

[FR Doc. 97–12210 Filed 5–8–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

May 1, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Bureau of Alcohol, Tobacco and Firearms (BATF)

OMB Number: 1512–0462.

Recordkeeping Requirement ID Number: ATF REC 5110/9.

Type of Review: Extension.

Title: Registration and Records of Vinegar Vaporizing Plants.

Description: Data is necessary to identify persons producing and using distilled spirits in the manufacture of vinegar and to account for spirits so produced and used.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 1.

Estimated Burden Hours Per Recordkeeper: 1 hour.

Frequency of Response: On occasion.

Estimated Total Recordkeeping Burden: 1 hour.

OMB Number: 1512–0466.

Recordkeeping Requirement ID Number: ATF REC 5170/7.

Type of Review: Extension.

Title: Alternate Methods or Procedures and Emergency Variations From Requirements for Exports of Liquors. Description: ATF allows exporters to request approval of alternate methods from those specified in regulations under 27 CFR Part 252. ATF uses the information to evaluate need, jeopardy to the revenue, and compliance with law. Also used to identify areas where regulations need change.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 500.

Estimated Burden Hours Per Recordkeeper: 2 hours.

Frequency of Response: On occasion.

Estimated Total Recordkeeping Burden: 200 hours.

OMB Number: 1512–0469.

Form Number: None.

Type of Review: Extension.

Title: Labeling of Sulfites in Alcoholic Beverages.

Description: In a final rule published in the **Federal Register** on July 9, 1986 (51 FR 34706) the Food and Drug Administration established 10 parts per million as the threshold for declaration of sulfites in food and wine products. The Bureau of Alcohol, Tobacco and Firearms on September 30, 1986, published a final rule (ATF–236) (51 FR 34706) establishing the threshold for declaration of sulfites in alcoholic beverages.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 4,787.

Estimated Burden Hours Per Respondent: 40 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 3,159 hours.

OMB Number: 1512–0482.

Recordkeeping Requirement ID Number: ATF Reporting Requirement 5100/1.

Type of Review: Extension.

Title: Labeling and Advertising Requirements Under the Federal Alcohol Administration Act.

Description: Bottlers and importers of alcohol beverages are required to display certain information for consumers on labels and in advertisements. Other optional statements are also required.

Respondents: Business or other for-profit, Not-for-profit institutions.

Estimated Number of Respondents: 6,060.

Estimated Burden Hours Per Respondent: 1 hour.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 1 hour.

Clearance Officer: Robert N. Hogarth (202) 927–8930, Bureau of Alcohol, Tobacco and Firearms, Room 3200, 650 Massachusetts Avenue, N.W., Washington, DC 20226.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 97–12086 Filed 5–8–97; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

May 2, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Bureau of Alcohol, Tobacco and Firearms (BATF)

OMB Number: 1512–0017.

Form Number: ATF F 6 Part I (5330.3A).

Type of Review: Extension.

Title: Application and Permit for Importation of Firearms, Ammunition and Implements of War.

Description: This information collection is needed to determine whether firearms, ammunition and implements of war are eligible for importation into the United States. Used to secure authorization to import such articles. All persons who desire to import such articles except for persons who are members of the United States Armed Forces.

Respondents: Individuals or households, Business or other for-profit, Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents: 9,000.

Estimated Burden Hours Per Respondent: 30 minutes. Frequency of Response: On occasion.

Estimated Total Reporting Burden: 4,500 hours.

OMB Number: 1512–0073.

Form Number: ATF F 5150.19.

Type of Review: Extension.

Title: Formula and/or Process for Articles Made with Specially Denatured Spirits

Description: ATF F 5150.19 is completed by persons who use specially denatured spirits in the manufacture of certain articles. ATF uses the information provided on the form to insure the manufacturing formulas and processes conform to the requirements of 26 U.S.C. 5273.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 2,683.

Estimated Burden Hours Per Respondent: 54 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 2,415 hours.

OMB Number: 1512–0075.

Form Number: ATF F 5150.18.

Type of Review: Extension.

Title: Users' Report of Denatured Spirits.

Description: The information on ATF F 5150.18 is used to pinpoint unusual activities in the use of specially denatured spirits. The form shows a summary of activities at permit premises. ATF examines and verifies certain entries on these reports to identify unusual activities, errors and omissions.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 2,765.

Estimated Burden Hours Per Respondent: 18 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 830 hours.

OMB Number: 1512–0138.

Form Number: ATF F 5120.20 (2650).

Type of Review: Extension.

Title: Certification of Tax Determination—Wine.

Description: Refund of tax on wine that has been manufactured, produced, bottled or packaged in bulk containers in the United States and then exported. This form verifies that the wine was tax paid or withdrawn from U.S. bond. ATF F 5120.20 (2605) supports the exporter's claim for drawback.

Respondents: Business or other for-profit, Individuals or households.

Estimated Number of Respondents: 1,000.

Estimated Burden Hours Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 500 hour.

OMB Number: 1512–0207.

Form Number: ATF F 5110.43.

Recordkeeping Requirement ID Number: ATF REC 5110/04.

Type of Review: Extension.

Title: Distilled Spirits Plant (DSP) Denaturation Records and Reports.

Description: The information collected is necessary to account for and verify the denaturation of distilled spirits. It is used to audit plant operations, monitor the industry for the efficient allocation of personnel resources, and compile statistics for government economic planning.

Respondents: Business or other for-profit.

Estimated Number of Respondents/Recordkeepers: 98.

Estimated Burden Hours Per Respondent/Recordkeeper: 1 hour.

Frequency of Response: Monthly.

Estimated Total Reporting/Recordkeeping Burden: 1,176 hours.

OMB Number: 1512–0250.

Recordkeeping Requirement ID Number: ATF REC 5110/5.

Type of Review: Extension.

Title: Distilled Spirits Plants (DSP)—Transaction and Supporting Records.

Description: Transaction records provide the source data for accounts of distilled spirits in all DSP operations. They are used by DSP proprietors to account for spirits and by ATF to verify those accounts and consequent liabilities.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 278.

Estimated Burden Hours Per Recordkeeper: 22 hours.

Estimated Total Recordkeeping Burden: 6,060 hours.

OMB Number: 1512–0460.

Recordkeeping Requirement ID Number: ATF REC 5110/12.

Type of Review: Extension.

Title: Equipment and Structures.

Description: Marks, signs and calibrations are necessary on equipment and structures at a distilled spirits plant for the identification of major equipment and of the accurate determination of contents.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 281.

Estimated Burden Hours Per Recordkeeper: 1 hour.

Frequency of Response: On occasion.

Estimated Total Recordkeeping Burden: 1 hour.

Clearance Officer: Robert N. Hogarth (202) 927–8930, Bureau of Alcohol, Tobacco and Firearms, Room 3200, 650 Massachusetts Avenue, N.W., Washington, DC 20226.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 97–12087 Filed 5–8–97; 8:45 am]

BILLING CODE 4810–31–P

federal register

Friday
May 9, 1997

Part II

Department of Health and Human Services

Food and Drug Administration

International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline; Notice of Availability

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0219]

International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guideline entitled ''Good Clinical Practice: Consolidated Guideline.'' The guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guideline is intended to define ''Good Clinical Practice'' and to provide a unified standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. The guideline also describes the minimum information that should be included in an Investigator's Brochure (IB) and provides a suggested format. In addition, the guideline describes the essential documents that individually and collectively permit evaluation of the conduct of a clinical study and the quality of the data produced.

DATES: Effective May 9, 1997. Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Good Clinical Practice: Consolidated Guideline'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. The ''Good Clinical Practice: Consolidated Guideline'' and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Bette L. Barton, Center for Drug Evaluation and Research (HFD–344), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1032.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of August 17, 1995 (60 FR 42948), FDA published a draft tripartite guideline entitled ''Good Clinical Practice.'' In the **Federal Register** of August 9, 1994, FDA published draft tripartite guidelines entitled ''Guideline for the Investigator's Brochure'' (59 FR 40772) and ''Guideline for Essential Documents for the Conduct of a Clinical Study'' (59 FR 40774). The notices gave interested persons an opportunity to submit comments.

After consideration of the comments received and revisions to the guidelines, the three guidelines were consolidated into one guideline on good clinical practice. The consolidated guideline was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies at the ICH meeting held on April 30, 1996.

The guideline defines ''Good Clinical Practice'' and provides a unified standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with Good Clinical Practice provides public assurance that the rights, well-being, and confidentiality of trial subjects are protected and that trial data are credible. The guideline should be followed when generating clinical data that are intended to be submitted to regulatory authorities. The principles established in this guideline should also be applied to other investigations that involve therapeutic intervention in, or observation of, human subjects.

The guideline also describes the minimum information that should be included in an IB, such as information on the drug's physical, chemical, and pharmaceutical properties, and its effect in humans; a suggested format for the IB is also provided. The guideline also describes the purpose of essential documents in a clinical study and explains whether the documents should be filed in the investigator's files or the sponsor's files.

This guideline represents the agency's current thinking on good clinical practices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

As with all of FDA's guidelines, the public is encouraged to submit written comments with new data or other new information pertinent to this guideline. The comments in the docket will be periodically reviewed, and, where appropriate, the guideline will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guideline. 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. A copy of the guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this guideline is available via Internet. Type http://www.fda.gov/cder and go to the ''Regulatory Guidance'' section.

The text of the guideline follows:

Good Clinical Practice: Consolidated Guideline

Table of Contents

Introduction

1. Glossary
2. The Principles of ICH CGP
3. Institutional Review Board/Independent Ethics Committee (IRB/IEC)
3.1 Responsibilities
3.2 Composition, Functions, and Operations
3.3 Procedures
3.4 Records
4. Investigator
4.1 Investigator's Qualifications and Agreements
4.2 Adequate Resources
4.3 Medical Care of Trial Subjects
4.4 Communication with IRB/IEC
4.5 Compliance with Protocol
4.6 Investigational Product(s)
4.7 Randomization Procedures and Unblinding
4.8 Informed Consent of Trial Subjects
4.9 Records and Reports
4.10 Progress Reports
4.11 Safety Reporting
4.12 Premature Termination or Suspension of a Trial
4.13 Final Report(s) by Investigator/Institution
5. Sponsor
5.1 Quality Assurance and Quality Control
5.2 Contract Research Organization (CRO)
5.3 Medical Expertise
5.4 Trial Design
5.5 Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring Committee
5.6 Investigator Selection
5.7 Allocation of Duties and Functions
5.8 Compensation to Subjects and Investigators
5.9 Financing
5.10 Notification/Submission to Regulatory Authority(ies)
5.11 Confirmation of Review by IRB/IEC
5.12 Information on Investigational Product(s)
5.13 Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)
5.14 Supplying and Handling Investigational Product(s)
5.15 Record Access
5.16 Safety Information
5.17 Adverse Drug Reaction Reporting
5.18 Monitoring
5.18.1 Purpose
5.18.2 Selection and Qualifications of Monitors
5.18.3 Extent and Nature of Monitoring
5.18.4 Monitor's Responsibilities
5.18.5 Monitoring Procedures
5.18.6 Monitoring Report
5.19 Audit
5.19.1 Purpose
5.19.2 Selection and Qualification of Auditors
5.19.3 Auditing Procedures
5.20 Noncompliance
5.21 Premature Termination or Suspension of a Trial
5.22 Clinical Trial/Study Reports
5.23 Multicenter Trials
6. Clinical Trial Protocol and Protocol Amendment(s)
6.1 General Information
6.2 Background Information
6.3 Trial Objectives and Purpose
6.4 Trial Design
6.5 Selection and Withdrawal of Subjects
6.6 Treatment of Subjects
6.7 Assessment of Efficacy
6.8 Assessment of Safety
6.9 Statistics
6.10 Direct Access to Source Data/Documents
6.11 Quality Control and Quality Assurance
6.12 Ethics
6.13 Data Handling and Recordkeeping
6.14 Financing and Insurance
6.15 Publication Policy
6.16 Supplements
7. Investigator's Brochure
7.1 Introduction
7.2 General Considerations
7.2.1 Title Page
7.2.2 Confidentiality Statement
7.3 Contents of the Investigator's Brochure
7.3.1 Table of Contents
7.3.2 Summary
7.3.3 Introduction
7.3.4 Physical, Chemical, and Pharmaceutical Properties and Formulation
7.3.5 Nonclinical Studies
7.3.6 Effects in Humans
7.3.7 Summary of Data and Guidance for the Investigator
7.4 Appendix 1
7.5 Appendix 2
8. Essential Documents for the Conduct of a Clinical Trial
8.1 Introduction
8.2 Before the Clinical Phase of the Trial Commences
8.3 During the Clinical Conduct of the Trial
8.4 After Completion or Termination of the Trial

Introduction

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries, and the World Health Organization (WHO).

This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

1. *Glossary*

1.1 *Adverse Drug Reaction (ADR)*

In the preapproval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase ''responses to a medicinal product'' means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

Regarding marketed medicinal products: A response to a drug that is noxious and unintended and that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.2 *Adverse Event (AE)*

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.3 *Amendment (to the protocol)*

See Protocol Amendment.

1.4 *Applicable Regulatory Requirement(s)*

Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products of the jurisdiction where a trial is conducted.

1.5 *Approval (in relation to Institutional Review Boards (IRB's))*

The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements.

1.6 *Audit*

A systematic and independent examination of trial-related activities and documents to

determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOP's), good clinical practice (GCP), and the applicable regulatory requirement(s).

1.7 *Audit Certificate*

A declaration of confirmation by the auditor that an audit has taken place.

1.8 *Audit Report*

A written evaluation by the sponsor's auditor of the results of the audit.

1.9 *Audit Trail*

Documentation that allows reconstruction of the course of events.

1.10 *Blinding/Masking*

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the subject(s) being unaware, and double blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

1.11 *Case Report Form (CRF)*

A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

1.12 *Clinical Trial/Study*

Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

1.13 *Clinical Trial/Study Report*

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports).

1.14 *Comparator (Product)*

An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

1.15 *Compliance (in relation to trials)*

Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.

1.16 *Confidentiality*

Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

1.17 *Contract*

A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

1.18 *Coordinating Committee*

A committee that a sponsor may organize to coordinate the conduct of a multicenter trial.

1.19 *Coordinating Investigator*

An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicenter trial.

1.20 *Contract Research Organization (CRO)*

A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

1.21 *Direct Access*

Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

1.22 *Documentation*

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

1.23 *Essential Documents*

Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see 8. ''Essential Documents for the Conduct of a Clinical Trial'').

1.24 *Good Clinical Practice (GCP)*

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

1.25 *Independent Data Monitoring Committee (IDMC) (Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee)*

An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

1.26 *Impartial Witness*

A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

1.27 *Independent Ethics Committee (IEC)*

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and nonmedical/nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The legal status, composition, function, operations, and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

1.28 *Informed Consent*

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

1.29 *Inspection*

The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

1.30 *Institution (medical)*

Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

1.31 *Institutional Review Board (IRB)*

An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

1.32 *Interim Clinical Trial/Study Report*

A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

1.33 *Investigational Product*

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

1.34 *Investigator*

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Subinvestigator.

1.35 *Investigator/Institution*

An expression meaning ''the investigator and/or institution, where required by the applicable regulatory requirements.''

1.36 *Investigator's Brochure*

A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the

investigational product(s) in human subjects (see 7. ''Investigator's Brochure'').

1.37 *Legally Acceptable Representative*

An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

1.38 *Monitoring*

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOP's), GCP, and the applicable regulatory requirement(s).

1.39 *Monitoring Report*

A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOP's.

1.40 *Multicenter Trial*

A clinical trial conducted according to a single protocol but at more than one site, and, therefore, carried out by more than one investigator.

1.41 *Nonclinical Study*

Biomedical studies not performed on human subjects.

1.42 *Opinion (in relation to Independent Ethics Committee)*

The judgment and/or the advice provided by an Independent Ethics Committee (IEC).

1.43 *Original Medical Record*

See Source Documents.

1.44 *Protocol*

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline, the term protocol refers to protocol and protocol amendments.

1.45 *Protocol Amendment*

A written description of a change(s) to or formal clarification of a protocol.

1.46 *Quality Assurance (QA)*

All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

1.47 *Quality Control (QC)*

The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

1.48 *Randomization*

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

1.49 *Regulatory Authorities*

Bodies having the power to regulate. In the ICH GCP guideline, the expression ''Regulatory Authorities'' includes the authorities that review submitted clinical data and those that conduct inspections (see 1.29). These bodies are sometimes referred to as competent authorities.

1.50 *Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)*

Any untoward medical occurrence that at any dose:

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity,

or

- Is a congenital anomaly/birth defect.

(See the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.)

1.51 *Source Data*

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

1.52 *Source Documents*

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

1.53 *Sponsor*

An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

1.54 *Sponsor-Investigator*

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

1.55 *Standard Operating Procedures (SOP's)*

Detailed, written instructions to achieve uniformity of the performance of a specific function.

1.56 *Subinvestigator*

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.

1.57 *Subject/Trial Subject*

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

1.58 *Subject Identification Code*

A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data.

1.59 *Trial Site*

The location(s) where trial-related activities are actually conducted.

1.60 *Unexpected Adverse Drug Reaction*

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product). (See the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.)

1.61 *Vulnerable Subjects*

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

1.62 *Well-being (of the trial subjects)*

The physical and mental integrity of the subjects participating in a clinical trial.

2. *The Principles of ICH GCP*

2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.–

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

2.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

2.6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favorable opinion.

2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.

2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

2.12 Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

2.13 Systems with procedures that assure the quality of every aspect of the trial should be implemented.

3. *Institutional Review Board/Independent Ethics Committee (IRB/IEC)*

3.1 *Responsibilities*

3.1.1 An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.

3.1.2 The IRB/IEC should obtain the following documents:

Trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may require to fulfill its responsibilities.

The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed, and the dates for the following:

- Approval/favorable opinion;
- Modifications required prior to its approval/favorable opinion;
- Disapproval/negative opinion; and
- Termination/suspension of any prior approval/favorable opinion.

3.1.3 The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.

3.1.4 The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

3.1.5 The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgment of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety, and/or well-being of the subjects.

3.1.6 When a nontherapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.

3.1.7 Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e., in emergency situations).

3.1.8 The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.

3.1.9 The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.

3.2 *Composition, Functions, and Operations*

3.2.1 The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:

(a) At least five members.

(b) At least one member whose primary area of interest is in a nonscientific area.

(c) At least one member who is independent of the institution/trial site.

Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

A list of IRB/IEC members and their qualifications should be maintained.

3.2.2 The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

3.2.3 An IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present.

3.2.4 Only members who participate in the IRB/IEC review and discussion should vote/provide their opinion and/or advise.

3.2.5 The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB/IEC or in the vote/opinion of the IRB/IEC.

3.2.6 An IRB/IEC may invite nonmembers with expertise in special areas for assistance.

3.3 *Procedures*

The IRB/IEC should establish, document in writing, and follow its procedures, which should include:

3.3.1 Determining its composition (names and qualifications of the members) and the authority under which it is established.

3.3.2 Scheduling, notifying its members of, and conducting its meetings.

3.3.3 Conducting initial and continuing review of trials.

3.3.4 Determining the frequency of continuing review, as appropriate.

3.3.5 Providing, according to the applicable regulatory requirements, expedited review and approval/favorable opinion of minor change(s) in ongoing trials that have the approval/favorable opinion of the IRB/IEC.

3.3.6 Specifying that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favorable opinion of the trial.

3.3.7 Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favorable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s)) (see 4.5.2).

3.3.8 Specifying that the investigator should promptly report to the IRB/IEC:

(a) Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects (see 3.3.7, 4.5.2, 4.5.4).

(b) Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial (see 4.10.2).

(c) All adverse drug reactions (ADR's) that are both serious and unexpected.

(d) New information that may affect adversely the safety of the subjects or the conduct of the trial.

3.3.9 Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:

(a) Its trial-related decisions/opinions.

(b) The reasons for its decisions/opinions.

(c) Procedures for appeal of its decisions/opinions.

3.4 *Records*

The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies).

The IRB/IEC may be asked by investigators, sponsors, or regulatory authorities to provide copies of its written procedures and membership lists.

4. *Investigator*

4.1 *Investigator's Qualifications and Agreements*

4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).

4.1.2 The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information, and in other information sources provided by the sponsor.

4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

4.1.4 The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom

the investigator has delegated significant trial-related duties.

4.2 *Adequate Resources*

4.2.1 The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

4.2.3 The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

4.3 *Medical Care of Trial Subjects*

4.3.1 A qualified physician (or dentist, when appropriate), who is an investigator or a subinvestigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

4.3.2 During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

4.3.3 It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

4.3.4 Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.

4.4 *Communication with IRB/IEC*

4.4.1 Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.

4.4.2 As part of the investigator's/institution's written application to the IRB/IEC, the investigator/institution should provide the IRB/IEC with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the IRB/IEC.

4.4.3 During the trial the investigator/institution should provide to the IRB/IEC all documents subject to its review.

4.5 *Compliance with Protocol*

4.5.1 The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and which was given approval/favorable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm their agreement.

4.5.2 The investigator should not implement any deviation from, or changes of, the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), change of telephone number(s)).

4.5.3 The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

4.5.4 The investigator may implement a deviation from, or a change in, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favorable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

(a) To the IRB/IEC for review and approval/favorable opinion;

(b) To the sponsor for agreement; and, if required,

(c) To the regulatory authority(ies).

4.6 *Investigational Product(s)*

4.6.1 Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.

4.6.2 Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

4.6.3 The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor.

4.6.4 The investigational product(s) should be stored as specified by the sponsor (see 5.13.2 and 5.14.3) and in accordance with applicable regulatory requirement(s).

4.6.5 The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.

4.6.6 The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product(s) to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.

4.7 *Randomization Procedures and Unblinding*

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

4.8 *Informed Consent of Trial Subjects*

4.8.1 In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB/IEC's written approval/favorable opinion of the written informed consent form and any other written information to be provided to subjects.

4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favorable opinion in advance of use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.

4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

4.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

4.8.5 The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information given approval/favorable opinion by the IRB/IEC.

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as nontechnical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

4.8.7 Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the

satisfaction of the subject or the subject's legally acceptable representative.

4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial, and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

(a) That the trial involves research.

(b) The purpose of the trial.

(c) The trial treatment(s) and the probability for random assignment to each treatment.

(d) The trial procedures to be followed, including all invasive procedures.

(e) The subject's responsibilities.

(f) Those aspects of the trial that are experimental.

(g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

(h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

(i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

(j) The compensation and/or treatment available to the subject in the event of trial-related injury.

(k) The anticipated prorated payment, if any, to the subject for participating in the trial.

(l) The anticipated expenses, if any, to the subject for participating in the trial.

(m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

(n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

(o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

(p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

(q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

(r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

(s) The expected duration of the subject's participation in the trial.

(t) The approximate number of subjects involved in the trial.

4.8.11 Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

4.8.12 When a clinical trial (therapeutic or nontherapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should assent, sign and personally date the written informed consent.

4.8.13 Except as described in 4.8.14, a nontherapeutic trial (i.e., a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written informed consent form.

4.8.14 Nontherapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

(a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally.

(b) The foreseeable risks to the subjects are low.

(c) The negative impact on the subject's well-being is minimized and low.

(d) The trial is not prohibited by law.

(e) The approval/favorable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/favorable opinion covers this aspect.

Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

4.8.15 In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject's legally acceptable representative is not available, enrollment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favorable opinion by the IRB/IEC, to protect the rights, safety, and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate (see 4.8.10) should be requested.

4.9 *Records and Reports*

4.9.1 The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRF's and in all required reports.

4.9.2 Data reported on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

4.9.3 Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections (see 5.18.4(n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRF's made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see 8.) and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents.

4.9.5 Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see 5.5.12).

4.9.6 The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.
4.9.7 Upon request of the monitor, auditor, IRB/IEC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.
4.10 *Progress Reports*
4.10.1 Where required by the applicable regulatory requirements, the investigator should submit written summaries of the trial's status to the institution. The investigator/institution should submit written summaries of the status of the trial to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC.
4.10.2 The investigator should promptly provide written reports to the sponsor, the IRB/IEC (see 3.3.8), and, where required by the applicable regulatory requirements, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.
4.11 *Safety Reporting*
4.11.1 All serious adverse events (SAE's) should be reported immediately to the sponsor except for those SAE's that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC.
4.11.2 Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
4.11.3 For reported deaths, the investigator should supply the sponsor and the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports).
4.12 *Premature Termination or Suspension of a Trial*

If the trial is terminated prematurely or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies). In addition:
4.12.1 If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution, where required by the applicable regulatory requirements, and the investigator/institution should promptly inform the sponsor and the IRB/IEC, and should provide the sponsor and the IRB/IEC a detailed written explanation of the termination or suspension.
4.12.2 If the sponsor terminates or suspends a trial (see 5.21), the investigator should promptly inform the institution, where required by the applicable regulatory requirements, and the investigator/institution should promptly inform the IRB/IEC and provide the IRB/IEC a detailed written explanation of the termination or suspension.
4.12.3 If the IRB/IEC terminates or suspends its approval/favorable opinion of a trial (see 3.1.2 and 3.3.9), the investigator should inform the institution, where required by the applicable regulatory requirements, and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.
4.13 *Final Report(s) by Investigator/Institution*

Upon completion of the trial, the investigator should, where required by the applicable regulatory requirements, inform the institution, and the investigator/institution should provide the sponsor with all required reports, the IRB/IEC with a summary of the trial's outcome, and the regulatory authority(ies) with any report(s) they require of the investigator/institution.
5. *Sponsor*
5.1 *Quality Assurance and Quality Control*
5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOP's to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
5.1.2 The sponsor is responsible for securing agreement from all involved parties to ensure direct access (see 1.21) to all trial-related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.
5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.
5.1.4 Agreements, made by the sponsor with the investigator/institution and/or with any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement.
5.2 *Contract Research Organization (CRO)*
5.2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.
5.2.2 Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.
5.2.3 Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.
5.2.4 All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial-related duties and functions of a sponsor.
5.3 *Medical Expertise*

The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on trial-related medical questions or problems. If necessary, outside consultant(s) may be appointed for this purpose.
5.4 *Trial Design*
5.4.1 The sponsor should utilize qualified individuals (e.g., biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRF's and planning the analyses to analyzing and preparing interim and final clinical trial/study reports.
5.4.2 For further guidance: Clinical Trial Protocol and Protocol Amendment(s) (see 6.), the ICH Guideline for Structure and Content of Clinical Study Reports, and other appropriate ICH guidance on trial design, protocol, and conduct.
5.5 *Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring Committee*
5.5.1 The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
5.5.2 The sponsor may consider establishing an independent data monitoring committee (IDMC) to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints at intervals, and to recommend to the sponsor whether to continue, modify, or stop a trial. The IDMC should have written operating procedures and maintain written records of all its meetings.
5.5.3 When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

(a) Ensure and document that the electronic data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e., validation).

(b) Maintain SOP's for using these systems.

(c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail).

(d) Maintain a security system that prevents unauthorized access to the data.

(e) Maintain a list of the individuals who are authorized to make data changes (see 4.1.5 and 4.9.3).

(f) Maintain adequate backup of the data.

(g) Safeguard the blinding, if any (e.g., maintain the blinding during data entry and processing).

5.5.4 If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data.
5.5.5 The sponsor should use an unambiguous subject identification code (see 1.58) that allows identification of all the data reported for each subject.
5.5.6 The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial. (See 8. ''Essential Documents for the Conduct of a Clinical Trial.'')
5.5.7 The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the sponsor intends to apply for approval(s).

5.5.8 If the sponsor discontinues the clinical development of an investigational product (i.e., for any or all indications, routes of administration, or dosage forms), the sponsor should maintain all sponsor-specific essential documents for at least 2 years after formal discontinuation or in conformance with the applicable regulatory requirement(s).

5.5.9 If the sponsor discontinues the clinical development of an investigational product, the sponsor should notify all the trial investigators/institutions and all the appropriate regulatory authorities.

5.5.10 Any transfer of ownership of the data should be reported to the appropriate authority(ies), as required by the applicable regulatory requirement(s).

5.5.11 The sponsor-specific essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirement(s) or if needed by the sponsor.

5.5.12 The sponsor should inform the investigator(s)/institution(s) in writing of the need for record retention and should notify the investigator(s)/institution(s) in writing when the trial-related records are no longer needed (see 4.9.5).

5.6 *Investigator Selection*

5.6.1 The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be qualified by training and experience and should have adequate resources (see 4.1, 4.2) to properly conduct the trial for which the investigator is selected. If a coordinating committee and/or coordinating investigator(s) are to be utilized in multicenter trials, their organization and/or selection are the sponsor's responsibility.

5.6.2 Before entering an agreement with an investigator/institution to conduct a trial, the sponsor should provide the investigator(s)/institution(s) with the protocol and an up-to-date Investigator's Brochure, and should provide sufficient time for the investigator/institution to review the protocol and the information provided.

5.6.3 The sponsor should obtain the investigator's/institution's agreement:

(a) To conduct the trial in compliance with GCP, with the applicable regulatory requirement(s), and with the protocol agreed to by the sponsor and given approval/favorable opinion by the IRB/IEC;

(b) To comply with procedures for data recording/reporting: and

(c) To permit monitoring, auditing, and inspection (see 4.1.4).

(d) To retain the essential documents that should be in the investigator/institution files (see 8.) until the sponsor informs the investigator/institution these documents are no longer needed (see 4.9.4, 4.9.5, and 5.5.12).

The sponsor and the investigator/institution should sign the protocol, or an alternative document, to confirm this agreement.

5.7 *Allocation of Duties and Functions*

Prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions.

5.8 *Compensation to Subjects and Investigators*

5.8.1 If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.

5.8.2 The sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s).

5.8.3 When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s).

5.9 *Financing*

The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

5.10 *Notification/Submission to Regulatory Authority(ies)*

Before initiating the clinical trial(s), the sponsor (or the sponsor and the investigator, if required by the applicable regulatory requirement(s)), should submit any required application(s) to the appropriate authority(ies) for review, acceptance, and/or permission (as required by the applicable regulatory requirement(s)) to begin the trial(s). Any notification/submission should be dated and contain sufficient information to identify the protocol.

5.11 *Confirmation of Review by IRB/IEC*

5.11.1 The sponsor should obtain from the investigator/institution:

(a) The name and address of the investigator's/institution's IRB/IEC.

(b) A statement obtained from the IRB/IEC that it is organized and operates according to GCP and the applicable laws and regulations.

(c) Documented IRB/IEC approval/favorable opinion and, if requested by the sponsor, a current copy of protocol, written informed consent form(s) and any other written information to be provided to subjects, subject recruiting procedures, and documents related to payments and compensation available to the subjects, and any other documents that the IRB/IEC may have requested.

5.11.2 If the IRB/IEC conditions its approval/favorable opinion upon change(s) in any aspect of the trial, such as modification(s) of the protocol, written informed consent form and any other written information to be provided to subjects, and/or other procedures, the sponsor should obtain from the investigator/institution a copy of the modification(s) made and the date approval/favorable opinion was given by the IRB/IEC.

5.11.3 The sponsor should obtain from the investigator/institution documentation and dates of any IRB/IEC reapprovals/reevaluations with favorable opinion, and of any withdrawals or suspensions of approval/favorable opinion.

5.12 *Information on Investigational Product(s)*

5.12.1 When planning trials, the sponsor should ensure that sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

5.12.2 The sponsor should update the Investigator's Brochure as significant new information becomes available. (See 7. ''Investigator's Brochure.'')

5.13 *Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)*

5.13.1 The sponsor should ensure that the investigational product(s) (including active comparator(s) and placebo, if applicable) is characterized as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labeled in a manner that protects the blinding, if applicable. In addition, the labeling should comply with applicable regulatory requirement(s).

5.13.2 The sponsor should determine, for the investigational product(s), acceptable storage temperatures, storage conditions (e.g., protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion, if any. The sponsor should inform all involved parties (e.g., monitors, investigators, pharmacists, storage managers) of these determinations.

5.13.3 The investigational product(s) should be packaged to prevent contamination and unacceptable deterioration during transport and storage.

5.13.4 In blinded trials, the coding system for the investigational product(s) should include a mechanism that permits rapid identification of the product(s) in case of a medical emergency, but does not permit undetectable breaks of the blinding.

5.13.5 If significant formulation changes are made in the investigational or comparator product(s) during the course of clinical development, the results of any additional studies of the formulated product(s) (e.g., stability, dissolution rate, bioavailability) needed to assess whether these changes would significantly alter the pharmacokinetic profile of the product should be available prior to the use of the new formulation in clinical trials.

5.14 *Supplying and Handling Investigational Product(s)*

5.14.1 The sponsor is responsible for supplying the investigator(s)/institution(s) with the investigational product(s).

5.14.2 The sponsor should not supply an investigator/institution with the investigational product(s) until the sponsor obtains all required documentation (e.g., approval/favorable opinion from IRB/IEC and regulatory authority(ies)).

5.14.3 The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

5.14.4 The sponsor should:

(a) Ensure timely delivery of investigational product(s) to the investigator(s).

(b) Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s). (See 8. ''Essential Documents for the Conduct of a Clinical Trial.'')

(c) Maintain a system for retrieving investigational products and documenting this retrieval (e.g., for deficient product recall, reclaim after trial completion, expired product reclaim).

(d) Maintain a system for the disposition of unused investigational product(s) and for the documentation of this disposition.

5.14.5 The sponsor should:

(a) Take steps to ensure that the investigational product(s) are stable over the period of use.

(b) Maintain sufficient quantities of the investigational product(s) used in the trials to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and characteristics. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

5.15 *Record Access*

5.15.1 The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) provide direct access to source data/documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection.

5.15.2 The sponsor should verify that each subject has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, audit, IRB/IEC review, and regulatory inspection.

5.16 *Safety Information*

5.16.1 The sponsor is responsible for the ongoing safety evaluation of the investigational product(s).

5.16.2 The sponsor should promptly notify all concerned investigator(s)/institution(s) and the regulatory authority(ies) of findings that could affect adversely the safety of subjects, impact the conduct of the trial, or alter the IRB/IEC's approval/favorable opinion to continue the trial.

5.17 *Adverse Drug Reaction Reporting*

5.17.1 The sponsor should expedite the reporting to all concerned investigator(s)/institutions(s), to the IRB(s)/IEC(s), where required, and to the regulatory authority(ies) of all adverse drug reactions (ADR's) that are both serious and unexpected.

5.17.2 Such expedited reports should comply with the applicable regulatory requirement(s) and with the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

5.17.3 The sponsor should submit to the regulatory authority(ies) all safety updates and periodic reports, as required by applicable regulatory requirement(s).

5.18 *Monitoring*

5.18.1 *Purpose.* The purposes of trial monitoring are to verify that:

(a) The rights and well-being of human subjects are protected.

(b) The reported trial data are accurate, complete, and verifiable from source documents.

(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

5.18.2 *Selection and Qualifications of Monitors.*

(a) Monitors should be appointed by the sponsor.

(b) Monitors should be appropriately trained, and should have the scientific and/or clinical knowledge needed to monitor the trial adequately. A monitor's qualifications should be documented.

(c) Monitors should be thoroughly familiar with the investigational product(s), the protocol, written informed consent form and any other written information to be provided to subjects, the sponsor's SOP's, GCP, and the applicable regulatory requirement(s).

5.18.3 *Extent and Nature of Monitoring.*

The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. In general there is a need for on-site monitoring, before, during, and after the trial; however, in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigators' training and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP. Statistically controlled sampling may be an acceptable method for selecting the data to be verified.

5.18.4 *Monitor's Responsibilities.*

The monitor(s), in accordance with the sponsor's requirements, should ensure that the trial is conducted and documented properly by carrying out the following activities when relevant and necessary to the trial and the trial site:

(a) Acting as the main line of communication between the sponsor and the investigator.

(b) Verifying that the investigator has adequate qualifications and resources (see 4.1, 4.2, 5.6) and these remain adequate throughout the trial period, and that the staff and facilities, including laboratories and equipment, are adequate to safely and properly conduct the trial and these remain adequate throughout the trial period.

(c) Verifying, for the investigational product(s):

(i) That storage times and conditions are acceptable, and that supplies are sufficient throughout the trial.

(ii) That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).

(iii) That subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s).

(iv) That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.

(v) That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor's authorized procedures.

(d) Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.

(e) Verifying that written informed consent was obtained before each subject's participation in the trial.

(f) Ensuring that the investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).

(g) Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.

(h) Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.

(i) Verifying that the investigator is enrolling only eligible subjects.

(j) Reporting the subject recruitment rate.

(k) Verifying that source data/documents and other trial records are accurate, complete, kept up-to-date, and maintained.

(l) Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.

(m) Checking the accuracy and completeness of the CRF entries, source data/documents, and other trial-related records against each other. The monitor specifically should verify that:

(i) The data required by the protocol are reported accurately on the CRF's and are consistent with the source data/documents.

(ii) Any dose and/or therapy modifications are well documented for each of the trial subjects.

(iii) Adverse events, concomitant medications, and intercurrent illnesses are reported in accordance with the protocol on the CRF's.

(iv) Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRF's.

(v) All withdrawals and dropouts of enrolled subjects from the trial are reported and explained on the CRF's.

(n) Informing the investigator of any CRF entry error, omission, or illegibility. The monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialed by the investigator or by a member of the investigator's trial staff who is authorized to initial CRF changes for the investigator. This authorization should be documented.

(o) Determining whether all adverse events (AE's) are appropriately reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, the applicable regulatory requirement(s), and indicated in the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

(p) Determining whether the investigator is maintaining the essential documents. (See 8. ''Essential Documents for the Conduct of a Clinical Trial.'')

(q) Communicating deviations from the protocol, SOP's, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

5.18.5 *Monitoring Procedures.*

The monitor(s) should follow the sponsor's established written SOP's as well as those procedures that are specified by the sponsor for monitoring a specific trial.

5.18.6 *Monitoring Report.*

(a) The monitor should submit a written report to the sponsor after each trial-site visit or trial-related communication.

(b) Reports should include the date, site, name of the monitor, and name of the investigator or other individual(s) contacted.

(c) Reports should include a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken, and/or actions recommended to secure compliance.

(d) The review and follow-up of the monitoring report by the sponsor should be documented by the sponsor's designated representative.

5.19 *Audit*

If or when sponsors perform audits, as part of implementing quality assurance, they should consider:

5.19.1 *Purpose.*

The purpose of a sponsor's audit, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOP's, GCP, and the applicable regulatory requirements.

5.19.2 *Selection and Qualification of Auditors.*

(a) The sponsor should appoint individuals, who are independent of the clinical trial/data collection system(s), to conduct audits.

(b) The sponsor should ensure that the auditors are qualified by training and experience to conduct audits properly. An auditor's qualifications should be documented.

5.19.3 *Auditing Procedures.*

(a) The sponsor should ensure that the auditing of clinical trials/systems is conducted in accordance with the sponsor's written procedures on what to audit, how to audit, the frequency of audits, and the form and content of audit reports.

(b) The sponsor's audit plan and procedures for a trial audit should be guided by the importance of the trial to submissions to regulatory authorities, the number of subjects in the trial, the type and complexity of the trial, the level of risks to the trial subjects, and any identified problem(s).

(c) The observations and findings of the auditor(s) should be documented.

(d) To preserve the independence and value of the audit function, the regulatory authority(ies) should not routinely request the audit reports. Regulatory authority(ies) may seek access to an audit report on a case-by-case basis, when evidence of serious GCP noncompliance exists, or in the course of legal proceedings or investigations.

(e) Where required by applicable law or regulation, the sponsor should provide an audit certificate.

5.20 *Noncompliance*

5.20.1 Noncompliance with the protocol, SOP's, GCP, and/or applicable regulatory requirement(s) by an investigator/institution, or by member(s) of the sponsor's staff should lead to prompt action by the sponsor to secure compliance.

5.20.2 If the monitoring and/or auditing identifies serious and/or persistent noncompliance on the part of an investigator/institution, the sponsor should terminate the investigator's/institution's participation in the trial. When an investigator's/institution's participation is terminated because of noncompliance, the sponsor should notify promptly the regulatory authority(ies).

5.21 *Premature Termination or Suspension of a Trial*

If a trial is terminated prematurely or suspended, the sponsor should promptly inform the investigators/institutions, and the regulatory authority(ies) of the termination or suspension and the reason(s) for the termination or suspension. The IRB/IEC should also be informed promptly and provided the reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s).

5.22 *Clinical Trial/Study Reports*

Whether the trial is completed or prematurely terminated, the sponsor should ensure that the clinical trial/study reports are prepared and provided to the regulatory agency(ies) as required by the applicable regulatory requirement(s). The sponsor should also ensure that the clinical trial/study reports in marketing applications meet the standards of the ICH Guideline for Structure and Content of Clinical Study Reports. (NOTE: The ICH Guideline for Structure and Content of Clinical Study Reports specifies that abbreviated study reports may be acceptable in certain cases.)

5.23 *Multicenter Trials*

For multicenter trials, the sponsor should ensure that:

5.23.1 All investigators conduct the trial in strict compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and given approval/favorable opinion by the IRB/IEC.

5.23.2 The CRF's are designed to capture the required data at all multicenter trial sites. For those investigators who are collecting additional data, supplemental CRF's should also be provided that are designed to capture the additional data.

5.23.3 The responsibilities of the coordinating investigator(s) and the other participating investigators are documented prior to the start of the trial.

5.23.4 All investigators are given instructions on following the protocol, on complying with a uniform set of standards for the assessment of clinical and laboratory findings, and on completing the CRF's.

5.23.5 Communication between investigators is facilitated.

6. *Clinical Trial Protocol and Protocol Amendment(s)*

The contents of a trial protocol should generally include the following topics. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as an Investigator's Brochure.

6.1 *General Information*

6.1.1 Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).

6.1.2 Name and address of the sponsor and monitor (if other than the sponsor).

6.1.3 Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.

6.1.4 Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.

6.1.5 Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

6.1.6 Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable) who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).

6.1.7 Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

6.2 *Background Information*

6.2.1 Name and description of the investigational product(s).

6.2.2 A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.

6.2.3 Summary of the known and potential risks and benefits, if any, to human subjects.

6.2.4 Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).

6.2.5 A statement that the trial will be conducted in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

6.2.6 Description of the population to be studied.

6.2.7 References to literature and data that are relevant to the trial, and that provide background for the trial.

6.3 *Trial Objectives and Purpose*

A detailed description of the objectives and the purpose of the trial.

6.4 *Trial Design*

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design should include:

6.4.1 A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.

6.4.2 A description of the type/design of trial to be conducted (e.g., double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures, and stages.

6.4.3 A description of the measures taken to minimize/avoid bias, including (for example):

(a) Randomization.
(b) Blinding.
6.4.4 A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labeling of the investigational product(s).
6.4.5 The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.
6.4.6 A description of the ''stopping rules'' or ''discontinuation criteria'' for individual subjects, parts of trial, and entire trial.
6.4.7 Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.
6.4.8 Maintenance of trial treatment randomization codes and procedures for breaking codes.
6.4.9 The identification of any data to be recorded directly on the CRF's (i.e., no prior written or electronic record of data), and to be considered to be source data.
6.5 *Selection and Withdrawal of Subjects*
6.5.1 Subject inclusion criteria.
6.5.2 Subject exclusion criteria.
6.5.3 Subject withdrawal criteria (i.e., terminating investigational product treatment/trial treatment) and procedures specifying:
(a) When and how to withdraw subjects from the trial/ investigational product treatment.
(b) The type and timing of the data to be collected for withdrawn subjects.
(c) Whether and how subjects are to be replaced.
(d) The follow-up for subjects withdrawn from investigational product treatment/trial treatment.
6.6 *Treatment of Subjects*
6.6.1 The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.
6.6.2 Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.
6.6.3 Procedures for monitoring subject compliance.
6.7 *Assessment of Efficacy*
6.7.1 Specification of the efficacy parameters.
6.7.2 Methods and timing for assessing, recording, and analyzing efficacy parameters.
6.8 *Assessment of Safety*
6.8.1 Specification of safety parameters.
6.8.2 The methods and timing for assessing, recording, and analyzing safety parameters.
6.8.3 Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.
6.8.4 The type and duration of the follow-up of subjects after adverse events.
6.9 *Statistics*
6.9.1 A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).
6.9.2 The number of subjects planned to be enrolled. In multicenter trials, the number of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
6.9.3 The level of significance to be used.
6.9.4 Criteria for the termination of the trial.
6.9.5 Procedure for accounting for missing, unused, and spurious data.
6.9.6 Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in the protocol and/or in the final report, as appropriate).
6.9.7 The selection of subjects to be included in the analyses (e.g., all randomized subjects, all dosed subjects, all eligible subjects, evaluate-able subjects).
6.10 *Direct Access to Source Data/Documents*
The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s) by providing direct access to source data/documents.
6.11 *Quality Control and Quality Assurance*
6.12 *Ethics*
Description of ethical considerations relating to the trial.
6.13 *Data Handling and Recordkeeping*
6.14 *Financing and Insurance*
Financing and insurance if not addressed in a separate agreement.
6.15 *Publication Policy*
Publication policy, if not addressed in a separate agreement.
6.16 *Supplements*
(NOTE: Since the protocol and the clinical trial/study report are closely related, further relevant information can be found in the ICH Guideline for Structure and Content of Clinical Study Reports.)
7. *Investigator's Brochure*
7.1 *Introduction*
The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration, and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial. The information should be presented in a concise, simple, objective, balanced, and nonpromotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial. For this reason, a medically qualified person should generally participate in the editing of an IB, but the contents of the IB should be approved by the disciplines that generated the described data.
This guideline delineates the minimum information that should be included in an IB and provides suggestions for its layout. It is expected that the type and extent of information available will vary with the stage of development of the investigational product. If the investigational product is marketed and its pharmacology is widely understood by medical practitioners, an extensive IB may not be necessary. Where permitted by regulatory authorities, a basic product information brochure, package leaflet, or labeling may be an appropriate alternative, provided that it includes current, comprehensive, and detailed information on all aspects of the investigational product that might be of importance to the investigator. If a marketed product is being studied for a new use (i.e., a new indication), an IB specific to that new use should be prepared. The IB should be reviewed at least annually and revised as necessary in compliance with a sponsor's written procedures. More frequent revision may be appropriate depending on the stage of development and the generation of relevant new information. However, in accordance with GCP, relevant new information may be so important that it should be communicated to the investigators, and possibly to the Institutional Review Boards (IRB's)/Independent Ethics Committees (IEC's) and/or regulatory authorities before it is included in a revised IB.
Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator(s) and the investigators are responsible for providing the up-to-date IB to the responsible IRB's/IEC's. In the case of an investigator-sponsored trial, the sponsor-investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor-investigator, then he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol that contains the minimum current information described in this guideline.
7.2 *General Considerations*
The IB should include:
7.2.1 *Title Page.* This should provide the sponsor's name, the identity of each investigational product (i.e., research number, chemical or approved generic name, and trade name(s) where legally permissible and desired by the sponsor), and the release date. It is also suggested that an edition number, and a reference to the number and date of the edition it supersedes, be provided. An example is given in Appendix 1.
7.2.2 *Confidentiality Statement.* The sponsor may wish to include a statement instructing the investigator/recipients to treat the IB as a confidential document for the sole information and use of the investigator's team and the IRB/IEC.
7.3 *Contents of the Investigator's Brochure.* The IB should contain the following sections, each with literature references where appropriate:
7.3.1 *Table of Contents.* An example of the Table of Contents is given in Appendix 2.
7.3.2 *Summary.* A brief summary (preferably not exceeding two pages) should be given, highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetic, metabolic,

and clinical information available that is relevant to the stage of clinical development of the investigational product.

7.3.3 *Introduction.* A brief introductory statement should be provided that contains the chemical name (and generic and trade name(s) when approved) of the investigational product(s), all active ingredients, the investigational product(s) pharmacological class and its expected position within this class (e.g., advantages), the rationale for performing research with the investigational product(s), and the anticipated prophylactic, therapeutic, or diagnostic indication(s). Finally, the introductory statement should provide the general approach to be followed in evaluating the investigational product.

7.3.4 *Physical, Chemical, and Pharmaceutical Properties and Formulation.* A description should be provided of the investigational product substance(s) (including the chemical and/or structural formula(e)), and a brief summary should be given of the relevant physical, chemical, and pharmaceutical properties.

To permit appropriate safety measures to be taken in the course of the trial, a description of the formulation(s) to be used, including excipients, should be provided and justified if clinically relevant. Instructions for the storage and handling of the dosage form(s) should also be given.

Any structural similarities to other known compounds should be mentioned.

7.3.5 *Nonclinical Studies.*

Introduction:

The results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies should be provided in summary form. This summary should address the methodology used, the results, and a discussion of the relevance of the findings to the investigated therapeutic and the possible unfavorable and unintended effects in humans.

The information provided may include the following, as appropriate, if known/available:

Species tested;

Number and sex of animals in each group;

Unit dose (e.g., milligram/kilogram (mg/kg));

Dose interval;

Route of administration;

Duration of dosing;

Information on systemic distribution;

Duration of post-exposure follow-up;

Results, including the following aspects:

- Nature and frequency of pharmacological or toxic effects;
- Severity or intensity of pharmacological or toxic effects;
- Time to onset of effects;
- Reversibility of effects;
- Duration of effects;
- Dose response.

Tabular format/listings should be used whenever possible to enhance the clarity of the presentation.

The following sections should discuss the most important findings from the studies, including the dose response of observed effects, the relevance to humans, and any aspects to be studied in humans. If applicable, the effective and nontoxic dose findings in the same animal species should be compared (i.e., the therapeutic index should be discussed). The relevance of this information to the proposed human dosing should be addressed. Whenever possible, comparisons should be made in terms of blood/tissue levels rather than on a mg/kg basis.

(a) Nonclinical Pharmacology

A summary of the pharmacological aspects of the investigational product and, where appropriate, its significant metabolites studied in animals should be included. Such a summary should incorporate studies that assess potential therapeutic activity (e.g., efficacy models, receptor binding, and specificity) as well as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect(s)).

(b) Pharmacokinetics and Product Metabolism in Animals

A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species studied should be given. The discussion of the findings should address the absorption and the local and systemic bioavailability of the investigational product and its metabolites, and their relationship to the pharmacological and toxicological findings in animal species.

(c) Toxicology

A summary of the toxicological effects found in relevant studies conducted in different animal species should be described under the following headings where appropriate:

Single dose;

Repeated dose;

Carcinogenicity;

Special studies (e.g., irritancy and sensitization);

Reproductive toxicity;

Genotoxicity (mutagenicity).

7.3.6 *Effects in Humans.*

Introduction:

A thorough discussion of the known effects of the investigational product(s) in humans should be provided, including information on pharmacokinetics, metabolism, pharmacodynamics, dose response, safety, efficacy, and other pharmacological activities. Where possible, a summary of each completed clinical trial should be provided. Information should also be provided regarding results from any use of the investigational product(s) other than in clinical trials, such as from experience during marketing.

(a) Pharmacokinetics and Product Metabolism in Humans

A summary of information on the pharmacokinetics of the investigational product(s) should be presented, including the following, if available:

Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination).

Bioavailability of the investigational product (absolute, where possible, and/or relative) using a reference dosage form.

Population subgroups (e.g., gender, age, and impaired organ function).

Interactions (e.g., product-product interactions and effects of food).

Other pharmacokinetic data (e.g., results of population studies performed within clinical trial(s)).

(b) Safety and Efficacy

A summary of information should be provided about the investigational product's/products' (including metabolites, where appropriate) safety, pharmacodynamics, efficacy, and dose response that were obtained from preceding trials in humans (healthy volunteers and/or patients). The implications of this information should be discussed. In cases where a number of clinical trials have been completed, the use of summaries of safety and efficacy across multiple trials by indications in subgroups may provide a clear presentation of the data. Tabular summaries of adverse drug reactions for all the clinical trials (including those for all the studied indications) would be useful. Important differences in adverse drug reaction patterns/incidences across indications or subgroups should be discussed.

The IB should provide a description of the possible risks and adverse drug reactions to be anticipated on the basis of prior experiences with the product under investigation and with related products. A description should also be provided of the precautions or special monitoring to be done as part of the investigational use of the product(s).

(c) Marketing Experience

The IB should identify countries where the investigational product has been marketed or approved. Any significant information arising from the marketed use should be summarized (e.g., formulations, dosages, routes of administration, and adverse product reactions). The IB should also identify all the countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.

7.3.7 *Summary of Data and Guidance for the Investigator.*

This section should provide an overall discussion of the nonclinical and clinical data, and should summarize the information from various sources on different aspects of the investigational product(s), wherever possible. In this way, the investigator can be provided with the most informative interpretation of the available data and with an assessment of the implications of the information for future clinical trials.

Where appropriate, the published reports on related products should be discussed. This could help the investigator to anticipate adverse drug reactions or other problems in clinical trials.

The overall aim of this section is to provide the investigator with a clear understanding of the possible risks and adverse reactions, and of the specific tests, observations, and precautions that may be needed for a clinical trial. This understanding should be based on the available physical, chemical, pharmaceutical, pharmacological, toxicological, and clinical information on the investigational product(s). Guidance should also be provided to the clinical investigator on the recognition and treatment of possible overdose and adverse drug reactions that is based on previous human experience and on

the pharmacology of the investigational product.

7.4 *Appendix 1:*

TITLE PAGE OF INVESTIGATOR'S BROCHURE (Example)

Sponsor's Name:

Product:

Research Number:

Name(s): Chemical, Generic (if approved)

Trade Name(s) (if legally permissible and desired by the sponsor)

Edition Number:

Release Date:

Replaces Previous Edition Number:

Date:

7.5 *Appendix 2:*

TABLE OF CONTENTS OF INVESTIGATOR'S BROCHURE (Example)

- Confidentiality Statement (optional)–
- Signature Page (optional)–

1. Table of Contents –
2. Summary –
3. Introduction –
4. Physical, Chemical, and Pharmaceutical Properties and Formulation –
5. Nonclinical Studies –
5.1 Nonclinical Pharmacology –
5.2 Pharmacokinetics and Product Metabolism in Animals
5.3 Toxicology
6. Effects in Humans
6.1 Pharmacokinetics and Product Metabolism in Humans
6.2 Safety and Efficacy
6.3 Marketing Experience
7. Summary of Data and Guidance for the Investigator

NB: References on

1. Publications
2. Reports

These references should be found at the end of each chapter.

Appendices (if any)

8. *Essential Documents for the Conduct of a Clinical Trial*

8.1 *Introduction*

Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements.

Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor, and monitor. These documents are also the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

The minimum list of essential documents that has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated: (1) Before the clinical phase of the trial commences, (2) during the clinical conduct of the trial, and (3) after completion or termination of the trial. A description is given of the purpose of each document, and whether it should be filed in either the investigator/institution or sponsor files, or both. It is acceptable to combine some of the documents, provided the individual elements are readily identifiable.

Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the appropriate files.

Any or all of the documents addressed in this guideline may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

8.2 *Before the Clinical Phase of the Trial Commences*

During this planning stage the following documents should be generated and should be on file before the trial formally starts.

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.2.1	Investigator's brochure	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X
8.2.2	Signed protocol and amendments, if any, and sample case report form (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF	X	X
8.2.3	Information given to trial subject - Informed consent form (Including all applicable translations)	To document the informed consent	X	X
	- Any other written information	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent	X	X
	- Advertisement for subject recruitment (if used)	To document that recruitment measures are appropriate and not coercive	X	
8.2.4	Financial aspects of the trial	To document the financial agreement between the investigator/institution and the sponsor for the trial	X	X
8.2.5	Insurance statement (where required)	To document that compensation to subject(s) for trial-related injury will be available	X	X
8.2.6	Signed agreement between involved parties, e.g.:	To document agreements		
	- Investigator/institution and sponsor		X	X
	- Investigator/institution and CRO		X	X (Where required)
	- Sponsor and CRO			X
	- Investigator/institution and authority(ies) (Where required)		X	X

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.2.7	Dated, documented approval/favorable opinion of IRB/IEC of the following: - Protocol and any amendments - CRF (if applicable) - Informed consent form(s) - Any other written information to be provided to the subject(s) - Advertisement for subject recruitment (if used) - Subject compensation (if any) - Any other documents given approval/favorable opinion	To document that the trial has been subject to IRB/IEC review and given approval/favorable opinion. To identify the version number and date of the document(s).	X	X
8.2.8	Institutional review board/independent ethics committee composition	To document that the IRB/IEC is constituted in agreement with GCP	X	X (where required)
8.2.9	Regulatory authority(ies) authorization/approval/notification of protocol (where required)	To document appropriate authorization/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	X (where required)	X (where required)
8.2.10	Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and subinvestigators	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	X	X
8.2.11	Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol	To document normal values and/or ranges of the tests	X	X
8.2.12	Medical/laboratory/technical procedures/tests - Certification or - Accreditation or - Established quality control and/or external quality assessment or - Other validation (where required)	To document competence of facility to perform required test(s), and support reliability of results	X (where required)	X
8.2.13	Sample of label(s) attached to investigational product container(s)	To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects	X	X
8.2.14	Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or Investigator's Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of investigational products and trial-related materials	X	X
8.2.15	Shipping records for investigational product(s) and trial-related materials	To document shipment dates, batch numbers, and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability.	X	X
8.2.16	Certificate(s) of analysis of investigational product(s) shipped	To document identity, purity, and strength of investigational products to be used in the trial.		X
8.2.17	Decoding procedures for blinded trials	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment	X	X (third party if applicable)
8.2.18	Master randomization list	To document method for randomization of trial population		X (third party if applicable)
8.2.19	Pretrial monitoring report	To document that the site is suitable for the trial (may be combined with 8.2.20)		X
8.2.20	Trial initiation monitoring report	To document that trial procedures were reviewed with the investigator and investigator's trial staff (may be combined with 8.2.19)	X	X

8.3 *During the Clinical Conduct of the Trial*

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.3.1	Investigator's Brochure updates	To document that investigator is informed in a timely manner of relevant information as it becomes available	X	X
8.3.2	Any revisions to: - Protocol/amendment(s) and CRF - Informed consent form - Any other written information provided to subjects - Advertisement for subject recruitment (if used)	To document revisions of these trial-related documents that take effect during trial	X	X
8.3.3	Dated, documented approval/favorable opinion of institutional review board (IRB)/independent ethics committee (IEC) of the following: - Protocol amendment(s) - Revision(s) of: - Informed consent form - Any other written information to be provided to the subject - Advertisement for subject recruitment (if used) - Any other documents given approval/favorable opinion - Continuing review of trial (see 3.1.4)	To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favorable opinion. To identify the version number and date of the document(s)	X	X
8.3.4	Regulatory authority(ies) authorizations/approvals/notifications where required for: - Protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements	X (where required)	X
8.3.5	Curriculum vitae for new investigator(s) and/or subinvestigators	(See 8.2.10)	X	X
8.3.6	Updates to normal value(s)/range(s) for medical laboratory/technical procedure(s)/test(s) included in the protocol	To document normal values and ranges that are revised during the trial (see 8.2.11)	X	X
8.3.7	Updates of medical/laboratory/technical procedures/tests - Certification or - Accreditation or - Established quality control and/or external quality assessment or - Other validation (where required)	To document that tests remain adequate throughout the trial period (see 8.2.12)	X (where required)	X
8.3.8	Documentation of investigational product(s) and trial-related materials shipment	(See 8.2.15)	X	X
8.3.9	Certificate(s) of analysis for new batches of investigational products	(See 8.2.16)		X
8.3.10	Monitoring visit reports	To document site visits by, and findings of, the monitor		X
8.3.11	Relevant communications other than site visits - Letters - Meeting notes - Notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	X	X
8.3.12	Signed informed consent forms	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission (see 8.2.3)	X	
8.3.13	Source documents	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject	X	
8.3.14	Signed, dated, and completed case report forms (CRF's)	To document that the investigator or authorized member of the investigator's staff confirms the observations recorded	X (copy)	X (original)

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.3.15	Documentation of CRF corrections	To document all changes/additions or corrections made to CRF after initial data were recorded	X (copy)	X (original)
8.3.16	Notification by originating investigator to sponsor of serious adverse events and related reports	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with 4.11	X	X
8.3.17	Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s)/IEC(s) of unexpected serious adverse drug reactions and of other safety information	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions in accordance with 5.17 and 4.11.1 and of other safety information in accordance with 4.11.2 and 5.16.2	X (where required)	X
8.3.18	Notification by sponsor to investigators of safety information	Notification by sponsor to investigators of safety information in accordance with 5.16.2	X	X
8.3.19	Interim or annual reports to IRB/IEC and authority(ies)	Interim or annual reports provided to IRB/IEC in accordance with 4.10 and to authority(ies) in accordance with 5.17.3	X	X (where required)
8.3.20	Subject screening log	To document identification of subjects who entered pretrial screening	X	X (where required)
8.3.21	Subject identification code list	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject	X	
8.3.22	Subject enrollment log	To document chronological enrollment of subjects by trial number	X	
8.3.23	Investigational product(s) accountability at the site	To document that investigational products(s) have been used according to the protocol	X	X
8.3.24	Signature sheet	To document signatures and initials of all persons authorized to make entries and/or corrections on CRF's	X	X
8.3.25	Record of retained body fluids/tissue samples (if any)	To document location and identification of retained samples if assays need to be repeated	X	X

8.4 *After Completion or Termination of the Trial*

After completion or termination of the trial, all of the documents identified in sections 8.2 and 8.3 should be in the file together with the following:

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.4.1	Investigational product(s) accountability at site	To document that the investigational product(s) have been used according to the protocol. To document the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor	X	X
8.4.2	Documentation of investigational product(s) destruction	To document destruction of unused investigational product(s) by sponsor or at site	X (if destroyed at site)	X
8.4.3	Completed subject identification code list	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time	X	
8.4.4	Audit certificate (if required)	To document that audit was performed (if required) (see 5.19.3(e))		X
8.4.5	Final trial close-out monitoring report	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files		X

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.4.6	Treatment allocation and decoding documentation	Returned to sponsor to document any decoding that may have occurred		X
8.4.7	Final report by investigator/institution to IRB/IEC where required, and where applicable, to the regulatory authority(ies) (see 4.13)	To document completion of the trial	X	
8.4.8	Clinical study report (see 5.22)	To document results and interpretation of trial	X (if applicable)	X

Dated: April 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12138 Filed 5–8–97; 8:45 am]

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federal register

Friday
May 9, 1997

Part III

Department of Health and Human Services

Food and Drug Administration

International Conference on Harmonisation; Draft Guideline on Statistical Principles for Clinical Trials; Notice of Availability

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0174]

International Conference on Harmonisation; Draft Guideline on Statistical Principles for Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline entitled ''Statistical Principles for Clinical Trials.'' The draft guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline is intended to provide recommendations to sponsors and scientific experts regarding statistical principles and methodology which, when applied to clinical trials for marketing applications, will facilitate the general acceptance of analyses and conclusions drawn from the trials.

DATES: Written comments by June 23, 1997.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the draft guideline are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the draft guideline may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448 or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Robert T. O'Neill, Center for Drug Evaluation and Research (HFD–700), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3195.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

On January 17, 1997, the ICH Steering Committee agreed that a draft guideline entitled ''Statistical Principles for Clinical Trials'' should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the other regulatory agency members of the Efficacy Expert Working Group.

The draft guideline addresses principles of statistical methodology applied to clinical trials for marketing applications. The draft guideline provides recommendations to sponsors in the design, conduct, analysis, and evaluation of clinical trials of an investigational product in the context of its overall clinical development. The draft guideline also provides guidance to scientific experts in preparing application summaries or assessing evidence of efficacy and safety, principally from late Phase II and Phase III clinical trials. Application of the principles of statistical methodology is intended to facilitate the general acceptance of analyses and conclusions drawn from clinical trials.

This draft guideline represents the agency's current thinking on statistical principles for clinical trials of drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before June 23, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guideline. 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. The draft guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this draft guideline is available on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cder/guidance.htm) or through the CBER home page (http://www.fda.gov/cber/cberftp.html).

The text of the draft guideline follows:

Statistical Principles for Clinical Trials

Note: A Glossary of terms and definitions is provided as an annex to this guideline.

Table of Contents

I. Introduction
1.1 Background and Purpose
1.2 Scope and Direction
II. Considerations for Overall Clinical Development
2.1 Study Context
2.1.1 Development Plan
2.1.2 Confirmatory Trial
2.1.3 Exploratory Trial
2.2 Study Scope
2.2.1 Population
2.2.2 Primary and Secondary Variables
2.3 Design Techniques to Avoid Bias
2.3.1 Blinding
2.3.2 Randomization
III. Study Design Considerations
3.1 Study Configuration
3.1.1 Parallel Group Design
3.1.2 Cross-Over Design
3.1.3 Factorial Designs

3.2 Multicenter Trials
3.3 Type of Comparison
3.3.1 Trials to Show Superiority
3.3.2 Trials to Show Equivalence or Non-inferiority
3.3.3 Dose-Response Designs
3.4 Group Sequential Designs
3.5 Sample Size
3.6 Data Capture and Processing
IV. Study Conduct
4.1 Trial Monitoring
4.2 Changes in Inclusion and Exclusion Criteria
4.3 Accrual Rates
4.4 Sample Size Adjustment
4.5 Interim Analysis and Early Stopping
4.6 Role of Independent Data Monitoring Committee (IDMC)
V. Data Analysis
5.1 Prespecified Analysis Plan
5.2 Analysis Sets
5.2.1 All Randomized Subjects
5.2.2 Per Protocol Subjects
5.2.3 Roles of the All Randomized Subjects Analysis and the Per Protocol Analysis
5.3 Missing Values and Outliers
5.4 Data Transformation/Modification
5.5 Estimation, Confidence Intervals and Hypothesis Testing
5.6 Adjustment of Type I Error and Confidence Levels
5.7 Subgroups, Interactions and Covariates
5.8 Integrity of Data and Computer Software
VI. Evaluation of Safety and Tolerability
6.1 Scope of Evaluation
6.2 Choice of Variables and Data Collection
6.3 Set of Subjects to be Evaluated and Presentation of Data
6.4 Statistical Evaluation
6.5 Single Study versus Integrated Summary
VII. Reporting
7.1 Evaluation and Reporting
7.2 Summarizing the Clinical Database
7.2.1 Efficacy Data
7.2.2 Safety Data
Annex 1 Glossary

I. Introduction

1.1 Background and Purpose

The efficacy and safety of medicinal products should be demonstrated by clinical trials that follow the guidance in ''Good Clinical Practice: Consolidated Guideline (E6)'' adopted by the ICH, May 1, 1996. The role of statistics in clinical trial design and analysis is acknowledged as essential in that ICH guideline. The proliferation of statistical research in the area of clinical trials coupled with the critical role of clinical research in the drug approval process and health care in general necessitate a succinct document on statistical issues related to clinical trials. This guideline is written primarily to attempt to harmonize the principles of statistical methodology applied to clinical trials for marketing applications submitted in Europe, Japan, and the United States.

As a starting point, this guideline utilized the CPMP (Committee for Proprietary Medicinal Products) Note for Guidance entitled ''Biostatistical Methodology in Clinical Trials in Applications for Marketing Authorizations for Medicinal Products'' (December 1994). It was also influenced by ''Guidelines on the Statistical Analysis of Clinical Studies'' (March 1992) from the Japanese Ministry of Health and Welfare and the U.S. FDA document entitled ''Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications'' (July 1988). Some topics related to statistical principles and methodology are also embedded within other ICH guidelines, particularly those listed below. The specific guideline that contains related text will be identified in various sections of this document.

E1: The Extent of Population Exposure to Assess Clinical Safety

E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

E2B: Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

E2C: Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs

E3: Structure and Content of Clinical Study Reports

E4: Dose-Response Information to Support Drug Registration

E5: Ethnic Factors in the Acceptability of Foreign Clinical Data

E6: Good Clinical Practice: Consolidated Guideline

E7: Studies in Support of Special Populations: Geriatrics

E8: General Considerations for Clinical Trials

E10: Choice of Control Group in Clinical Trials

M1: Standardization of Medical Terminology for Regulatory Purposes

M3: Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals

This guideline is intended to give direction to sponsors in the design, conduct, analysis, and evaluation of clinical trials of an investigational product in the context of its overall clinical development. The document will also assist scientific experts charged with preparing application summaries or assessing evidence of efficacy and safety, principally from late Phase II and Phase III clinical trials.

1.2 Scope and Direction

The focus of this guideline is on statistical principles. It does not address the use of specific statistical procedures or methods. Specific procedural steps to ensure that principles are implemented properly are the responsibility of the sponsor. Integration of data across clinical trials is discussed, but is not a primary focus of this guideline. Selected principles and procedures related to data management or clinical trial monitoring activities are covered in other ICH guidelines and are not addressed here.

This guideline should be of interest to individuals from a broad range of scientific disciplines. However, it is assumed that the actual responsibility for all statistical work associated with clinical trials will lie with an appropriately qualified and experienced statistician, as indicated in the ''ICH Guideline for Good Clinical Practice.'' The involvement of the statistician, in collaboration with other clinical trial professionals, is to ensure that statistical principles are applied appropriately in clinical trials supporting drug development. Thus, the statistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guideline.

All important details of the design, conduct, and proposed analysis of each clinical trial contributing to a marketing application should be clearly specified in a protocol written before the trial begins. The extent to which the procedures in the protocol are followed and the primary analysis is planned a priori will contribute to the degree of confidence in the final results and conclusions of the trial. The protocol and subsequent amendments should be approved by the responsible personnel, including the trial statistician. The trial statistician should ensure that the protocol and any amendments cover all relevant statistical issues clearly and accurately, using technical terminology as appropriate.

The principles outlined in this guideline are primarily relevant to clinical trials conducted in the later phases of development, many of which are confirmatory trials of efficacy. In addition to efficacy, confirmatory trials may have as their primary variable a safety variable (e.g., an adverse event, a clinical laboratory variable, or an electrocardiographic measure) or a pharmacodynamic or pharmacokinetic variable (as in a confirmatory bioequivalence trial). Furthermore, some confirmatory findings may be derived from data integrated across studies, and selected principles in this guideline are applicable in this situation. Finally, although the early phases of drug development consist mainly of clinical trials that are exploratory in nature, statistical principles are also relevant to these clinical trials. Hence, the substance of this document should be applied as far as possible to all phases of clinical development.

Many of the principles delineated in this guideline deal with minimizing bias and maximizing precision. As used in this guideline, the term ''bias'' describes the systematic tendency of any factors associated with the design, conduct, analysis, and interpretation of the results of clinical trials to make the estimate of a treatment effect deviate from its true value. It is important to identify potential sources of bias to the extent possible so that attempts to limit such bias may be made. The presence of bias may seriously compromise the ability to draw valid conclusions from clinical studies.

Some sources of bias arise from the design of the trial, for example an assignment of treatments such that subjects at lower risk are systematically assigned to one treatment. Other sources of bias arise during the conduct and analysis of a clinical trial. For example, protocol violations and exclusion of subjects from analysis based upon knowledge of subject outcomes are possible sources of bias that may affect the accurate assessment of treatment effect. Because bias can occur in subtle or unknown ways and its effect is not measurable directly, it is important to evaluate the robustness of the results and

primary conclusions of the trial. Robustness is a concept that refers to the sensitivity of the overall conclusions to various limitations of the data, assumptions, and analytic approaches to data analysis. Robustness implies that, if a variety of analyses of the data that take into account changing assumptions were to be performed, the treatment effect and primary conclusions of the trial would be consistent. The interpretation of statistical measures of uncertainty of the treatment effect and treatment comparisons should involve consideration of the potential contribution of bias to the p-value, confidence interval, or inference.

This guideline largely refers to the use of frequentist methods when discussing hypothesis testing and/or confidence intervals. However, the use of Bayesian or other approaches may be considered when the reasons for their use are clear and when the resulting conclusions are sufficiently robust compared to alternative assumptions.

II. Considerations for Overall Clinical Development

2.1 Study Context

2.1.1 Development Plan

The broad aim of the process of clinical development of a new drug is to find out whether there is a dose range and schedule at which the drug can be shown to be simultaneously safe and effective, to the extent that the risk-benefit relationship is acceptable. The particular subjects who may benefit from the drug and the specific indications for its use also need to be defined.

Satisfying these broad aims usually requires an ordered program of clinical trials, each with its own specific objectives. This should be specified in a clinical plan, or a series of plans, with appropriate decision points and flexibility to allow modification as knowledge accumulates. A marketing application should clearly describe the main content of such plans, and the contribution made by each trial. Interpretation and assessment of the evidence from the total program of trials involves synthesis of the evidence from the individual trials (see section 7.2). This is facilitated by ensuring that common standards are adopted for a number of features of the trials, such as dictionaries of medical terms, definition and timing of the main measurements, handling of protocol deviations, and so on. A statistical overview or meta-analysis may be informative when medical questions are addressed in more than one trial. Where possible, this should be envisaged in the plan so that the relevant trials are clearly identified and any necessary common features of their designs are specified in advance. Other major statistical issues (if any) that are expected to affect a number of trials in a common plan should be addressed in that plan.

2.1.2 Confirmatory Trial

A confirmatory trial is a controlled trial in which a hypothesis is stated in advance and evaluated. As a rule, confirmatory trials are necessary to provide firm evidence of efficacy or safety. In such trials, the key hypothesis of interest follows directly from the trial's primary objective, is always predefined, and is the hypothesis that is subsequently tested when the trial is complete. In a confirmatory trial, it is equally important to estimate with due precision the size of the effects attributable to the treatment of interest and to relate these effects to their clinical significance.

Confirmatory trials are intended to provide firm evidence in support of claims. Therefore, adherence to their planned design and procedures is particularly important; unavoidable changes should be explained and documented, and their effect examined. A justification of the design of each such trial and of all other statistical aspects, such as the planned analysis, should be set out in the protocol. Each trial should address only a limited number of questions.

Firm evidence in support of claims requires that the results of the confirmatory trials demonstrate that the investigational product under test has clinical benefits. The confirmatory trials should therefore be sufficient to answer each key clinical question relevant to the efficacy or safety claim clearly and definitively. In addition, it is important that the basis for generalization to the intended patient population is understood and explained; this may also influence the number and type of centers and/or trials needed. The results of the confirmatory trial(s) should be robust. In some circumstances, the weight of evidence from a single confirmatory trial may be sufficient.

2.1.3 Exploratory Trial

The rationale and design of confirmatory trials nearly always rests on earlier clinical work carried out in a series of exploratory studies. Like all clinical trials, these exploratory studies should have clear and precise objectives. However, in contrast to confirmatory trials, their objectives may not always lead to simple tests of predefined hypotheses. In addition, exploratory trials may sometimes require a more flexible approach to design so that changes can be made in response to accumulating results. Their analysis may entail data exploration; tests of hypothesis may be carried out, but the choice of hypothesis may be data dependent. Such trials cannot be the basis of the formal proof of efficacy, although they may contribute to the total body of relevant evidence.

Any individual trial may have both confirmatory and exploratory aspects. For example, in most confirmatory trials the data are also subjected to exploratory analyses which serve as a basis for explaining or supporting their findings and for suggesting further hypotheses for later research. The protocol should make a clear distinction between the aspects of a trial that will be used for confirmatory proof and the aspects that will provide data for exploratory analysis.

2.2 Study Scope

2.2.1 Population

In the earlier phases of drug development, the choice of subjects for a clinical trial may be heavily influenced by the wish to maximize the chance of observing specific clinical effects of interest. Hence, they may come from a very narrow subgroup of the total patient population for which the drug may eventually be indicated. However, by the time the confirmatory trials are undertaken, the subjects in the trials should more closely mirror the intended users. In these trials, it is generally helpful to relax the inclusion and exclusion criteria as much as possible within the target indication, while maintaining sufficient homogeneity to permit a successful trial to be carried out. No individual clinical trial can be expected to be totally representative of future users because of the possible influences of geographical location, the time when it is conducted, the medical practices of the particular investigator(s) and clinics, and so on. However, the influence of such factors should be reduced wherever possible and subsequently discussed during the interpretation of the trial results.

2.2.2 Primary and Secondary Variables

The primary variable (''target'' variable, primary endpoint) should be the variable capable of providing the most clinically relevant and convincing evidence directly related to the primary objective of the trial. There should generally be only one primary variable. This will usually be an efficacy variable, because the primary objective of most confirmatory trials is to provide strong scientific evidence regarding efficacy. Safety/tolerability may sometimes be the primary variable, and will always be an important consideration. Measurements relating to quality of life and health economics are further potential primary variables. The selection of the primary variable should reflect the accepted norms and standards in the relevant field of research. The use of a reliable and validated variable with which experience has been gained either in earlier studies or in published literature is recommended. There should be sufficient evidence that the primary variable can provide a valid and reliable measure of some clinically relevant and important treatment benefit in the subject population described by the inclusion and exclusion criteria. The primary variable should generally be the one used when estimating the sample size (see section 3.5).

In many cases, and especially when treatment is directed at a chronic rather than an acute process, the approach to assessing subject outcome may not be straightforward and should be carefully defined. For example, it is inadequate to specify mortality as a primary variable without further clarification; mortality may be assessed by comparing proportions alive at fixed points in time, or by comparing overall distributions of survival times over a specified interval. Another common example is a recurring outcome. The measure of treatment effect may again be a simple dichotomous variable (any occurrence during a specified interval), time to first occurrence, or rate of occurrence (events per time units of observation), to give a few possibilities. The assessment of functional status over time in studying treatment for chronic disease presents other challenges in selection of the primary variable. There are many possible

approaches, such as comparisons of the assessments done at the beginning and end of the interval of observation, comparison of slopes calculated from all assessments throughout the interval, or comparisons of the proportions of subjects exceeding or declining beyond a prespecified threshold. To avoid multiplicity concerns, it is critical to specify in the protocol the precise definition of the primary variable as it will be used in the statistical analysis. In addition, the clinical relevance of the specific primary variable selected and the validity of the associated measurement procedures will generally need to be addressed and justified in the protocol.

The primary variable should be specified in the protocol, along with the rationale for its selection. Redefinition of the primary variable after unblinding will almost always be unacceptable, since the biases this introduces are difficult to assess. When relevant, the validity and reliability of the primary variable should be described. Secondary variables are either supportive measurements related to the primary objective or measurements of effects related to the secondary objectives. Their predefinition in the protocol is also important, as well as an explanation of their relative importance and roles in interpretation of trial results. When the clinical effect defined by the primary objective is to be measured in more than one way, the protocol should identify one of the measurements as the primary variable on the basis of clinical relevance, importance, objectivity, and/or other relevant characteristics, whenever such selection is feasible. Another strategy that may be useful in some situations is to integrate or combine the multiple measurements into a single or ''composite'' variable, using a predefined algorithm. Indeed, the primary variable sometimes arises as a combination of multiple clinical measurements (e.g., the rating scales used in arthritis, psychiatric disorders, and elsewhere). This approach addresses the multiplicity problem without requiring adjustment for multiple comparisons. The method of combining the multiple measurements should be specified in the protocol, and an interpretation of the resulting scale should be provided in terms of the size of a clinically relevant benefit. When composite variables are used as primary variables, the individual components of these variables are often analyzed separately. When a rating scale is used as a primary variable, it is especially important to address factors such as content validity, inter- and intrarater reliability, and sensitivity for discriminating different medical conditions.

In some cases, ''global assessment'' variables are developed to measure the overall safety, overall efficacy, and/or overall usefulness of a treatment. This type of variable integrates objective variables and the investigator's overall impression about the state or change in the state of the subject, and is usually a scale of ordered categorical ratings. Global assessments of overall effectiveness are well established in many therapeutic areas, especially psychotropic drugs and nonsteroidal anti-inflammatory drugs.

Global assessment variables generally have a subjective component. When a global assessment scale is used as a primary or secondary variable, fuller details should be included in the protocol with respect to:

(1) The relevance of the global scale to the primary objective of the trial;

(2) The basis for the validity of the scale;

(3) How to utilize the data collected on an individual subject to assign him/her to a unique category of the global assessment scale;

(4) How to uniquely categorize subjects with missing data.If objective variables are considered by the investigator when making a global assessment, then those objective variables should be considered additional primary or, at least, important secondary variables.

Overall usefulness integrates components of both benefit and risk and reflects the decisionmaking process of the treating physician, who must weigh benefit and risk in making product use decisions. A problem with global usefulness scales is that their use could in some cases lead to the result of two products being declared equivalent despite having very different profiles of beneficial and adverse effects. For example, judging the global usefulness of a treatment as equivalent or superior to an alternative may mask the fact that it has little or no efficacy but fewer adverse effects. Therefore, if usefulness is used as a primary variable, it is important to consider specific efficacy and safety outcomes separately as additional primary variables.

It may sometimes be desirable to use more than one primary variable, each of which (or a subset of which) could be a sufficient basis for marketing approval, to cover the range of effects of the therapies. The planned manner of interpretation of this type of evidence should be carefully spelled out. For example, it should be clear whether an impact on any of the variables, some minimum number of them, or all of them, would be considered necessary for approval. The primary hypothesis or hypotheses should be clearly stated with respect to the primary variables identified and the approach to testing the hypotheses described. This should include specification of the statistical parameters being tested (e.g., mean, percentage, distribution). The effect on the Type I error should be explained because of the potential for multiple comparison problems (see section 5.6); the method of controlling Type I error should be given in the protocol. The extent of intercorrelation among the proposed primary variables may be considered in evaluating the impact on Type I error. If the success of the trial depends upon demonstrating effects on all of the designated primary variables, then there is no need for adjustment of the Type I error, but the impact on Type II error and sample size needs should be carefully considered.

When direct assessment of the clinical benefit to the subject through observing actual clinical efficacy is not practical, indirect criteria (surrogate variables) may be considered. Commonly accepted surrogate variables are used in a number of indications where they are believed to be reliable predictors of clinical benefit. There are two principal concerns with the introduction of any proposed surrogate variable. First, it may not be a true predictor of the clinical outcome of interest. For example, it may measure treatment activity along one particular pathway, but may not provide full information on the range of actions and ultimate effects of the treatment, whether positive or negative. There have been many instances where treatments showing a highly positive effect on a proposed surrogate have ultimately been shown to be detrimental to the subjects' clinical status; conversely, there are cases of treatments conferring clinical benefit without measurable impact on proposed surrogates. Additionally, proposed surrogate variables may not yield a quantitative measure of clinical benefit that can be weighed directly against adverse effects. Statistical criteria for validating surrogate variables have been proposed, but the experience with their use is relatively limited. In practice, the strength of the evidence for surrogacy depends upon the biological plausibility of the relationship, the demonstration in epidemiological studies of the prognostic value of the surrogate for the clinical outcome, and evidence from clinical trials that treatment effects on the surrogate correspond to effects on the clinical outcome. Relationships between clinical and surrogate variables for one product do not necessarily apply to a product with a different mode of action for treating the same disease.

Dichotomization or other categorization of continuous or ordinal variables may sometimes be desirable. Criteria of ''success'' and ''response'' are common examples of dichotomies that should be specified precisely in terms of, for example, a minimum percentage improvement (relative to baseline) in a continuous variable or a ranking categorized as at or above some threshold level (e.g., ''good'') on an ordinal rating scale. The reduction of diastolic blood pressure below 90 mmHg is a common dichotomization. Categorizations are most useful when they have clear clinical relevance. The criteria for categorization should be predefined and specified in the protocol, as knowledge of trial results could easily bias the choice of such criteria. Because categorization normally implies a loss of information, a consequence will be a loss of power in the analysis; this should be accounted for in the sample size calculation.

2.3 Design Techniques to Avoid Bias

The two most important design techniques for avoiding bias in clinical trials are blinding and randomization, and these should be a normal feature of most controlled clinical trials intended to be included in a marketing application. Most such trials follow a double-blind approach in which treatments are prepacked in accordance with a suitable randomization schedule and supplied to the trial center(s) labeled only with the subject number and the treatment period, so that no one involved in the conduct of the trial is aware of the specific treatment allocated to any particular subject, not even as a code letter. This approach will be assumed in section 2.3.1 and most of section 2.3.2, exceptions being considered at the end. The protocol should also specify

procedures aimed at minimizing any anticipated irregularities in study conduct that might impair a satisfactory analysis, including various types of protocol violations, withdrawals, and missing values. The protocol should consider ways both to reduce frequency of such problems and to handle the problems that do occur in the analysis of data.

2.3.1 Blinding

Blinding is intended to limit the occurrence of conscious and unconscious bias in the conduct and interpretation of a clinical trial arising from the influence that knowledge of treatment may have on the recruitment and allocation of subjects, their subsequent care, the attitudes of subjects to the treatments, the assessment of end points, the handling of withdrawals, the exclusion of data from analysis, and so on. The essential aim is to prevent identification of the treatments until all such opportunities for bias have passed.

A double-blind trial is one in which neither the subject nor any of the investigator or sponsor staff involved in the treatment or clinical evaluation of the subjects is aware of the treatment received. This includes anyone determining subject eligibility, evaluating endpoints, or assessing compliance with the protocol. This level of blinding is maintained throughout the conduct of the trial; only when the data are cleaned to an acceptable level of quality will appropriate personnel be unblinded. If any of the sponsor staff who are not involved in the treatment or clinical evaluation of the subjects are required to be unblinded to the treatment code (e.g., bioanalytical scientists, auditors, those involved in serious adverse event reporting), the sponsor should have adequate standard operating procedures (SOP's) to guard against inappropriate dissemination of treatment codes. In a single-blind trial the investigator and/or his staff are aware of the treatment but not the subject. In an open-label trial the identity of treatment is known to all. The double-blind trial is the optimal approach. This requires that the treatments to be applied during the trial cannot be distinguished in any way (appearance, taste, etc.) either before or during administration, and that the blind is maintained appropriately during the whole trial.

Difficulties in achieving the double-blind ideal can arise because: (1) The treatments may be of a completely different nature, for example, surgery and drug therapy; (2) two drugs may have different formulations and, although they could be made indistinguishable by the use of capsules, changing the formulation might also change the pharmacokinetic and/or pharmacodynamic properties, so that bioequivalence of the formulations may need to be established; (3) the daily pattern of administration of two treatments may differ. One way of achieving double-blind conditions under these circumstances is to use a ''double dummy'' technique. This technique may sometimes force an administration scheme that is sufficiently unusual to influence adversely the motivation and compliance of the subjects. Ethical difficulties may also interfere with its use when, for example, it entails dummy operative procedures. Nevertheless, extensive efforts should be made to overcome these difficulties.

In some clinical trials, although double blinding is planned, it may be partially compromised by apparent treatment induced effects. In such cases, blinding may be improved by blinding investigators to certain test results (e.g., selected clinical laboratory measures). Similar approaches (see below) to minimizing bias in open-label trials should be considered in trials where unique or specific treatment effects may lead to unblinding individual patients.

If a double-blind trial is not feasible, then the single-blind option should be considered. In some cases only an open-label trial is practically or ethically possible. Single-blind and open-label trials provide additional flexibility, but it is particularly important that the investigator's knowledge of the next treatment should not influence the decision to enter the subject; this decision should precede knowledge of the randomized treatment. Also, under either of these circumstances, clinical assessments should be made by medical staff who are not involved in treating the subjects and who remain blind to treatment. In single-blind or open-label trials, every effort should be made to minimize the various known sources of bias and primary variables should be as objective as possible. The reasons for the degree of blinding adopted, as well as steps taken to minimize bias by other means, should be explained in the protocol.

Breaking the blind (for a single subject) should be considered only when knowledge of the treatment assignment is deemed essential by the subject's physician for the subject's care. Any intentional or unintentional breaking of the blind should be reported and explained at the end of the trial, irrespective of the reason for its occurrence. The procedure and timing for revealing the treatment assignments should be documented.

In this document, the blind review of data refers to the checking of data during the period of time between trial completion (the last observation on the last subject) and the breaking of the blind. If specific sponsor staff need to be unblinded during this period to ensure the integrity of the database or the suitability of statistical assumptions, appropriate SOP's should be developed to describe how the treatment code will be protected from broader dissemination.

2.3.2 Randomization

Randomization introduces a deliberate element of chance into the assignment of treatments to subjects in a clinical trial. During subsequent analysis of the trial data, it provides a sound statistical basis for the quantitative evaluation of the evidence relating to treatment effects. It also tends to produce treatment groups in which the distributions of prognostic factors (known and unknown) are similar. In combination with blinding, randomization helps to avoid possible bias in the selection and allocation of subjects arising from the predictability of treatment assignments.

The randomization schedule of a clinical trial documents the random allocation of treatments to subjects. In the simplest situation, it is a sequential list of treatments (or treatment sequences in a crossover trial) or corresponding codes by subject number. The logistics of some trials, such as those with a screening phase, may make matters more complicated, but the unique preplanned assignment of treatment, or treatment sequence, to subject should be clear. Different trial designs should have different procedures for generating randomization schedules. The randomization schedule should be capable of being reproduced (if the need arises). Whenever possible, this should be accomplished through the use of the same random number table, or the same computer routine and seed for its random number generator.

Although unrestricted randomization is an acceptable approach, some advantages can generally be gained by randomizing subjects in blocks. This helps to increase the comparability of the treatment groups particularly when subject characteristics may change over time, as a result, for example, of changes in recruitment policy. It also provides a better guarantee that the treatment groups will be of nearly equal size. In cross-over trials, it provides the means of obtaining balanced designs with their greater efficiency and easier interpretation. Care should be taken to choose block lengths that are sufficiently short to limit possible imbalance, but long enough to avoid predictability towards the end of the sequence in a block. Investigators should generally be blind to the block length; the use of two or more block lengths, randomly selected for each block, can achieve the same purpose. (Theoretically, in a double-blind trial predictability does not matter, but the pharmacological effects of drugs often provide the opportunity for intelligent guesswork.)

In multicenter trials, the randomization procedures should be organized centrally. It is advisable to have a separate random scheme for each center, i.e., to stratify by center or to allocate several whole blocks to each center. More generally, stratification by important prognostic factors measured at baseline (e.g., severity of disease, age, sex, etc.) may sometimes be valuable in order to promote balanced allocation within strata; this has greater potential benefit in small trials. The use of more than two or three stratification factors is rarely necessary, is less successful at achieving balance, and is logistically troublesome. Where it is necessary, the use of a dynamic allocation procedure (see below) may help to achieve balance across all factors simultaneously, provided the rest of the trial procedures can be adjusted to accommodate an approach of this type.

The next subject to be randomized into a study should always receive the treatment corresponding to the next free number in the appropriate randomization schedule (in the respective stratum, if randomization is stratified). The appropriate number and associated treatment for the next subject should only be allocated when entry of that subject to the randomized part of the trial has been confirmed. These tasks will normally be carried out by staff at the investigator's center, who will then dispense the relevant blinded trial supplies. Details of the

randomization which facilitate predictability (e.g., block length) should not be contained in the study protocol. The randomization schedule itself should be filed securely by the sponsor or an independent party in a manner that ensures that blindness is properly maintained throughout the trial. Access to the randomization schedule during the trial should take into account the possibility that, in an emergency, the blind may have to be broken for any subject, either partially or completely. The procedure to be followed, the necessary documentation, and the subsequent treatment and assessment of the subject should all be described in the protocol.

Dynamic allocation is an alternative randomization procedure in which the allocation of treatment to a subject is influenced by the current balance of allocated treatments and, in a stratified trial, by the stratum to which the subject belongs and the balance within that stratum. Every effort should be made to retain the double-blind status of the trial. For example, knowledge of the treatment code may be restricted to a central trial office from where the dynamic allocation is controlled, generally through telephone contact. This in turn permits additional checks of eligibility criteria and establishes entry into the trial, features that can be valuable in certain types of multicenter trials. The usual system of prepacking and labeling drug supplies for double-blind trials can then be followed, but the order of their use is no longer sequential. It is desirable to use appropriate computer algorithms to keep personnel at the central trial office blind to the treatment code. The complexity of the logistics and potential impact on the analysis should be carefully evaluated when considering dynamic allocation.

III. Study Design Considerations

3.1 Study Configuration

3.1.1 Parallel Group Design

The most common clinical trial design for confirmatory trials is the parallel group design in which subjects are randomized to one of two or more arms, each arm being allocated a different treatment. These treatments will include the investigational product at one or more doses, and one or more control treatments, such as placebo and/or an active comparator. The assumptions underlying this design are less complex than for most other designs. However, there may be additional features of the design which complicate the analysis and interpretation (e.g., covariates, repeated measurements over time, interactions between design factors, protocol violations, dropouts, and withdrawals).

3.1.2 Cross-Over Design

In the cross-over design, each subject is randomized to a sequence of two or more treatments and hence acts as his own control for treatment comparisons. This simple maneuver is attractive primarily because it reduces the number of subjects and, usually, the number of assessments needed to achieve a specific power, sometimes to a marked extent. In the simplest 2x2 cross-over design, each subject receives each of two treatments in randomized order in two successive treatment periods, often separated by a washout period. The most common extension of this entails comparing n(>2) treatments in n periods, each subject receiving all n treatments. Numerous variations exist, such as designs in which each subject receives a subset of n(>2) treatments, or designs in which treatments are repeated within a subject.

Cross-over designs have a number of problems which can invalidate their results. The chief difficulty concerns carryover, that is, the residual influence of treatments in subsequent treatment periods. In an additive model, the effect of unequal carryover will be to bias direct treatment comparisons. In the 2x2 design, the relevant contrast cannot be statistically distinguished from the interaction between treatment and period, and the test for either of these lacks power because it is a ''between subject'' contrast. This problem is less acute in higher order designs, but cannot be entirely dismissed.

Therefore, when the cross-over design is used, it is important to avoid carryover. This is best done by selective and careful use of the design on the basis of adequate knowledge of both the disease area and the new medication. The disease under study should be chronic and stable. The relevant effects of the medication should develop fully within the treatment period. The washout periods should be sufficiently long for complete reversibility of drug effect. The fact that these conditions are likely to be met should be established in advance of the trial by means of prior information and data.

A common, and generally satisfactory, use of the 2x2 cross-over design is to demonstrate the bioequivalence of two formulations of the same medication. In this particular application in healthy volunteers, carryover effects on the relevant pharmacokinetic variable are rather unlikely to occur if the wash-out time between the two periods is sufficiently long. However, it is still important to check this assumption during analysis on the basis of the data obtained, for example, by demonstrating that no drug is detectable at the start of each period.

There are additional problems that need careful attention in cross-over trials. The most notable of these are the complications of analysis and interpretation arising from the loss of subjects. Also, the potential for carryover leads to difficulties in assigning adverse events that occur in later treatment periods to the appropriate treatment. These and other issues are described in the ICH E4 topic on ''Dose-Response Information to Support Drug Registration.'' The cross-over design should generally be restricted to situations where losses of subjects from the trial are expected to be small.

3.1.3 Factorial Designs

In a factorial design, two or more treatments are evaluated simultaneously in the same set of subjects through the use of varying combinations of the treatments. The simplest example is the 2x2 factorial design in which subjects are randomly allocated to one of the four possible combinations of two treatments, A and B. These are: A alone; B alone; both A and B; neither A nor B. In many cases this design is used for the specific purpose of examining the interaction of A and B. The statistical test of interaction is model dependent and may lack power to detect an interaction if the sample size was calculated based on the test for main effects. This consideration is important when this design is used for examining the joint effects of A and B, in particular, if the treatments are likely to be used together.

Another important use of the factorial design is to establish the dose-response characteristics of a combination product, e.g., one combining treatments C and D, especially when the efficacy of each monotherapy has been established at some dose in prior studies. A number, m, of doses of C is selected, usually including a zero dose (placebo), and a similar number, n, of doses of D. The full design then consists of mn treatment groups, each receiving a different combination of doses of C and D. The resulting estimate of the response surface may then be used to help identify an appropriate combination of doses of C and D for clinical use.

In some cases, the 2x2 design may be used to make efficient use of clinical trial subjects by evaluating the efficacy of the two treatments with the same number of subjects as would be required to evaluate the efficacy of either one alone. This strategy has proved to be particularly valuable for very large mortality studies. The efficiency of this approach depends upon the absence of interaction between treatments A and B so that the effects of A and B on the primary efficacy variables follow an additive model, hence the effect of A is virtually identical whether or not it is additional to the effect of B. As for the cross-over trial, evidence that this condition is likely to be met should be established in advance of the trial by means of prior information and data.

3.2 Multicenter Trials

Multicenter trials are carried out for two main reasons. First, a multicenter trial is an accepted way of evaluating a new medication more efficiently; under some circumstances, it may present the only practical means of accruing sufficient subjects to satisfy the trial objective within a reasonable timeframe. Multicenter trials of this nature may, in principle, be carried out at any stage of clinical development. They may have several centers with a large number of subjects per center or, in the case of a rare disease, they may have a large number of centers with very few subjects per center.

Second, a trial may be designed as a multicenter (and multi-investigator) trial primarily to provide a better basis for the subsequent generalization of its findings. This arises from the possibility of recruiting the subjects from a wider population and of administering the medication in a broader range of clinical settings, thus presenting an experimental situation that is more typical of future use. In this case, the involvement of a number of investigators also gives the potential for a wider range of clinical judgement concerning the value of the medication. Such a trial would be a confirmatory trial in the later phases of drug development and would be likely to involve a large number of investigators and centers.

It might sometimes be conducted in a number of different countries to facilitate generalizability even further.

If a multicenter trial is to be meaningfully interpreted and extrapolated, then the manner in which the protocol is implemented should be clear and similar at all centers. Furthermore, the usual sample size and power calculations depend upon the assumption that the differences between the compared treatments in the centers are unbiased estimates of the same quantity. It is important to design the common protocol and to conduct the trial with this background in mind. Procedures should be standardized as completely as possible. Variation of evaluation criteria and schemes can be reduced by investigator meetings, by the training of personnel in advance of the study, and by careful monitoring during the study. Good design should generally aim to achieve the same distribution of subjects to treatments within each center and good management should maintain this design objective. Trials which avoid excessive variation in the numbers of subjects per center and trials which avoid a few very small centers have advantages if it is later found necessary to examine the heterogeneity of the treatment effect from center to center, because they reduce the differences between different weighted estimates of the treatment effect. (This point does not apply to trials in which all centers are very small and in which center does not feature in the analysis.) Failure to take these precautions, combined with doubts about the homogeneity of the results, may, in severe cases, reduce the value of a multicenter trial to such a degree that it cannot be regarded as giving convincing evidence for the sponsor's claims.

In the simplest multicenter trial, each investigator will be responsible for the subjects recruited at one hospital, so that ''center'' is identified uniquely by either investigator or hospital. In many trials, however, the situation is more complex. One investigator may recruit subjects from several hospitals; one investigator may represent a team of clinicians (subinvestigators) who all recruit subjects from their own clinics at one hospital or at several associated hospitals. Whenever there is room for doubt about the definition of center in a statistical model, the statistical section of the protocol (see section 5.1) should clearly define the term (e.g., by investigator, location, or region) in the context of the particular trial. In most instances, centers can be satisfactorily defined through the investigators. (ICH Guideline E6 provides relevant guidance in this respect.) In cases of doubt, the aim should be to define centers to achieve homogeneity in the important factors affecting the measurements of the primary variables and the influence of the treatments. Any rules for combining centers in the analysis should be justified and specified prospectively in the protocol where possible, but in any case decisions concerning this approach should always be taken blind to treatment, for example, at the time of the blind review. It is sometimes possible to characterize the centers by historical measures of response to the control treatment or to other standard treatments, and this information may help to support decisions concerning the combination of centers for analysis.

The statistical model to be adopted for the comparison of treatments should be described in the protocol. The main treatment effect may be investigated first using a model that allows for center differences, but does not include a term for center by treatment interaction. In the absence of a true center by treatment interaction, the routine inclusion of interaction terms in the model reduces the efficiency of the test for the main effects. In the presence of a true center by treatment interaction, the interpretation of the main treatment effect is controversial.

In some studies, for example, some large mortality studies with very few subjects per center, there may be no reason to expect the centers to have any influence on the primary or secondary variables because they are unlikely to represent influences of clinical importance. In other studies, it may be recognized from the start that the limited numbers of subjects per center will make it impracticable to include the center effects in the statistical model. In these cases, it is not appropriate to include a term for center in the model, because in this situation randomization is rarely stratified by center.

If positive treatment effects are found in a trial with appreciable numbers of subjects per center, there should generally be a subsequent exploration of treatment by center interaction, as this may affect the generalizability of the conclusions. Marked treatment by center interaction may be identified by graphical display of the results of individual centers or by analytical methods, such as a significance test of the interaction. When using such a statistical significance test, it is important to recognize that this generally has low power in a trial designed to detect the main effect of treatment.

If a treatment by center interaction is found, this should be interpreted with care and vigorous attempts should be made to find an explanation in terms of other features of trial management or subject characteristics. Such an explanation will usually define the appropriate further analysis and interpretation. In the absence of an explanation, marked quantitative interactions imply that alternative estimates of the treatment effect may be needed, giving different weights to the centers, in order to substantiate the robustness of the estimates of treatment effect. It is even more important to understand the basis of any marked qualitative interactions, and failure to find an explanation may necessitate further clinical trials before the treatment effect can be reliably predicted.

3.3 Type of Comparison

3.3.1 Trials to Show Superiority

Scientifically, efficacy is most convincingly established by demonstrating superiority to placebo in a placebo-controlled trial, by showing superiority to an active control treatment, or by demonstrating a dose-response relationship. This type of trial is referred to as a ''superiority'' trial (see section 5.2.3). In this guideline, superiority trials are generally assumed unless explicitly stated otherwise.

For serious illnesses, when a therapeutic treatment that has been shown to be efficacious by superiority trial(s) exists, a placebo-controlled trial may be considered unethical. In that case, the scientifically sound use of the active control should be considered. The appropriateness of placebo control versus active control should be considered on a study-by-study basis.

3.3.2 Trials to Show Equivalence or Noninferiority

In some cases, an investigational product is compared to a reference treatment without the objective of showing superiority. This type of trial is divided into two major categories according to its objective; one is an ''equivalence'' trial and the other is a ''noninferiority'' trial.

Bioequivalence trials fall into the former category. In some situations, clinical equivalence trials are also undertaken for other regulatory reasons, such as demonstrating the clinical equivalence of a generic product to the marketed product when the compound is not absorbed and therefore not present in the blood stream.

Many active control trials are designed to show that the efficacy of an investigational product is no worse than that of the active comparator, and hence fall into the latter category. Another possibility is a ''relative potency assay,'' which is a study where multiple doses of the investigational drug are compared with the recommended dose or multiple doses of the standard drug.

Active control equivalence or noninferiority trials may also incorporate a placebo, thus pursuing multiple goals in one trial, for example, establishing superiority to placebo, thereby validating the study design and evaluating the degree of similarity of efficacy and safety to the active comparator. There are well-known limitations associated with the use of the active control equivalence (or noninferiority) trials that do not incorporate a placebo. These relate to the implicit lack of any measure of internal validity (in contrast to superiority trials), thus making external validation necessary. The equivalence (or noninferiority) trial is not conservative in nature, so many flaws in the design or conduct of the trial will tend to bias the results towards a conclusion of equivalence. For these reasons, the design features of such trials should receive special attention.

Active comparators should be chosen with care. An example of a suitable active comparator would be a widely used therapy whose efficacy in the relevant indication has been clearly established and quantified in well-designed and well-documented superiority trial(s) and that can be reliably expected to exhibit similar efficacy in the contemplated active control study. To this end, the new trial should have the same important design features (primary variables, the dose of the active comparator, eligibility criteria, etc.) as the previously conducted superiority trials in which the active comparator clearly demonstrated clinically relevant efficacy.

It is vital that the protocol of a trial designed to demonstrate equivalence or

noninferiority contain a clear statement that this is its explicit intention. An equivalence margin should be specified in the protocol; this margin is the largest difference which can be judged as being clinically acceptable. For the active control equivalence trial, both the upper and the lower equivalence margins are needed, while for the active control non-inferiority trial, only the lower margin is needed. There should be clinical justification for the choice of equivalence margins.

Statistical analysis is generally based on the use of confidence intervals (see section 5.5). For equivalence trials, the two-sided 1–2α (alpha) confidence limits should be used. Equivalence is inferred when the entire confidence interval falls within the equivalence margins. This is equivalent to the method of using two simultaneous one-sided tests to test the (composite) null hypothesis that the treatment difference is outside of the equivalence margins versus the (composite) alternative that the treatment difference is within the limits. With this method, the Type I error is controlled at a level of α. For noninferiority trials, the one-sided 1-α interval should be used. The confidence interval approach has a one-sided hypothesis test counterpart testing the null hypothesis that the treatment difference (investigational product minus control) is equal to the lower equivalence margin versus the alternative that the treatment difference is greater than the lower equivalence margin. Sample size calculations should be based on these methods (see section 3.5). The choice of α should be a consideration separate from the choice of a one-sided or two-sided test.

It is inappropriate to conclude equivalence or noninferiority based on observing a nonsignificant test result of the null hypothesis that there is no difference between the investigational product and the active comparator.

There are also special issues in the choice of analysis sets. Subjects who withdraw or drop out of the treatment group or the comparator group will tend to have a lack of response, hence the analysis of all randomized subjects may be biased toward demonstrating equivalence (see section 5.2.3).

3.3.3 Dose-Response Designs

How response is related to the dose of a new investigational product is a question to which answers may be obtained in all phases of development and by a variety of approaches (see ICH E4). Dose-response studies may serve a number of objectives, among which the following are of particular importance: The confirmation of efficacy; the investigation of the shape and location of the dose-response curve; the estimation of an appropriate starting dose; the identification of optimal strategies for individual dose adjustments; the determination of a maximal dose beyond which additional benefit would be unlikely to occur. These objectives should be addressed using the data collected at a number of doses under investigation, including a placebo (zero dose) wherever appropriate. For this purpose, the application of estimation procedures, including the construction of confidence intervals and of graphical methods is as important as the use of statistical tests. The hypothesis tests that are used may need to be tailored to the natural ordering of doses or to particular questions regarding the shape of the dose-response curve (e.g., monotonicity). The details of the planned statistical procedures should be given in the protocol.

3.4 Group Sequential Designs

Group sequential designs are used to facilitate the conduct of interim analysis (see section 4.5). While group sequential designs are not the only acceptable types of designs permitting interim analysis, they are the most commonly applied because it is more practicable to assess grouped subject outcomes at periodic intervals during the trial than on a continuous basis as data from each subject become available. The statistical methods should be fully specified in advance of the availability of information on treatment outcomes and subject treatment assignments (i.e., blind breaking, see section 4.5). An independent data monitoring committee (IDMC) may be used to conduct the interim analysis of data arising from a group sequential design (see section 4.6). While the design has been most widely and successfully used in large, long-term trials of mortality or major nonfatal endpoints, its use is growing in other circumstances. In particular, it is recognized that safety must be monitored in all trials, therefore, the need for formal procedures to cover early stopping for safety reasons should always be considered.

3.5 Sample Size

The number of subjects in a clinical trial should always be large enough to provide a reliable answer to the questions addressed. This number is usually determined by the primary objective of the trial. If the sample size is determined on some other basis, this should be made clear and justified. For example, a trial sized on the basis of safety questions or requirements may need larger numbers of subjects than one sized on the basis of efficacy questions. (See, for example, ICH E1A ''Population Exposure: The Extent of Population Exposure to Assess Clinical Safety.'')

When determining the appropriate sample size, the following items should be specified: A primary variable; the test statistic; the null hypothesis; the alternative (''working'') hypothesis at the chosen dose(s) (embodying consideration of the treatment difference to be detected or rejected at the dose and in the subject population selected); the probability of erroneously rejecting the null hypothesis (the Type I error) and the probability of erroneously failing to reject the null hypothesis (the Type II error); as well as the approach to dealing with treatment withdrawals and protocol violations. In some instances, the event rate is of primary interest for evaluating power, and assumptions should be made to extrapolate from the required number of events to the eventual sample size for the trial.

The method by which the sample size is calculated should be given in the protocol, together with the estimates of any quantities used in the calculations (such as variances, mean values, response rates, event rates, difference to be detected). The basis of these estimates should also be given. It is important to investigate the sensitivity of the sample size estimate to a variety of deviations from these assumptions and this may be facilitated by providing a range of sample sizes appropriate for a reasonable range of deviations from assumptions. In confirmatory studies, assumptions should normally be based on published data or on the results of earlier studies. The treatment difference to be detected may be based on a judgement concerning the minimal effect that has clinical relevance in the management of patients or on a judgement concerning the anticipated effect of the new treatment, where this is larger. Conventionally, the probability of Type I error is set at 5 percent or less or as dictated by any adjustments made necessary for multiplicity considerations; the precise choice is influenced by the prior plausibility of the hypothesis under test and the desired impact of the results. The probability of Type II error is conventionally set at 20 percent or less; it is in the sponsor's interest to keep this figure as low as feasible, especially in the case of studies that are difficult or impossible to repeat.

Sample size calculations should refer to the number of subjects required for the primary analysis. If this is the ''all randomized subjects'' set, estimates about the effect size may need to be reduced compared to the per protocol set. This is due to the diluting effect of the inclusion of treatment withdrawals. The assumptions of variability may also need to be revised.

The sample size of an equivalence trial or a noninferiority trial (see section 3.3.2) should normally be based on the objective of obtaining a confidence interval for the treatment difference that shows that the treatments differ at most by a clinically acceptable difference. For equivalence trials, the power is usually assessed at a true difference of zero but can be underestimated if the true difference is not zero. For noninferiority trials, the power is usually assessed at an expected (nonzero) difference, but can be underestimated if the true difference is less than expected. The choice of a ''clinically acceptable'' difference needs justification, and may be smaller than the ''clinically relevant'' difference referred to above in the context of superiority trials designed to establish that a difference exists.

The sample size in a group sequential trial cannot be fixed in advance because it depends upon the play of chance in combination with the chosen stopping rule and the true treatment difference. The design of the stopping rule should take into account the consequent distribution of the sample size, usually embodied in the expected and maximum sample sizes.

When event rates are lower than anticipated or variability is larger than expected, methods for sample size reestimation are available without unblinding data or making treatment comparisons (see section 4.4).

3.6 Data Capture and Processing

The collection of data and transfer of data from the investigator to the sponsor can take place through a variety of media, including paper case record forms, remote site

monitoring systems, medical computer systems, and electronic transfer. Whatever data capture instrument is used, the form and content of the information collected should be in full accordance with the protocol and should be established in advance of the conduct of the clinical trial. It should focus on the data necessary to implement the analysis plan, including the context information (such as timing assessments relative to dosing) necessary to confirm protocol compliance or identify important protocol deviations. ''Missing values'' should be distinguishable from the ''value zero'' or ''characteristic absent.''

The process of data capture, through to database finalization, should be carried out in accordance with good clinical practice (GCP) (see ICH E6, section 5). Specifically, timely and reliable processes for recording data and rectifying errors and omissions are necessary to ensure delivery of a quality database and the achievement of the trial objectives through the implementation of the analysis plan.

IV. Study Conduct

4.1 Trial Monitoring

Careful conduct of a clinical trial according to the protocol has a major impact on the credibility of the results. Careful monitoring can ensure that difficulties are noticed early and their occurrence or recurrence minimized.

There are two distinct types of monitoring that generally characterize confirmatory clinical trials sponsored by the pharmaceutical industry. Both types of trial monitoring, in addition to entailing different staff responsibilities, involve access to different types of study data and information, thus different principles apply for the control of potential statistical and operational bias.

One type of monitoring concerns the oversight of the quality of the trial, including whether the protocol is being followed, acceptability of data being accrued, success of planned accrual targets, checking the design assumptions, etc. (see sections 4.2 to 4.4). This type of monitoring does not require access to information on comparative treatment effects, nor unblinding of data, and therefore has no impact on Type I error. The monitoring of a trial for this purpose is the responsibility of the sponsor and can be carried out by the sponsor or an independent group selected by the sponsor. The period for this type of monitoring usually starts with the selection of the study sites and ends with the collection and cleaning of the last subject's data.

The other type of trial monitoring involves breaking the blind to make treatment comparisons. It therefore involves the accruing of comparative treatment results, which requires that a protocol (or appropriate amendments prior to a first analysis) contain statistical plans to prevent certain types of bias. This type of trial monitoring involves unblinded (i.e., key breaking) access to treatment group assignment (actual treatment assignment or identification of group assignment) and comparative treatment group summary information. This type of monitoring is discussed in sections 4.5 and 4.6.

4.2 Changes in Inclusion and Exclusion Criteria

Inclusion and exclusion criteria should remain constant, as specified in the protocol, throughout the period of subject recruitment. Occasionally, however, changes may be appropriate; in long-term studies, for example, growing medical knowledge either from outside the trial or from interim analyses may suggest a change of entry criteria. Changes may also result from the discovery by monitoring staff that regular violations of the entry criteria are occurring, or that seriously low recruitment rates are due to over-restrictive criteria. Changes should be made without breaking the blind and should always be described by a protocol amendment that should cover any statistical consequences, such as sample size adjustments arising from different event rates, or modifications to the analysis plan, such as stratifying the analysis according to modified inclusion/exclusion criteria.

4.3 Accrual Rates

In studies with a long time-scale for the accrual of subjects, the rate of accrual should be monitored; if it falls appreciably below the projected level, the reasons should be identified and remedial actions taken to protect the power of the trial and allay concerns about selective entry and other aspects of quality. In a multicenter trial, these considerations apply to the individual centers.

4.4 Sample Size Adjustment

In long-term trials, there will usually be an opportunity to check the assumptions which underlie the original design and sample size calculations. This may be particularly important if the trial specifications have been made on preliminary and/or uncertain information. An interim check conducted on the blinded data may reveal that overall response variances, event rates, or survival experience are not as anticipated. A revised sample size may then be calculated using suitably modified assumptions, and should be justified and documented in a protocol amendment and in the final report. The steps taken to preserve blindness and the consequences, if any, for the Type I error and the width of confidence intervals should be explained. The potential need for reestimation of the sample size should be envisaged in the protocol whenever possible (see section 3.5).

4.5 Interim Analysis and Early Stopping

Any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to formal completion of a trial is an interim analysis. Because the number, methods, and consequences of these comparisons affect the interpretation of the trial, all interim analyses should be carefully planned in advance and described in the protocol, or otherwise specified in amendments prior to unblinded access to treatment comparison data. When an interim analysis is planned with the intention of deciding whether or not to terminate a trial, this is usually accomplished by the use of a group sequential design that employs statistical monitoring schemes as guidelines (see section 3.4). The goal of such an interim analysis is to stop the trial early if the superiority of the treatment under study is clearly established, if the demonstration of a relevant treatment difference has become unlikely, or if unacceptable adverse effects are apparent. Generally, boundaries for monitoring efficacy require more evidence to terminate a trial early (i.e., more conservative) than do boundaries to terminate a trial for safety reasons. When the trial design and monitoring objective involve multiple endpoints, then this aspect of multiplicity may also need to be taken into account.

The schedule of interim analyses, or at least the considerations which will govern its generation, should be stated in the protocol or a protocol amendment before the time of the first interim analysis; as flexible statistical methods are available to conduct interim analyses according to a variety of needs (early or late in a trial), the stopping guidelines and their properties should be clearly stated in the protocol or amendments. This material should be written or approved by the data monitoring committee, when the study has one (see section 4.6). Deviations from the planned procedure always bear the potential of invalidating the study results. If it becomes necessary to make changes to the trial, any consequent changes to the statistical procedures should be specified in an amendment to the protocol at the earliest opportunity, especially discussing the impact on any analysis and inferences that such changes may cause. The procedures selected should always ensure that the overall probability of Type I error is controlled.

The execution of an interim analysis should be a completely confidential process because unblinded data and results are potentially involved. All staff involved in the conduct of the trial should remain blind to the results of such analyses because of the possibility that their attitudes to the trial will be modified and cause changes in recruitment patterns or biases in treatment comparisons. This principle applies to the investigators and their staff and to staff employed by the sponsor that come into contact with clinic staff or subjects. Investigators should be informed only about the decision to continue or to discontinue the trial, or to implement modifications to trial procedures.

Most clinical trials intended to support the efficacy and safety of an investigational product should proceed to full completion of planned sample size accrual; trials should be stopped early only for ethical reasons or if the power is no longer acceptable. However, it is recognized that drug development plans involve the need for sponsor access to comparative treatment data for a variety of reasons, such as planning other studies or when only a subset of trials will involve the study of serious life-threatening outcomes or mortality which may need sequential monitoring of accruing comparative treatment effects for ethical reasons. In either of these situations, plans for interim statistical analysis should be in place in the protocol or in protocol amendments prior to the unblinded access to comparative treatment data in order to deal with the

potential statistical and operational bias that may be introduced.

For many clinical trials of investigational products, especially those that have major public health significance, the responsibility for monitoring comparisons of efficacy and/or safety outcomes should be assigned to an external, independent group, often called an independent data monitoring committee (IDMC), a data and safety monitoring board, or a data monitoring committee, whose responsibilities should be clearly described.

When a sponsor assumes the role of monitoring efficacy or safety comparisons and therefore has access to unblinded comparative information, particular care should be taken to protect the integrity of the trial and the sharing of information. The sponsor should ensure and document that the internal monitoring committee has complied with written SOP's and that minutes of decisionmaking meetings are maintained.

Any interim analysis that is not planned in the protocol or specified in an amendment to the protocol prior to unblinding the data (with or without the consequences of stopping the trial early) may flaw the results of a trial and possibly weaken confidence in the conclusions drawn. Therefore, such analyses should be avoided. If unplanned interim analysis is conducted, the study report should explain why it was necessary and the degree to which blindness had to be broken, and provide an assessment of the potential magnitude of bias introduced and the impact on the interpretation of the results.

4.6 Role of Independent Data Monitoring Committee (IDMC)

(see sections 1.25 and 5.5.2 of ICH Guideline E6)

An IDMC may be established by the sponsor to assess at intervals the progress of a clinical trial, safety data, and critical efficacy variables and recommend to the sponsor whether to continue, modify, or terminate a trial. The IDMC should have written operating procedures and maintain records of its meetings. The independence of the IDMC is intended to control the sharing of important comparative information and to protect the integrity of the clinical trial from adverse impact resulting from access to trial information. The IDMC is a separate entity from an institutional review board (IRB) or an ethics board, and its composition should include clinical trial scientists knowledgeable in the appropriate disciplines, including statistics.

When there are sponsor representatives on the IDMC, their role should be clearly defined in the operating procedures of the committee (for example, covering whether or not they can vote on key issues). Since these sponsor staff would have access to unblinded information, the procedures should also address the control of dissemination of interim trial results within the sponsor organization.

V. Data Analysis

5.1 Prespecified Analysis Plan

When designing a clinical trial, the principal features of the eventual statistical analysis of the data should be described in the statistical section of the protocol. This section should include all features of the proposed confirmatory analysis of the primary variable(s) and the way in which anticipated analysis problems will be handled. In the case of exploratory trials, this section could describe more general principles and directions.

Subsequently, a statistical analysis plan may be written as a separate document. In this document, a more technical and detailed elaboration of the principal features stated in the protocol may be included. The statistical analysis plan is usually an internal document and may include detailed procedures for executing the statistical analysis. The statistical analysis plan should be reviewed and possibly updated as a result of the blind review of the data (see section 7.1 for definition).

If the blind review suggests changes to the principal features stated in the protocol, these should be documented in a protocol amendment. Otherwise, it will suffice to update the statistical analysis plan with the considerations suggested from the blind review. Only results from analyses envisaged in the protocol (including amendments) can be regarded as confirmatory.

The statistical methodology, including when in the clinical trial process methodology decisions were made, should be clearly described in the statistical section of the clinical study report (see ICH E3).

5.2 Analysis Sets

The set of subjects whose data are to be included in the main analyses should be defined in the statistical section of the protocol. In addition, documentation for all subjects for whom study procedures (e.g., run-in period) were initiated may be useful. The content of this subject documentation depends on detailed features of the particular trial, but at least demographic and baseline data on disease status should be collected whenever possible.

If all subjects randomized into a clinical trial satisfied all entry criteria, followed all trial procedures perfectly with no losses to followup, and provided complete data records, then the set of subjects to be included in the analysis would be self-evident. The design and conduct of a trial should aim to approach this ideal as closely as possible, but, in practice, it is doubtful if it can ever be fully achieved. Hence, the statistical section of the protocol should address any anticipated problems prospectively in terms of how these affect the subjects and data to be analyzed. The protocol should also specify procedures aimed at minimizing any anticipated irregularities in study conduct that might impair a satisfactory analysis, including various types of protocol violations, withdrawals, and missing values. The protocol should consider ways both to reduce the frequency of such problems and to handle the problems that occur in the analysis of data. The blind review of data to identify possible amendments to the analysis plan due to the protocol violations should be carried out before unblinding. It is desirable to identify any important protocol violation with respect to the time when it occurred, its cause, and its influence on the trial result. The frequency and type of protocol violations, missing values, and other problems should be documented in the study report and their potential influence on the trial results should be described (see ICH E3).

Decisions concerning the analysis set should be guided by the following principles: (1) To minimize bias and (2) to avoid inflation of Type I error.

5.2.1 All Randomized Subjects

The intention-to-treat principle implies that the primary analysis should include all randomized subjects. In practice, this ideal may be difficult to achieve, for reasons to be described. Hence, analysis sets referred to as ''all randomized subjects'' may not, in fact, include every subject. For example, it is common practice to exclude from the all randomized set any subject who failed to take at least one dose of trial medication or any subject without data post randomization. No analysis is complete unless the potential biases arising from these exclusions are addressed and can be reasonably dismissed.

In many clinical trials, the ''all randomized subjects'' approach is conservative and also gives estimates of treatment effects that are more likely to mirror those observed in subsequent practice. Randomization prevents biased allocation of subjects to treatments and provides the foundation of statistical tests. The problems associated with the analysis of all randomized subjects lie in the handling of protocol violations and the subtleties that this can involve.

There are two types of major protocol violations. One is violation of entry criteria. The second is violation of the protocol after randomization. Subjects who fail to satisfy an objective entry criterion measured prior to randomization, but who enter the trial, may be excluded from analysis without introducing bias into the treatment comparison, assuming all subjects receive equal scrutiny for eligibility violations. (This may be difficult to ensure if the data are unblinded.) Not all entry criteria are sufficiently objective for this to be done satisfactorily. Reasons for excluding subjects from the analysis of all randomized subjects should be justified.

Other problems occur after randomization (error in treatment assignment, use of excluded medications, poor compliance, loss to followup, missing data, and other protocol violations). These problems are especially difficult when their occurrence is related to treatment assignment. It is good practice to assess the pattern of such problems with respect to frequency and time to occurrence among treatment groups. Subjects withdrawn from treatment may introduce serious bias and, if they have provided no data after withdrawal, there is no obvious solution. Severe protocol violation, such as use of excluded medication, may also introduce serious bias into measurements after such a violation. The necessary inclusion of such subjects in the analysis may require some redefinition of the primary variable or some assumptions about the subjects' outcomes.

Measurements of primary variables made at the time of the loss to followup of a subject for any reason or at the time of a severe

protocol violation, or subsequently collected in accordance with the protocol, are valuable in the context of all randomized subjects analysis. Their use in analysis should be described and justified in the statistical section of the protocol and their collection described elsewhere in the protocol. However, the use of imputation techniques can lead to biased estimates of treatment effects, particularly when the likelihood of the loss of a subject is related to treatment or response. Any other methods to be employed to ensure the availability of measurements of primary variables for every subject in the all randomized subjects analysis should be described.

Because of the unpredictability of some problems, it may sometimes be preferable to defer detailed consideration of the manner of dealing with irregularities until the blind review of the data at the end of the study and, if so, this should be stated in the protocol.

5.2.2 Per Protocol Subjects

The ''per protocol'' set of subjects, sometimes described as the ''valid cases,'' the ''efficacy'' sample, or the ''evaluable subjects'' sample, defines a subset of the data used in the all randomized subjects analysis and is characterized by the following criteria:

(i) The completion of a certain prespecified minimal exposure to the treatment regimen;

(ii) The availability of measurements of the primary variable(s);

(iii) The absence of any major protocol violations, including the violation of entry criteria where the nature of and reasons for these protocol violations should be defined and documented before breaking the blind.

This set may maximize the opportunity for a new treatment to show additional efficacy in the analysis, and most closely reflects the scientific model underlying the protocol. However, it may or may not be conservative, depending on the study, and may be subject to bias (possibly severe) because the subjects adhering most diligently to the study protocol may not be representative of the entire study population.

5.2.3 Roles of the All Randomized Subjects Analysis and the Per Protocol Analysis

In general, it is advantageous to demonstrate a lack of sensitivity of the principal trial results to alternative choices of the set of subjects analyzed. In confirmatory trials, it is usually appropriate to plan to conduct both all randomized subjects and per protocol analyses, so that any differences between them can be the subject of explicit discussion and interpretation. In some cases, it may be desirable to plan further exploration of the sensitivity of conclusions to the choice of the set of subjects analyzed. When the all randomized subjects and the per protocol analyses come to essentially the same conclusions, confidence in the study results is increased, bearing in mind, however, that the need to exclude a substantial proportion of subjects from the per protocol analysis throws some doubt on the overall validity of the study.

All randomized subjects and per protocol analyses play different roles in superiority trials (which seek to show the investigational product to be superior) and in equivalence or noninferiority trials (which seek to show the investigational product to be comparable, see section 3.3.2). In superiority studies, the all randomized subjects analysis usually tends to avoid the optimistic estimate of efficacy which may result from a per protocol analysis, since the noncompliers included in an all randomized subjects analysis will generally diminish the overall treatment effect. However, in an equivalence or noninferiority trial, the all randomized subjects analysis is no longer conservative and its role should be considered very carefully.

5.3 Missing Values and Outliers

Missing values represent a potential source of bias in a clinical trial. Hence, every effort should be undertaken to fulfill all the requirements of the protocol concerning the collection and management of data. However, in reality there will almost always be some missing data. A study may be regarded as valid, nonetheless, provided the methods of dealing with missing values are sensible, particularly if those methods are predefined in the analysis plan of the protocol. Predefinition of methods may be facilitated by updating this aspect of the analysis plan during the blind review. Unfortunately, no universally applicable methods of handling missing values can be recommended. An investigation should be made concerning the sensitivity of the results of analysis to the method of handling missing values, especially if the number of missing values is substantial.

A similar approach should be adopted to exploring the influence of outliers, the statistical definition of which is, to some extent, arbitrary. Clear identification of a particular value as an outlier is most convincing when justified medically as well as statistically, and the medical context will then often define the appropriate action. Any outlier procedure set out in the protocol should not favor any treatment group a priori. Once again, this aspect of the analysis plan can be usefully updated during blind review. If no procedure for dealing with outliers was foreseen in the study protocol, one analysis with the actual values and at least one other analysis eliminating or reducing the outlier effect should be performed and differences between their results discussed.

5.4 Data Transformation/Modification

The decision to transform key variables prior to analysis is best made during the design of the trial on the basis of similar data from earlier clinical trials. Transformations (e.g., square root, logarithm) should be specified in the protocol and a rationale provided, especially for the primary variable(s). The general principles guiding the use of transformations to ensure that the assumptions underlying the statistical methods are met are to be found in standard texts; conventions for particular variables have been developed in a number of specific clinical areas. The decision on whether and how to transform a variable should be influenced by the preference for a scale that facilitates clinical interpretation.

Similar considerations apply to other data modifications sometimes used to create a variable for analysis, such as the use of change from baseline, percentage change from baseline, the ''area under the curve'' of repeated measures, or the ratio of two different variables. Subsequent clinical interpretation should be carefully considered, and the modification should be justified in the protocol. Closely related points are made in section 2.2.2.

5.5 Estimation, Confidence Intervals, and Hypothesis Testing

The statistical section of the protocol should specify the hypotheses that are to be tested and/or the treatment effects that are to be estimated to satisfy the objectives of the trial. The statistical methods to be used to accomplish these tasks should be described for the primary (and preferably the secondary) variables, and the underlying statistical model should be made clear. Estimates of treatment effects should be accompanied by confidence intervals, whenever possible, and the way in which these will be calculated should be identified. The plan should also describe any intentions to use baseline data to improve precision and to adjust estimates for potential baseline differences, for example, by means of analysis of covariance. The reporting of precise p-values (e.g., ''P=0.034'') should be envisaged in the plan, rather than exclusive reference to critical values (e.g., ''P<0.05''). It is important to clarify whether one- or two-sided tests of statistical significance will be used and, in particular, to justify prospectively the use of one-sided tests. If formal hypothesis tests are not considered appropriate, then the alternative process for arriving at statistical conclusions should be given.

The particular statistical model chosen should reflect the current state of medical and statistical knowledge about the variables to be analyzed. All effects to be fitted in the analysis (for example, in analysis of variance models) should be fully specified and the manner, if any, in which this set of effects might be modified in response to preliminary results should be explained. The same considerations apply to the set of covariates fitted in an analysis of covariance. (See also section 5.7.). In the choice of statistical methods, due attention should be paid to the statistical distribution of both primary and secondary variables. When making this choice, it is important to bear in mind the need to provide statistical estimates of the size of treatment effects together with confidence intervals (in addition to significance tests), as this may influence the choice when there is any doubt about the appropriateness of the method.

The primary analysis of the primary variable should be clearly distinguished from supporting analyses of the primary or secondary variables. Within the statistical section of the protocol there should also be an outline of the way in which data other than the primary and secondary variables will be summarized and reported. This should include a reference to any approaches adopted for the purpose of achieving consistency of analysis across a range of studies, for example, for safety data.

5.6 Adjustment of Type I Error and Confidence Levels

When multiplicity is present, the usual frequentist approach to the analysis of clinical trial data may necessitate an adjustment to the Type I error. Multiplicity may arise, for example, from multiple primary variables (see section 2.2.2), multiple comparisons of treatments, repeated evaluation over time, and/or interim analyses (see section 4.6). Methods to avoid or reduce multiplicity are sometimes preferable when available, such as the identification of the key primary variable (multiple variables), the choice of a critical treatment contrast (multiple comparisons), the use of a summary measure such as ''area under the curve'' (repeated measures). In confirmatory analyses, any aspects of multiplicity that remain after steps of this kind have been taken should be identified in the protocol; adjustment should always be considered and the details of any adjustment procedure or an explanation of why adjustment is not thought to be necessary should be set out in the analysis plan.

5.7 Subgroups, Interactions, and Covariates

The primary variable(s) is often systematically related to other influences apart from treatment. For example, there may be relationships to covariates such as age and sex, or there may be differences between specific subgroups of subjects, such as those treated at the different centers of a multicenter trial. In some instances, an adjustment for the influence of covariates or for subgroup effects is an integral part of the analysis plan and hence should be set out in the protocol. Prestudy deliberations should identify those covariates and factors expected to have an important influence on the primary variable(s), and should consider how to account for these in the analysis to improve precision and to compensate for any lack of balance between treatment groups. When the potential value of an adjustment is in doubt, it is often advisable to nominate the unadjusted analysis as the one for primary attention, the adjusted analysis being supportive. Special attention should be paid to center effects and to the role of baseline measurements of the primary variable. It is not advisable to adjust the main analyses for covariates measured after randomization because they may be affected by the treatments.

The treatment effect itself may also vary with subgroup or covariate—for example, the effect may decrease with age or may be larger in a particular diagnostic category of subjects. In some cases such interactions are anticipated, hence a subgroup analysis or a statistical model including interactions is part of the confirmatory analysis plan. In most cases, however, subgroup or interaction analyses are exploratory and should be clearly identified as such; they should explore the uniformity of any treatment effects found overall. In general, such analyses should proceed first through the addition of interaction terms to the statistical model in question, complemented by additional exploratory analysis within relevant subgroups of subjects, or within strata defined by the covariates. When exploratory, these analyses should be interpreted cautiously; any conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses are unlikely to be accepted.

5.8 Integrity of Data and Computer Software

The credibility of the numerical results of the analysis depends on the quality and validity of the methods and software used both for data management (data entry, storage, verification, correction, and retrieval) and for processing the data statistically. Data management activities should therefore be based on thorough and effective SOP's. The computer software used for data management and statistical analysis should be reliable, and documentation of appropriate software testing procedures should be available.

VI. Evaluation of Safety and Tolerability

6.1 Scope of Evaluation

In all clinical trials, evaluation of safety and tolerability constitutes an important element. In early phases, this evaluation is mostly of an exploratory nature and is only sensitive to frank expressions of toxicity, whereas in later phases, the establishment of the safety and tolerability profile of a drug can be characterized more fully in larger samples of subjects. Later phase controlled trials represent an important means of exploring, in an unbiased manner, any new potential adverse effects, even if such trials generally lack power in this respect.

Certain studies may be designed with the purpose of making specific claims about superiority or equivalence with regard to safety and tolerability compared to another drug or to another dose of the investigational drug. Such specific claims should be supported by relevant evidence from confirmatory studies, similar to that necessary for corresponding efficacy claims.

6.2 Choice of Variables and Data Collection

In any clinical trial, the methods and measurements chosen to evaluate the safety and tolerability of a drug will depend on a number of factors, including knowledge of the adverse effects of closely related drugs, information from nonclinical and earlier clinical studies, and possible consequences of the pharmacodynamic/pharmacokinetic properties of the particular drug, the mode of administration, the type of subjects to be studied, and the duration of the study. Laboratory tests concerning clinical chemistry and hematology, vital signs, and clinical adverse events (diseases, signs, and symptoms) usually form the main body of the safety and tolerability data. The occurrence of serious adverse events and treatment discontinuations due to adverse events are particularly important to register (see ICH E2A and ICH E3).

Furthermore, it is recommended that a consistent methodology be used for the data collection and evaluation throughout a clinical trial program to facilitate the combining of data from different trials. The use of a common adverse event dictionary is particularly important. This dictionary has a structure that makes it possible to summarize the adverse event data on three different levels: System-organ class, preferred term, or included term. The preferred term is the level on which adverse events usually are summarized, and preferred terms belonging to the same system-organ class could then be brought together in the descriptive presentation of data (see ICH E2B).

6.3 Set of Subjects to be Evaluated and Presentation of Data

For the overall safety and tolerability assessment, the set of subjects to be summarized is usually defined as those subjects who received at least one dose of the investigational drug. Safety and tolerability variables should be collected as comprehensively as possible from these subjects, including type of adverse event, severity, onset, and duration (see ICH E2B). Additional safety and tolerability evaluations may be needed in specific subpopulations, such as females, the elderly (see ICH E7), the severely ill, or those who have a common concomitant treatment. These evaluations may need to address more specific issues (see ICH E3).

All safety and tolerability variables need attention during evaluation, and the broad approach should be indicated in the protocol. All adverse events should be reported, whether or not they are considered to be related to treatment. All available data in the study population should be accounted for in the evaluation. Definitions of measurement units and reference ranges of laboratory variables should be made with care; if different units or different reference ranges appear in the same trial (e.g., if more than one laboratory is involved), then measurements should be appropriately standardized to allow a unified evaluation. Use of a toxicity grading scale should be prespecified and justified.

The incidence of a certain adverse event is usually expressed in the form of a proportion relating number of subjects experiencing events to number of subjects at risk. However, it is not always self-evident how to assess incidence. For example, depending on the situation, the number of exposed subjects or the extent of exposure (in person-years) could be considered for the denominator. Whether the purpose of the calculation is to estimate a risk or to make a comparison between treatment groups, it is important that the definition is given in the protocol. This is especially important if long-term treatment is planned and a substantial proportion of treatment withdrawals or deaths are expected. For such situations, survival analysis methods should be considered and cumulative adverse event rates calculated in order to avoid the risk of underestimation.

Methods to account for situations where there is a substantial background noise of signs and symptoms (e.g., in psychiatric trials) should be considered in the estimation of risk for different adverse events. One such method is to make use of the ''treatment emergent'' concept in which adverse events are recorded only if they emerge or worsen relative to pretreatment baseline.

Other methods to reduce the background noise may also be appropriate, such as ignoring adverse events of mild severity or requiring that an event should have been

observed at repeated visits to qualify for inclusion in the numerator. Such methods should be explained and justified in the protocol.

6.4 Statistical Evaluation

The investigation of safety and tolerability is a multidimensional problem. Although some specific adverse effects can usually be anticipated and specifically monitored for any drug, the range of possible adverse effects is very large, and new and unforeseeable effects are always possible. Further, an adverse event experienced after a protocol violation, such as use of an excluded medication, may introduce a bias. This background underlies the statistical difficulties associated with the analytical evaluation of safety and tolerability of drugs, and means that confirmatory information from Phase III clinical trials is the exception rather than the rule.

In most trials, the safety and tolerability implications are best addressed by applying descriptive statistical methods to the data, supplemented by calculation of confidence intervals wherever this aids interpretation. It is also valuable to make use of graphical presentations in which patterns of adverse events are displayed both within treatment groups and within subjects.

The calculation of p-values is sometimes useful, either as an aid to evaluating a specific difference of interest or as a ''flagging'' device applied to a large number of safety and tolerability variables to highlight differences worthy of further attention. This is particularly useful for laboratory data, which otherwise can be difficult to summarize appropriately. It is recommended that laboratory data be subjected to both a quantitative analysis, e.g., evaluation of treatment means, and a qualitative analysis, where counting of numbers above or below certain thresholds are calculated.

If hypothesis tests are used, statistical adjustments for multiplicity to quantitate the Type I error are appropriate, but the Type II error is usually of more concern. Care should be taken when interpreting putative statistically significant findings when there is no multiplicity adjustment.

In the majority of studies, investigators are seeking to establish that there are no clinically unacceptable differences in safety and tolerability compared with either a comparator drug or a placebo. As is the case for noninferiority or equivalence evaluation of efficacy, the use of confidence intervals is preferred to hypothesis testing in this situation. In this way, the considerable imprecision often arising from low frequencies of occurrence is clearly demonstrated.

6.5 Single Study versus Integrated Summary

The safety and tolerability properties of a drug are commonly summarized across studies continuously during an investigational product's development and, in particular, for the submission of a marketing application. The usefulness of this summary, however, is dependent on adequate and well-controlled individual studies with high data quality.

The overall usefulness of a drug is always a question of balance between risk and benefit; in a single trial, such a perspective could also be considered even if the assessment of risk/benefit usually is performed in the summary of the entire clinical trial program. (See section 7.1.2.)

For more details of safety and tolerability reports, see section 12 of the ICH Guideline E3 on ''Clinical Study Reports: Structure and Content.''

VII. Reporting

7.1 Evaluation and Reporting

As stated in the introduction, the structure and content of clinical reports is the subject of ICH Guideline E3. That ICH guideline fully covers the reporting of statistical work, appropriately integrated with clinical and other material. The current section is therefore relatively brief.

During the planning phase of a trial, the principal features of the analysis should have been specified in the protocol as described in section 5. When the conduct of the trial is over and the data are assembled and available for preliminary inspection, it is valuable to carry out the blind review of the planned analysis also described in section 5. This preanalysis review, blinded to treatment, should: (1) Cover decisions concerning the exclusion of subjects or data from the analysis sets; (2) check possible transformations and define outliers; (3) add to the model important covariates identified in other recent research; (4) reconsider the use of parametric or nonparametric methods. Decisions made at this time should be described in the report and should be distinguished from those made after the statistician has had access to the treatment codes, as blind decisions will generally introduce less potential for bias.

Many of the more detailed aspects of presentation and tabulation should be finalized at or about the time of the blind review so that, by the time of the actual analysis, full plans exist for all its aspects including subject selection, data selection and modification, data summary and tabulation, estimation and hypothesis testing. Once data validation is complete, the analysis should proceed according to the predefined plans; the more these plans are adhered to, the greater the credibility of the results. Particular attention should be paid to any differences between the planned analysis and the actual analysis as described in the protocol, the protocol amendments, or the updated statistical analysis plan based on a blind review of data. A careful explanation should be provided for deviations from the planned analysis.

All subjects who entered the trial should be accounted for in the report, whether or not they are included in the analysis. All reasons for exclusion from analysis should be documented; for any subject included in the set of all randomized subjects but not in the per-protocol set, the reasons for exclusion from the latter should also be documented. Similarly, for all subjects included in an analysis set, the measurements of all important variables should be accounted for at all relevant time-points.

The effect of all losses of subjects or data, withdrawals from treatment, and major protocol violations on the main analyses of the primary variable(s) should be considered carefully. Subjects lost to followup, withdrawn from treatment, or with a severe protocol violation should be identified; a descriptive analysis of the subjects should be provided, including the reasons for their loss and the relationship of the loss to treatment and outcome.

Descriptive statistics form an indispensable part of reports. Suitable tables and/or graphical presentations should illustrate clearly the important features of the primary and secondary variables and of key prognostic and demographic variables. The results of the main analyses relating to the objectives of the trial should be the subject of particularly careful descriptive presentation.

Although the primary goal of the analysis of a clinical trial should be to answer the questions posed by its main objectives, new questions based on the observed data may well emerge during the unblinded analysis. Additional and perhaps complex statistical analysis may be the consequence. This additional work should be strictly distinguished in the report from work that was planned in the protocol.

The play of chance may lead to unforeseen imbalances between the treatment groups in terms of baseline measurements not predefined as covariates in the analysis plan but having some prognostic importance nevertheless. This is best dealt with by showing that a subsidiary analysis that accounts for these imbalances reaches essentially the same conclusions as the planned analysis. If this is not the case, the effect of the imbalances on the conclusions should be discussed.

In general, sparing use should be made of unplanned subsidiary analyses. Subsidiary analyses are often carried out when it is thought that the treatment effect may vary according to some other factor or factors. An attempt may then be made to identify subgroups of subjects for whom the effect is particularly beneficial. The potential dangers of over-interpretation of unplanned subgroup analyses are well known (see also section 5.7) and should be carefully avoided. Although similar problems of interpretation arise if a treatment appears to have no benefit, or an adverse effect, in a subgroup of subjects, such possibilities need to be properly assessed and should therefore be reported.

Finally, statistical judgement should be brought to bear on the analysis, interpretation, and presentation of the results of a clinical trial. To this end, the trial statistician should be a member of the team responsible for the study report and should approve the final report.

7.2 Summarizing the Clinical Database

An overall summary and synthesis of the evidence on safety and efficacy from all the reported clinical trials is required for a marketing application. This may be accompanied, when appropriate, by a statistical combination of results.

Within the summary a number of areas of specific statistical interest arise: Describing the demography and clinical features of the population treated during the course of the

clinical trial program; addressing the key questions of efficacy by considering the results of the relevant (usually controlled) trials and highlighting the degree to which they reinforce or contradict each other; summarizing the safety information available from the combined database of all the studies whose results contribute to the marketing application and identifying potential safety issues. During the design of a clinical program, careful attention should be paid to the uniform definition and collection of measurements which will facilitate subsequent interpretation of the series of trials, particularly if they are likely to be combined across trials. A common dictionary for recording the details of medication, medical history, and adverse events should be selected and used. A common definition of the primary and secondary variables is nearly alway aworthwhile and is essential for meta-analysis. The manner of measuring key efficacy variables, the timing of assessments relative to randomization/entry, the handling of protocol violators and deviators, and perhaps the definition of prognostic factors, should all be kept compatible unless there are valid reasons not to do so.

Any statistical procedures used to combine data across trials should be described in detail. Attention should be paid to the possibility of bias associated with the selection of trials, to the homogeneity of their results, and to the proper modeling of the various sources of variation. The sensitivity of conclusions to the assumptions and selections made should be explored.

7.2.1 Efficacy Data

Individual clinical trials should always be large enough to satisfy their objectives. Additional valuable information may also be gained by summarizing a series of clinical trials that address essentially identical key efficacy questions. The main results of such a set of studies should be presented in an identical form to permit comparison, usually in tables or graphs that focus on estimates plus confidence limits. The use of meta-analytic techniques to combine these estimates is often a useful addition because it allows a more precise overall estimate of the size of the treatment effects to be generated and provides a complete and concise summary of the results of the trials. Under exceptional circumstances, a meta-analytic approach may also be the most appropriate way, or the only way, of providing sufficient overall evidence of efficacy via an overall hypothesis test.

7.2.2 Safety Data

In summarizing safety data, it is important to examine the safety database thoroughly for any indications of potential toxicity and to follow up any indications by looking for an associated supportive pattern of observations. The combination of the safety data from all human exposure to the drug provides an important source of information because its larger sample size provides the best chance of detecting the rarer adverse events and, perhaps, of estimating their approximate incidence. However, incidence data from this database are difficult to evaluate without a natural comparator group, and data from comparative studies are especially valuable in overcoming this difficulty. The results from studies that use a common comparator (placebo or specific active comparator) should be combined and presented separately for each comparator providing sufficient data.

All indications of potential toxicity arising from exploration of the data should be reported. The evaluation of the reality of these potential adverse effects should take into account the issue of multiplicity arising from the numerous comparisons made. The evaluation should also make appropriate use of survival analysis methods to exploit the potential relationship of the incidence of adverse events to duration of exposure and/or followup. The risks associated with identified adverse effects should be appropriately quantified to allow a proper assessment of the risk/benefit relationship.

Annex 1 Glossary

All randomized subjects—The analysis set that includes all subjects who were randomized to treatment, with these subjects assigned to the treatment group to which they were randomized. Practical considerations, such as missing data, may lead to some subjects in this set not being included in the corresponding analysis.

Analysis plan—The strategy for analysis predefined in the statistical section of the protocol and/or protocol amendments. The plan may be elaborated in a separate document (internal to the sponsor) to cover technical details and procedures for implementing the statistical analyses. The plan should be reviewed and possibly updated as a result of the blind review of the data.

Bayesian approaches—Approaches to data analysis that provide a posterior probability distribution for some parameter (e.g., treatment effect), derived from the observed data and a prior probability distribution for the parameter. The posterior distribution is then used as the basis for statistical inference.

Bias (statistical and operational)—The systematic tendency of any factors associated with the design, conduct, analysis, and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value. Bias introduced through deviations in conduct is referred to as ''operational'' bias. The other sources of bias listed above are referred to as ''statistical.''

Blind review—The checking and assessment of data during the course of the study, but before the breaking of the blind, for the purpose of finalizing the analysis plan.

Content validity—The extent to which a variable (e.g., a rating scale) measures what it is supposed to measure.

Double dummy—A technique for retaining the blind when administering supplies in a clinical trial, when the two treatments cannot be made identical. Supplies are prepared for Treatment A (active and indistinguishable placebo) and for Treatment B (active and indistinguishable placebo). Subjects then take two sets of treatment; either A (active) and B (placebo), or A (placebo) and B (active).

Dropout—A subject in a clinical trial who for any reason fails to continue in the trial until the last visit required of him/her by the study protocol.

Equivalence trial—A trial with the primary objective of showing that the response to two or more treatments differs by an amount which is clinically unimportant. This is usually demonstrated by showing that the true treatment difference is likely to lie between a lower and an upper equivalence margin of clinically acceptable differences.

Frequentist methods—Statistical methods, such as significance tests and confidence intervals, which can be interpreted in terms of the frequency of certain outcomes occurring in hypothetical repeated realizations of the same experimental situation.

Generalizability, generalization—The extent to which the findings of a clinical trial can be reliably extrapolated from the subjects who participated in the trial to a broader patient population.

Global assessment variable—A single variable, usually a scale of ordered categorical ratings, that integrates objective variables and the investigator's overall impression about the state or change in state of a subject.–

Independent data monitoring committee (IDMC) (data and safety monitoring board, monitoring committee, data monitoring committee)—An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Intention-to-treat principle—The principle that asserts that the effect of a treatment policy can be best assessed by evaluating on the basis of the intention to treat a subject (i.e., the planned treatment regimen) rather than the actual treatment given. It has the consequence that subjects allocated to a treatment group should be followed up, assessed, and analyzed as members of that group irrespective of their compliance to the planned course of treatment.

Interaction (qualitative and quantitative)—The situation in which a treatment contrast (e.g., difference between investigational product and control) is dependent on another factor (e.g., center). A quantitative interaction refers to the case where the magnitude of the contrast differs at the different levels of the factor, whereas for a qualitative interaction the direction of the contrast differs for at least one level of the factor.

Inter- and intrarater reliability—The level of consistency of a rater (intra) or a group of raters (inter) in making an assessment of treatment outcome.

Interim analysis—Any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to the formal completion of a trial.

Meta-analysis—The formal evaluation of the quantitative evidence from two or more trials bearing on the same question. This most commonly involves the statistical combination of summary statistics from the various trials, but the term is sometimes used to refer to the combination of the raw data.

Multicenter trial—A trial involving two or more study centers, a common study protocol, and a single analysis plan pooling the data across all centers.

Noninferiority trial—A trial with the primary objective of showing that the response to the investigational product is not clinically inferior to a comparative agent (active or placebo control).

Preferred and included terms—In a hierarchical medical dictionary, for example, WHO-ART, the included term is the lowest level of dictionary term to which the investigator description is coded. The preferred term is the level of grouping of included terms typically used in reporting frequency of occurrence. For example, the investigator text ''Pain in the left arm'' might be coded to the included term ''Joint pain,'' which is reported at the preferred term level as ''Arthralgia.''

Per protocol set (valid cases, efficacy sample, evaluable subjects sample)—The set of data generated by the subset of subjects who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment according to the underlying scientific model. Compliance covers such considerations as exposure to treatment, availability of measurements, and absence of major protocol violations.

Safety and tolerability—The safety of a medical product concerns the medical risk to the subject, usually assessed in a clinical trial by laboratory tests (including clinical chemistry and hematology), vital signs, clinical adverse events (diseases, signs and symptoms), and other special safety tests (e.g., electrocardiograms, ophthalmology). The tolerability of the medical product represents the degree to which overt adverse effects can be tolerated by the subject.

Superiority trial—A trial with the primary objective of showing that the response to the investigational product is superior to a comparative agent (active or placebo control).

Surrogate variable—A variable that provides an indirect measurement of effect in situations where direct measurement of clinical effect is not feasible or practical.

Treatment effect—An effect attributed to a treatment in a clinical trial. In most clinical trials, the treatment effect of interest is a comparison (or contrast) of two or more treatments.

Treatment emergent—An event that emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state.

Dated: April 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12139 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

POSTAL SERVICE

Experimental Nonletter-Size Reply Mail Categories and Fees; Changes in Domestic Classifications and Fees

AGENCY: Postal Service.

ACTION: Notice of implementation of changes to the Domestic Mail Classification Schedule and accompanying fee changes.

SUMMARY: This notice sets forth the changes to the Domestic Mail Classification Schedule and the accompanying fee changes to be implemented as a result of the May 5, 1997, Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees.

EFFECTIVE DATE: June 8, 1997.

FOR FURTHER INFORMATION CONTACT: Michael Tidwell, (202) 268–2998.

SUPPLEMENTARY INFORMATION: On December 13, 1996, pursuant to its authority under 39 U.S.C. 3621, *et seq.*, the Postal Service filed with the Postal Rate Commission (PRC) a request for a recommended decision on experimental classifications and fees for nonletter-size Business Reply Mail. The PRC designated the filing as Docket No. MC97–1. The PRC published a notice of the filing, with a description of the Postal Service's proposals, on December 24, 1996, in the **Federal Register** (61 FR 67860–67862).

On April 2, 1997, pursuant to its authority under 39 U.S.C. 3624, the PRC issued to the Governors of the Postal Service its Recommended Decision on the Postal Service's Request. The PRC recommended the experimental nonletter-size Business Reply Mail classifications and fees requested by the Postal Service.

Pursuant to 39 U.S.C. 3625, the Governors of the United States Postal Service acted on the PRC's recommendations on May 5, 1997. Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees, Docket No. MC97–1. The Governors determined to approve the PRC's recommendations, and the Board of Governors set an implementation date of June 8, 1997, for the classifications and fee changes to take effect. A copy of the attachments to that Decision, setting forth the classification and fee changes approved by the Governors, is set forth below.

Also on May 5, 1997, the Board of Governors of the Postal Service, pursuant to their authority under 39 U.S.C. 3625(f), determined to make the classification and fee changes approved by the Governors effective at 12:01 a.m. on June 8, 1997 (Resolution No. 97–8).

In accordance with the Decision of the Governors and Resolution No. 97–8, the Postal Service hereby gives notice that the classification and fee changes set forth below will become effective at 12:01 a.m. on June 8, 1997. Implementing regulations also become effective at that time, as noted elsewhere in this issue.

Stanley F. Mires,

Chief Counsel, Legislative.

Attachment A to the Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees, (May 5, 1997)

CHANGES IN THE DOMESTIC MAIL CLASSIFICATION SCHEDULE

The following material represents changes to the Domestic Mail Classification Schedule (DMCS) approved by the Governors of the United States Postal Service in response to the Commission's Recommended Decision in Docket No. MC97–1. Changes are identified by underlining additions to the DMCS.

Domestic Mail Classification Schedule SS–2 Business Reply Mail

2.01 Definitions

2.010 Business reply mail is a service whereby business reply cards, envelopes, cartons and labels may be distributed by or for a business reply distributor for use by mailers for sending First-Class Mail without prepayment of postage to an address chosen by the distributor. A distributor is the holder of a business reply license.

2.011 A business reply mail piece is nonletter-size for purposes of Classification Schedule SS–2 if it meets addressing and other preparation requirements, but does not meet the machinability requirements prescribed by the Postal Service for mechanized or automated letter sortation.

This provision expires June 7, 1999.

2.02 Description of Service

2.020 The distributor guarantees payment on delivery of postage and fees for all returned business reply mail. Any distributor of business reply cards, envelopes, cartons and labels under any one license for return to several addresses guarantees to pay postage and fees on any returns refused by any such addressee.

2.03 Requirements of the Mailer

2.030 Business reply cards, envelopes, cartons and labels must be preaddressed and bear business reply markings.

2.031 Handwriting, typewriting or handstamping are not acceptable methods of preaddressing or marking business reply cards, envelopes, cartons, or labels.

2.04 Fees

2.040 The fees for business reply mail are set forth in Rate Schedule SS–2.

2.041 To qualify as an active business reply mail advance deposit trust account, the account must be used solely for business reply mail and contain sufficient postage and fees due for returned business reply mail.

2.042 An accounting fee as set forth in Rate Schedule SS–2 must be paid each year for each advance deposit business reply account at each facility where the mail is to be returned.

2.043 Experimental Reverse Manifest Fees

2.0431 A set-up/qualification fee as set forth in Rate Schedule SS–2 must be paid by each business reply mail advance deposit trust account holder at each destination postal facility at which it applies to receive nonletter-size business reply mail for which the postage and fees will be accounted for through a reverse manifest method approved by the Postal Service for ascertaining and verifying postage.

A distributor must pay this fee for each business reply mail advance deposit trust account for which participation in the nonletter-size business reply mail experiment is requested.

This provision expires June 7, 1999.

2.0432 A nonletter-size reverse manifest monthly fee as set forth in Rate Schedule SS–2 must be paid each month during which the distributor's reverse manifest account is active.

This fee applies to the (no more than) 10 advance deposit account holders which are selected by the Postal Service to participate in the reverse manifest nonletter-size business reply mail experiment and which utilize reverse manifest accounting methods approved by the Postal Service for ascertaining and verifying postage and fees.

This provision expires June 7, 1999.

2.044 Experimental Weight Averaging Fees

2.0441 A set-up/qualification fee as set forth in Rate Schedule SS–2 must be paid by each business reply mail

advance deposit trust account holder at each destination postal facility at which it applies to receive nonletter-size business reply mail for which the postage and fees will be accounted for through a weight averaging method approved by the Postal Service for ascertaining and verifying postage.

A distributor must pay this fee for each business reply mail advance deposit trust account for which participation in the nonletter-size business reply mail experiment is requested.

This provision expires June 7, 1999.

2.0442 A nonletter-size weight averaging monthly fee as set forth in Rate Schedule SS–2 must be paid each month during which the distributor's weight averaging account is active.

This fee applies to the (no more than) 10 advance deposit account holders which are selected by the Postal Service to participate in the weight averaging nonletter-size business reply mail experiment.

This provision expires June 7, 1999.

2.05 Authorizations and Licenses

2.050 In order to distribute business reply cards, envelopes, cartons or labels, the distributor must obtain a license or licenses from the Postal Service and pay the appropriate fee as set forth in Rate Schedule SS–2.

2.0501 Except as provided in section 2.0502, the license to distribute business reply cards, envelopes, cartons, or labels must be obtained at each office from which the mail is offered for delivery.

2.0502 If the business reply mail is to be distributed from a central office to be returned to branches or dealers in other cities, one license obtained from the post office where the central office is located may be used to cover all business reply mail.

2.051 The license to mail business reply mail may be canceled for failure to pay business reply postage and fees when due, and for distributing business reply cards or envelopes which do not conform to prescribed form, style or size.

2.052 Authorization to pay experimental nonletter-size business reply mail fees as set forth in Rate Schedule SS–2 may be canceled for failure of a business reply mail advance deposit trust account holder to meet the standards prescribed by the Postal Service for the applicable reverse manifest or weight averaging accounting method.

This provision expires June 7, 1999.

Attachment B to the Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees (May 5, 1997)

CHANGES TO RATE SCHEDULE SS–2

The following material represents changes in Rate Schedule SS–2 approved by the Governors of the United States Postal Service in response to the Commission's Recommended Decision in Docket No. MC97–1. Changes are identified by underlining additions to Rate Schedule SS–2.

RATE SCHEDULE SS–2

	Fee [1]
Active business reply advanced deposit account:	
Per piece:	
Prebarcoded	$.02
Nonletter-size, using reverse manifest (experimental)	.02
Nonletter-size, using weight averaging (experimental)	.03
Other	.10
Payment of postage due charges if active business reply mail advance deposit account not used:	.44
Annual License and Accounting Fees:	
Accounting Fee for Advance Deposit Account	205
Permit fee (with or without Advance Deposit Account)	85
Monthly Fees for customers using a reverse manifest or weight averaging for nonletter-size business reply:	
Nonletter-size, using reverse manifest (experimental)	1,000
Nonletter-size, using weight averaging (experimental)	3,000
Set-up/Qualification Fee for customers using a reverse manifest or weight averaging for nonletter-size business reply:	
Nonletter-size, using reverse manifest (experimental)	1,000
Nonletter-size, using weight averaging (experimental)	3,000

[1] Experimental per piece, monthly and set-up/qualification fees are applicable only to participants selected by the Postal Service for nonletter-size business reply mail experiment. The experimental fees expire on June 7, 1999.

[FR Doc. 97–12207 Filed 5–7–97; 9:42 am]

BILLING CODE 7710–12–U

federal register

Friday
May 9, 1997

Part VII

Department of Education

National Institute on Disability and Rehabilitation Research; Notice of Funding Priorities for FY 1997–1998; Office of Special Education and Rehabilitative Services, Notice Inviting Applications for New Awards Under Certain Programs for Fiscal Year 1997

DEPARTMENT OF EDUCATION

National Institute on Disability and Rehabilitation Research; Notice of Final Funding Priorities for Fiscal Years 1997–1998 for Research and Demonstration Projects, Rehabilitation Research and Training Centers, and a Knowledge Dissemination and Utilization Project

AGENCY: Department of Education.

SUMMARY: The Secretary announces final funding priorities for the Research and Demonstration Project (R&D) Program, the Rehabilitation Research and Training Center (RRTC) Program, and the Knowledge Dissemination and Utilization (D&U) Program under the National Institute on Disability and Rehabilitation Research (NIDRR) for fiscal years 1997–1998. The Secretary takes this action to focus research attention on areas of national need to improve rehabilitation services and outcomes for individuals with disabilities, and to assist in the solutions to problems encountered by individuals with disabilities in their daily activities.

EFFECTIVE DATE: These priorities take effect on June 9, 1997.

FOR FURTHER INFORMATION CONTACT: David Esquith. Telephone: (202) 205–8801. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–2742. Internet: David__—Esquith@ed.gov.

SUPPLEMENTARY INFORMATION: This notice contains final priorities to establish R&D projects for model systems for burn injury and traumatic brain injury, RRTCs for research related to aging with a spinal cord injury and severe problem behaviors, and a D&U project to improve the utilization of existing and emerging rehabilitation technology in the State vocational rehabilitation program.

These final priorities support the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

Note: This notice of final priorities does *not* solicit applications. A notice inviting applications under these competitions is published in a separate notice in this issue of the **Federal Register**.

Analysis of Comments and Changes

On March 4, 1997, the Secretary published a notice of proposed priorities in the **Federal Register** (62 FR 9886–9892). The Department of Education received ninety-four letters commenting on the notice of proposed priorities by the deadline date. Seventy-eight additional comments were received after the deadline date and were not considered in this response. Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under statutory authority—are not addressed.

Research and Demonstration Projects Program

Priority 1: Burn Injury Rehabilitation Model System

Comment: The Burn Injury Rehabilitation Model System projects should provide care from the point of injury to the completion of care.

Discussion: The projects are intended to provide care from the point of injury to the completion of care. The priority is not as clear as it could be on this point.

Changes: The initial purpose statement of the priority has been revised to require a project to provide care from the point of injury through community integration and long-term follow-up.

Comment: The 1992 Burn Model system's final priority excluded children. The new projects should provide care to children and adults.

Discussion: The 1992 final priority discussion of the exclusion of children from the Burn Model system's program stated, ''The burn injury model system will be developed initially to serve and collect data on adults since NIDRR's experience with the model systems for spinal cord injury and traumatic brain injury projects indicates that these systems can be successful with adults. The model systems can be adapted for children later.'' (57 FR 57284). The commenter is correct, and the Burn Model System program should be able to include children without jeopardizing the database or service delivery progress that has been made to date.

Including children will require the Burn Model System projects to address new and unique issues, such as the effect of the burn injury on physical, cognitive, and social development. It will also demand that the projects coordinate with children's service providers, including special educators. The annual funding of the Burn Model System projects has been increased in order to provide adequate support for the additional tasks that will result from this change.

Changes: The background statement and the priority have been revised to require the projects to include children in the model system and the projects' research and demonstration activities. The fourth purpose statement has been revised to include special education interventions and education outcomes.

Comment: The model system projects should be required to use electronic communication.

Discussion: The use of electronic communication is so common that it is unnecessary to require it.

Changes: None.

Comment: What guidelines have been established for defining the cost of care data from the data which are more commonly available, i.e., charges of care?

Discussion: There are no guidelines for defining cost of care. Applicants have the discretion to propose how they will define cost, and the peer review process will evaluate the merits of the definition. An applicant could propose to define cost as charges of care.

Changes: None.

Comment: A comment in response to the TBI Model System proposed priority questioned the use of the term ''multidisciplinary'' to describe the model system. The commenter opined that the manner in which care is rendered in most, if not all, the model systems is in an ''interdisciplinary'' or ''transdisciplinary'' fashion. ''Interdisciplinary'' or ''transdisciplinary'' should be used instead of ''multidisciplinary.''

Discussion: This comment, although not addressed to the proposed Burn Injury Rehabilitation Model System priority, applies equally to it. The term ''multidisciplinary'' was used to convey that the projects should involve all necessary and appropriate disciplines in the delivery of care. Since there are no universally accepted definitions of any of these terms, use of any one term could lead to a misunderstanding.

Changes: The term ''multidisciplinary'' has been deleted from the Burn Injury Rehabilitation Model System priority, and the priority requires the projects to involve all necessary and appropriate disciplines in the delivery of care.

Priority 2: Traumatic Brain Injury Model Systems

Comment: The priority limits inclusion in the model systems database to patients who are admitted to a participating trauma unit and then transferred to a participating acute rehabilitation hospital for inpatient services. This limitation excludes patients who, after participating in a trauma unit, receive services at alternative post-acute treatment sites such as a skilled nursing facility, a subacute rehabilitation facility, or at home. Increasingly, managed care

organizations and rehabilitation providers are utilizing these excluded treatment sites. These exclusions should be eliminated from the priority in order to allow the projects to study the impact of these alternative treatment pathways.

Discussion: This recommendation raises fundamental questions about the purpose and future directions of the TBI Model Systems program. As indicated in the background statement, ''NIDRR's multi-center model systems program is designed to study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute neuro-trauma management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services.'' Including other pathways of post-acute treatment such as skilled nursing facilities, subacute rehabilitation facilities, and home care would significantly change the nature of the model system that has been in place for since 1987. This change would require projects to engage in data collection activities from a wider range of treatment sites, and possibly a wider range of severity of brain injury. The nature and quality of services provided at these alternative treatment sites, as well as the population served, may vary significantly, and this variation would need to be addressed in the compilation of the national database.

Post-acute treatment of TBI is going through a period of transition, and it is necessary for the TBI Model system program to be equally dynamic in order to maintain the program's relevance. In order to facilitate a smooth transition, the priority is being changed to provide applicants with the option of expanding their scope of activities to include alternative post-acute treatment sites while maintaining the requirement that all projects include the current pathway of inpatient rehabilitation treatment. This change is made with the acknowledgment that complications may occur. For example, if some projects expand to include alternative post-acute treatment sites, while others maintain the current treatment pathway, the uniformity of the database will be affected. These complications should be outweighed by the new information that will be generated about the post-acute alternative treatment sites. In addition, if at some future date, the inclusion of alternative post-acute treatment sites becomes a requirement rather than an option, the experience of the next round of projects that include those sites in their systems will serve as a useful source of information about the transition.

Changes: The background statement and the priority have been revised to provide projects with the option of including alternative post-acute treatment sites in their system while maintaining the requirement that all projects include post-acute inpatient rehabilitation sites. In addition, the final priority includes an invitational priority in order to encourage applicants to pursue this option.

Comment: The phrase ''specific treatment interventions'' should be added to the fourth purpose of the priority.

Discussion: The fourth purpose of the priority requires a project to determine the relationship between cost of care and functional outcomes. In order to make this determination, the project should link the cost of care to a specific intervention. The commenter's recommendation clarifies this point.

Changes: The fourth purpose statement has been revised to require a project to determine the relationship between cost of care, specific treatment interventions, and functional outcomes.

Comment: The projects should examine the issues of aging with TBI.

Discussion: Applicants have the discretion to propose areas of investigation as long as those areas are within the purpose of the priority. However, examining issues of aging with TBI is outside of the scope of activities that an applicant could propose to fulfill the purpose of a project in the TBI Model Systems program. There is insufficient evidence to support establishing an absolute priority on this topic under other NIDRR research programs.

Changes: None.

Comment: The projects should examine the impact of pre-injury psychosocial factors on rehabilitation outcomes.

Discussion: Applicants have the discretion to propose areas of investigation as long as those areas are within the purpose of the priority. Thus, in response to the revised third purpose statement, an applicant could propose to delineate the role of premorbid factors in outcome in TBI. The peer review process will evaluate the merits of the proposal.

Changes: None.

Comment: The priority refers to a ''multidisciplinary'' model system of care. The manner in which care is rendered in most, if not all, the model systems is in an ''interdisciplinary'' or ''transdisciplinary'' fashion. ''Interdisciplinary'' or ''transdisciplinary'' should be used instead of ''multidisciplinary.''

Discussion: The term ''multidisciplinary'' was used to convey that the projects should involve all necessary and appropriate disciplines in the delivery of care. Since there are no universally accepted definitions of any of these terms, use of any one term could lead to a misunderstanding.

Changes: The term ''multidisciplinary'' has been deleted, and the priority requires the projects to involve all necessary and appropriate disciplines in the delivery of care.

Comment: In order to provide the priority with a consumer perspective, ''subjective well-being'' should be added to the third purpose statement.

Discussion: The third purpose statement requires the project to develop key predictors of rehabilitation outcomes at hospital discharge and at long-term follow-up. Including subjective well-being in the priority will promote the inclusion of consumers' perspectives among the rehabilitation outcomes.

Changes: The third purpose statement has been revised to require a project to address subjective well-being when it develops key predictors of rehabilitation outcomes.

Comment: The efficacy of interventions should not be weighed against the cost of interventions alone. Purposes statements four and five should be revised to refer to ''costs to society.''

Discussion: Determining ''costs to society'' is an imprecise endeavor. While ''cost of interventions'' admittedly constitutes a more limited perspective, it is a measure that can be used consistently across projects with a much higher degree of confidence.

Changes: None.

Comment: The projects should investigate potential systematic biases in longitudinal studies of persons with TBI.

Discussion: Applicants have the discretion to propose areas of investigation as long as those areas are within the purpose of the priority. However, investigating potential systematic biases in longitudinal studies of persons with TBI is outside of the scope of activities that an applicant could propose to fulfill the purpose of a project in the TBI Model Systems program. There is insufficient evidence to support establishing an absolute priority on this topic under other NIDRR research programs.

Changes: None.

Comment: The TBI Model Systems program should promote variation in care, along with systematic data collection, so that the impact of variations can be studied. To the extent

that all funded model systems are encouraged to develop similar systems of care, the opportunity to understand the impact of differences in care is lost. Specifically, the study of the impact of differences in the design and organization of rehabilitation interventions can be advanced by changing the enrollment constraints of model system patients, including those who are in a vegetative state, encouraging program innovations, developing innovative financing approaches to TBI rehabilitation, and supporting rigorous research on the treatment of both motor and cognitive impairments, including training regimens, pharmacologic treatments, and the use of orthotic and prosthetic devices.

Discussion: The TBI Model System program is intended to demonstrate the effectiveness of a prescribed system of care implemented in a similar fashion by a number of projects. Some degree of variation occurs across projects, and this variation will increase markedly if grantees exercise the option of including alternative post-acute treatments pathways in their model system of care. The commenter is correct that to the extent all funded model systems are encouraged to develop similar systems of care, the opportunity to understand the impact of differences in care is lost. However, there are substantial benefits in regard to the quality of the knowledge that can be generated by demonstrating and evaluating a prescribed system across projects. In light of the resources available to the program, those benefits outweigh benefits that would result from a model system that would systematically promote variation in care.

Changes: None.

Comment: The projects should study the impact of managed care on healthcare delivery to persons with TBI.

Discussion: Applicants have the discretion to propose areas of investigation so long as those areas are within the purpose of the priority. Thus, in response to the revised fourth purpose statement, an applicant could propose to study the impact of managed care on healthcare delivery to persons with TBI. The peer review process will evaluate the merits of the proposal. It should be noted that NIDRR has recently awarded an RRTC in fiscal year 1997 to study issues in Managed Health Care for individuals with disabilities.

Changes: None.

Comment: The impact of computers and technology should be emphasized in the priority.

Discussion: Emerging technology is having a significant impact on the rehabilitation outcomes of persons with TBI. In order to keep pace with these developments, all of the TBI Model Systems projects should identify and evaluate the effectiveness of interventions that use emerging technology.

Changes: The second purpose of the priority has been revised to require a project to examine the role of emerging technology in improving vocational outcomes and community integration.

Comment: Rather than determine the relationships between cost of care and functional outcomes, the fourth purpose of the priority should require a project to understand factors that determine costs, i.e., ''Quantify factors that affect the cost and benefits of care, such as functional outcomes.''

Discussion: In response to the fourth purpose of the priority, an applicant could propose to quantify factors that affect the cost and benefits of care. Determining the relationships between cost of care, specific treatment interventions, and functional outcomes, and understanding factors that determine costs are not necessarily exclusive activities.

Changes: None.

Comment: Control groups or stable baselines are needed to study the outcomes and value of TBI rehabilitation. Databases that allow comparisons of similar patients who may experience different treatment strategies are invaluable in research designed to infer the effectiveness of rehabilitative interventions. All projects should be required to participate in controlled research.

Discussion: Applicants have the discretion to propose the research design that a project will use, and the peer review process will evaluate the merits of the design. Thus, an applicant could propose to use controlled research, and the peer review process will evaluate the merits of the research design. However, requiring all projects to carry out controlled research could exclude equally effective research methodologies.

Changes: None.

Comment: The priority does not attend sufficiently to issues related to acute care of TBI. Attention should be focused on the prevention of secondary conditions through early rehabilitation interventions in the acute care setting. Incorporation of this component permits the investigation of novel pharmacologic strategies and early cognitive interventions to enhance long-term functional and vocational outcomes.

Discussion: In response to the revised second purpose statement, an applicant could propose to emphasize the prevention of secondary conditions through early rehabilitation interventions in the acute care setting, and the peer review process will evaluate the merits of the emphasis. However, there is insufficient evidence to warrant requiring all applicants to emphasize the prevention of secondary conditions through early rehabilitation interventions in the acute care setting.

Changes: None.

Comment: Projects should study the effectiveness of behavioral management strategies and the role of family dynamics in TBI patients.

Discussion: An applicant could propose to study the effectiveness of behavioral management strategies or the role of family dynamics under the second and third purpose statements, respectively. The peer review process will evaluate the merits of the proposals. However, there is insufficient evidence to warrant requiring all applicants to study the effectiveness of behavioral management strategies or the role of family dynamics.

Changes: None.

Rehabilitation Research and Training Centers (RRTCs)

Priority 4: Aging With Spinal Cord Injury

Comment: The background statement acknowledges an array of health maintenance problems including, but not limited to cardiovascular problems, urinary tract infections, pressure sores, hypertension, fractures, blood in the urine or bowel problems, and diabetes. However, the priority does not include a commensurate purpose statement requiring the RRTC to address these problems. The employment problems experienced by persons aging with SCI are usually problems of maintaining employment, and not gaining employment. Their difficulties maintaining employment are most often a function of a health maintenance problem. The priority places too much emphasis on employment-related issues and fails to address critical health issues.

Discussion: This concern was expressed by thirty-seven of the thirty-eight comments that the Department received on this proposed priority by the deadline date. The commenters are persuasive that the priority places too much emphasis on employment-related issues and fails to address critical health issues.

Changes: The priority has been revised to include a new purpose statement addressing health maintenance problems and to de-

emphasize employment-related issues. In addition, in recognition of the additional work that will be required to address health maintenance problems, the number of purpose statements has been reduced and the dissemination and training requirements have been consolidated and modified.

Comment: Forty-four percent of the people who get a SCI are members of a minority group. The RRTC should place special emphasis on people aging with a SCI from minority backgrounds.

Discussion: The commenter is correct. There are an increasing number of persons from minority backgrounds who are experiencing SCI, and their unique and varying needs merit special attention from the RRTC.

Changes: The background statement and priority have been revised to evidence the unique needs of persons aging with SCI from minority backgrounds and require the RRTC to address those needs.

Comment: Proper research designs need to be used to identify the potential causes of late life changes. Complex cross-sequential designs are needed to test these questions. Otherwise the results, even from longitudinal designs (which do not control from the effect of era), are flawed.

Discussion: An applicant could propose to use complex cross-sequential designs, and the peer review process will evaluate the merits of the design. However, requiring all projects to use complex cross-sequential designs could exclude equally effective research designs.

Changes: None.

Comment: The part of the second purpose of the priority that requires the RRTC to evaluate rehabilitation techniques that will assist individuals aging with SCI to cope with changes should be revised to develop better assessment and treatment methods for depression as people attempt to cope.

Discussion: In response to the second purpose statement, an applicants could propose to develop better assessment and treatment methods for depression as people attempt to cope, and the peer review process will evaluate the merits of the proposal. However, there is insufficient evidence to warrant requiring all applicants to develop better assessment and treatment methods for depression as people attempt to cope.

Changes: None.

Comment: The RRTC should address the significant ethnic differences that exist among caregivers as well as the great diversity in who serves as caregiver (spouse, parent, sibling, friend, paid attendant).

Discussion: An applicant could propose to address the significant ethnic differences that exist among caregivers as well as the diversity in who serves as caregiver under the third purpose of the priority. There is insufficient evidence to warrant requiring all applicants to propose to study these two topics.

Changes: None.

Comment: The data from the 1992 SCI Model Systems Annual Report that is included in the background statement is partially contradicted by the 1996 SCI Model Systems Annual Report. The background statement indicates that employment rate peaks at about 40 percent for persons with paraplegia and at 28 percent for persons with quadriplegia, and sharply declines about 18 years after the post-injury. However, the 1996 Report shows employment peaking at 39 percent at fifteen years after injury and at 38.4 percent at 20 years after injury.

Discussion: The 1992 and the 1996 report findings are different, but not contradictory. However, since the 1996 findings are more recent, they should be included in the background statement in place of the 1992 data.

Changes: The background statement uses the information from the 1996 SCI Model Systems Annual Report instead of the 1992 Report data.

Research and Demonstration Projects

Authority for the R&D program of NIDRR is contained in section 204(a) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760–762). Under this program the Secretary makes awards to public agencies and private agencies and organizations, including institutions of higher education, Indian tribes, and tribal organizations. This program is designed to assist in the development of solutions to the problems encountered by individuals with disabilities in their daily activities, especially problems related to employment (see 34 CFR 351.1). Under the regulations for this program (see 34 CFR 351.32), the Secretary may establish research priorities by reserving funds to support the research activities listed in 34 CFR 351.10.

Priorities

Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet one of the following priorities. The Secretary will fund under this program only applications that meet one of these absolute priorities:

Priority 1: Burn Injury Rehabilitation Model System

Background

Each year more than 2.0 million persons (about one percent of the population of the United States) receive a burn injury. Of these, 6,500 to 12,000 do not survive; 500,000 require medical care and result in temporary disability with respect to home, school, or work activities; and 70,000 to 100,000 are severe enough to be admitted to a hospital (Rice, D.P. and MacKenzie, E.J., ''Cost of Injury in the United States: A Report to Congress,'' Atlanta, GA: Centers for Disease Control, 1989).

In 1994, NIDRR provided funding to establish Burn Injury Rehabilitation Model Systems of Care. These R&D projects focused primarily on developing and demonstrating a comprehensive, multidisciplinary model system of rehabilitative services for individuals with severe burns, and evaluating the efficacy of that system through the collection and analysis of uniform data on system benefits, costs, and outcomes. NIDRR's multi-center model systems program is designed to study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute care management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services.

Burn rehabilitation requires interventions as soon as possible after admission to hospitals and has treatment implications for several years following hospital discharge. Burn trauma often causes injuries and impairments in addition to the burn, and many individuals with burn injuries have secondary complications related to the burn condition. These may include open wounds, contractures, neuropathies, cosmetic abnormalities, deconditioning, bony deformities, hypersensitivity to heat and cold, amputation, psychosocial distress, chronic pain, and scarring. The complicated nature of burn injuries, the difficulty of treatment, and the risk of infection with possible loss of function requires interventions quickly and frequently to attempt to maintain a functional lifestyle and return to living independently. Minimization of physical deterioration and prevention of further impairment and functional limitation is critical and research is needed to find the appropriate procedures for clinical applications. Research is needed to develop and refine methods to determine the effectiveness of interventions to prevent, manage, and reduce medical

complications that contribute to short and long-term disability in burn patients.

Children who are severely burned may present unique challenges to health care providers, educators, and family members due to the physical, cognitive and emotional development stages that they experience. For example, returning to school and neighborhood may pose a serious threat to the development of a child's self-esteem if disfigurement is evident. In order to minimize the impact of a severe burn on a child's development, an efficient, well-coordinated system of care must be in place that involves medical, rehabilitation, and educational service providers, including special educators.

Improved measures are needed of an individual's functional ability as a result of burn rehabilitation interventions. Functional assessment brings objectivity to rehabilitation by establishing appropriate, uniform descriptors of rehabilitation care and changes in individual capacity to perform activities of daily living or other measurable elements of an individual's major life activities (Granger, C. and Brownscheidle, C., ''Outcome Measurement in Medical Rehabilitation,'' *International Journal of Technology Assessment in Health Care,* 11:2, 1995). Increasingly, health and rehabilitation services require effectiveness and impact measures to evaluate their services as a part of procedures for cost-reimbursement and billing for services. With greater emphasis on individual choice in services delivery, consumers and advocates are likewise advocates for functional assessment measures as encoders of service effectiveness. Few existing functional assessment measures, however, address the specialized and complex combination of psychosocial and medical challenges encountered by an individual who has experienced severe burn injury (Rucker, K., et al., ''Analysis of Functional Assessment Instruments for Disability Rehabilitation Programs,'' SEW Contract No. 600–95–2194, Virginia Commonwealth University, 1996).

Burn injuries can produce emotional problems, such as post-traumatic stress disorders, anxiety, and depression. These problems may result from a variety of causes (e.g., reaction to cosmetic alterations, changes in functional abilities, changes in work status, restrictions on recreational activities) (Cromes, G.F. and Helm, P.A., ''Burn Injuries,'' in *Medical Aspects of Disability,* pgs. 92–104, 1993). The aesthetic disability of disfigurement is frequently more severe than the physical disability and may result in profound social consequences for those afflicted (Hurren, J.S., ''Rehabilitation of the Burned Patient: James Laing Memorial Essay for 1993,'' *Burns,* Vol. 21, No. 2, 1995). The more severe the burn, the greater the likelihood of long-term psychosocial adjustment issues related to both physical and psychosocial problems, that affect quality of life. Although psychosocial adjustment is a critical factor in the long-term recovery of burn injury patients, there continues to be limited emphasis on research in the area of psychosocial rehabilitation and its relationship to quality of life. Family and friends play an important role and provide major support in the psychological recovery of burn patients. Research in this area needs to address the role of the family and personal advocacy systems in providing support during the burn injury rehabilitation process.

Difficulty with long-term follow-up of all patients after hospital discharge has always been a problem, but it is even more difficult when the individual lives far from the specialized rehabilitation unit. Problems are also encountered with those individuals living in rural areas, where access to burn injury rehabilitation, including mental health services, may be quite limited due to lack of proximity to specialized practitioners, limited access to technological advances, and hospital closures.

Return-to-work and educational pursuits are important measures of rehabilitation success. Work is an important source of satisfaction, self-respect, and dignity, as well as an arena for socialization for individuals who have experienced burn injury (Salisbury, R., ''Burn Rehabilitation: Our Unanswered Challenge,'' 1992 Presidential Address to the American Burn Association, April, 1992). However, the efficacy of vocational rehabilitation interventions for this population has not been documented adequately. The physical, psychosocial, and emotional factors that lead to successful employment have not been clearly identified. Research is needed to examine relationships between vocational interventions and supports, employment, functional capacity, and degree of burn injury, including secondary complications.

Priority 1

The Secretary will establish Burn Injury Rehabilitation Model Systems R&D projects for the purpose of demonstrating a comprehensive, model system of rehabilitative services, involving all necessary and appropriate disciplines, for children and adults with severe burns from point of injury to community integration and long-term follow-up. An R&D project must:

(1) Identify and evaluate techniques to prevent secondary complications;

(2) Develop and evaluate outreach programs to improve follow-up services for rural populations;

(3) Develop and evaluate measures of functional outcome for burn rehabilitation; and

(4) Identify and evaluate interventions, including vocational rehabilitation and special education interventions, to improve psychosocial adjustment, quality of life, community integration, and education and employment-related outcomes.

In carrying out these purposes, the R&D project must:

- Participate in clinical and systems analysis studies of the burn injury rehabilitation model system by collecting and contributing data on patient characteristics, diagnoses, causes of injury, interventions, outcomes, and costs to a uniform, standardized national data base as prescribed by the Secretary; and
- Consider collaborative projects with other model systems.

Priority 2: Traumatic Brain Injury Model Systems

Background

An estimated 1.9 million Americans experience traumatic brain injury (TBI) each year (Collins, J.F., ''Types of Injuries by Selected Characteristics: US 1985–87,'' National Center for Health Statistics, Vital Health Stat 10 (175), 1990). Incidence is highest among youth and younger adults. Young males have the highest incidence rates of any group (''Disability Statistics Abstract,'' No. 14, Disability Statistics Rehabilitation Research & Training Center, University of California, San Francisco, November, 1995). Each year approximately 70,000 to 90,000 TBI survivors enter a life of continuing, debilitating loss of function; an estimated 5,000 survivors experience seizure disorders; and 2,000 enter into a persistent vegetative state. The number of people surviving head injuries has increased significantly over the last 25 years as a result of faster and better emergency treatment, more rapid and safer transport to specialized treatment facilities, and advances in medical treatment (National Foundation for Brain Research, Washington, DC, 1994).

In 1987, NIDRR provided funding to establish TBI Model Systems of Care. These R&D projects focused primarily

on developing and demonstrating a comprehensive, multidisciplinary model system of rehabilitative services for individuals with TBI, and evaluating the efficacy of that system through the collection and analysis of uniform data on system benefits, costs, and outcomes. NIDRR's multi-center model systems program is designed to study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute neuro-trauma management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services. Projects are being given an option at this time of including, in addition to comprehensive inpatient rehabilitation, alternative pathways of post-acute treatment such as skilled nursing facilities, subacute rehabilitation facilities, and home care.

The TBI Model Systems serve a substantial number of patients, allowing the projects to conduct clinical research and program evaluation, which maximize the potential for project replication. In addition, the TBI Model Systems have the advantage of a complex data collection and retrieval program with the capability to analyze the different system components and provide information on project cost effectiveness and benefits. Information is collected throughout the rehabilitation process, permitting long-term follow-up on the course of injury, outcomes, and changes in employment status, community integration, substance abuse and family needs. The TBI Model Systems projects serve as regional and national models for program development and as information centers for consumers, families, and professionals.

The TBI Model Systems National Database reports that the average length of stay in acute care has decreased approximately 50 percent, from 30 days in 1989 to 15 days in 1996; and the average length of stay in inpatient rehabilitation has decreased 38 percent, from 52 days in 1989 to 32 days in 1996. With the changing patterns of service delivery, there continues to be a need to establish and evaluate new rehabilitation interventions and strategies. Specialized measurement tools have been developed by the TBI Model Systems to assess progress and describe clinical and functional outcomes. Refinement of these measurement tools is necessary to demonstrate the effectiveness of rehabilitation interventions in inpatient and outpatient settings. After the individual is discharged from an inpatient setting, there is an ongoing need for outpatient and community reintegration services in order to continue therapeutic interventions and the educational and referral process. As the average length of stay in inpatient settings decreases, there is a greater need to evaluate outpatient and community reintegration programs.

Findings from a multi-center investigation of employment and community integration following TBI highlight the need for post-acute rehabilitation programs with particular emphasis on vocational rehabilitation (Sander, A., et al., *Journal of Head Trauma Rehabilitation,* Vol. 11, No. 5, pgs. 70–84, 1996). Kreutzer states that employment and productivity, relating to others in the community, and independently caring for oneself at home are important quality-of-life components (''TBI: Models and Systems of Care,'' Conference Syllabus, Medical College of Virginia, April, 1996). As functional recovery progresses during the first year or more after the injury, the focus of rehabilitation shifts from medical intervention and physical restoration to psychosocial and vocational adaptation. The ultimate goal of psychosocial and vocational rehabilitation is community reintegration and employment. It is important to emphasize that services aimed at community reintegration must consider not only attributes and limitations of the injured individuals, but also the social, educational, and vocational systems in which the individual will function. In addition, rates of competitive employment decrease substantially from pre-injury levels. Head injury frequently results in unemployment, and there are significant relationships between risk factors (e.g., substance abuse) and this changed employment status. However, there is no reliable information regarding the magnitude of risk associated with different factors, or with different levels of these factors (Dikmen, S., et al., ''Employment following Traumatic Head Injuries,'' *Archives of Neurology,* Vol. 51, February, 1994).

A major disability like TBI has a profoundly disorganizing impact on the lives of individuals with TBI and their families. Questions involving community, family, and vocational restoration, as well as generic concerns about future happiness and fulfillment, are common (Banja, J., & Johnston, M., ''Ethical Perspectives and Social Policy,'' *Archives of Physical Medicine Rehabilitation,* Vol. 75, SC–19, December, 1994). Even individuals who have integrated well into society experience adverse psychosocial effects. Employment instability, isolation from friends, and increased need for support are a few of the problems encountered by individuals with TBI. Families often function as the primary support system for individuals with TBI after they are discharged. There is a clear need for research to develop family treatment strategies and explore their effect on outcomes for individuals with TBI.

The health care costs associated with TBI are staggering. The direct medical costs of TBI treatment have been estimated at more than $4 billion annually (Max, W., et al., ''Head Injuries: Costs and Consequences,'' *Journal of Head Trauma Rehabilitation,* Vol. 6, pgs. 76–91, 1991). In view of current scrutiny of all health care spending, which may result in pressures to constrict or deny rehabilitation care to individuals with traumatic brain injury, it is important to gather information on the efficacy and cost-effectiveness of various treatment interventions and service delivery models. Credible outcome monitoring systems are needed to establish guidelines by which fair compromises can be reached (Johnston, M. & Hall, K., ''Outcomes Evaluation in TBI Rehabilitation, Part I: Overview and System Principles,'' *Archives of Physical Medicine and Rehabilitation,* Vol. 75, December, 1994). A greater emphasis on outcomes measurements and management will foster the gathering of information on efficacy and cost-effectiveness.

Violence-induced TBI is increasingly common, and has significant implications for rehabilitation and community reintegration. According to the 1991 National Health Interview Survey data, violence was responsible for nine percent of all non-fatal TBIs. In addition, violence was a cause of injury in 30 percent of the 684 external injury cases in the TBI Model Systems database (a higher frequency due, in part, to the urban setting of one of the TBI Model Systems). The frequency of violence as a cause of TBI, in part, can be attributed to the fact that the individuals most likely to sustain TBI (i.e., males under age 18) are also those most likely to be involved in crimes and violence. The increase in violence as a cause of brain injury may have consequences with regard to rehabilitation costs, treatment interventions and long-term outcomes. For example, individuals with violence-related injuries show more difficulties with community integration skills one year following injury, which evidences itself in areas of social integration and productivity. Further research is needed to examine whether individuals who sustain a TBI as a result of violence

require specialized rehabilitation interventions.

Priority 2

The Secretary will establish Model Systems TBI R&D projects for the purpose of demonstrating a comprehensive, model system of care for individuals with TBI, involving all necessary and appropriate disciplines. An R&D project must:

(1) Investigate the efficacy of alternative methods of service delivery interventions after inpatient rehabilitation discharge and after other post-acute treatment pathways when applicable;

(2) Identify and evaluate interventions, including those utilizing emerging technology, that can improve vocational outcomes and community integration;

(3) Develop key predictors of rehabilitation outcome, including subjective well-being, at hospital discharge and at long-term follow-up;

(4) Determine the relationship between cost of care, specific treatment interventions, and functional outcomes; and

(5) Examine the implications of violence as a cause of TBI on treatment interventions, rehabilitation costs, and long-term outcomes.

In carrying out these purposes, the R&D Systems project must:

- Participate in clinical and systems analysis studies of the traumatic brain injury model system by collecting and contributing data on patient characteristics, diagnoses, causes of injury, interventions, outcomes, and costs to a uniform, standardized national data base as prescribed by the Secretary;
- Consider collaborative projects with other model systems; and
- Coordinate research efforts with other NIDRR grantees that address TBI-related issues.

Invitational Priority: The Secretary is particularly interested in applications that address the following invitational priority within this absolute priority. However, under 34 CFR 75.105(c)(1) an application that meets an invitational priority does not receive competitive or absolute preference over other applications. The invitational priority is for projects that include, in addition to comprehensive inpatient rehabilitation, alternative pathways of post-acute treatment such as skilled nursing facilities, subacute rehabilitation facilities, and home care.

Rehabilitation Research and Training Centers (RRTCs)

Authority for the RRTC program of NIDRR is contained in section 204(b)(2) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760–762). Under this program the Secretary makes awards to public and private organizations, including institutions of higher education and Indian tribes or tribal organizations for coordinated research and training activities. These entities must be of sufficient size, scope, and quality to effectively carry out the activities of the Center in an efficient manner consistent with appropriate State and Federal laws. They must demonstrate the ability to carry out the training activities either directly or through another entity that can provide such training.

The Secretary may make awards for up to 60 months through grants or cooperative agreements. The purpose of the awards is for planning and conducting research, training, demonstrations, and related activities leading to the development of methods, procedures, and devices that will benefit individuals with disabilities, especially those with the most severe disabilities.

Under the regulations for this program (see 34 CFR 352.32) the Secretary may establish research priorities by reserving funds to support particular research activities.

Description of the Rehabilitation Research and Training Center Program

RRTCs are operated in collaboration with institutions of higher education or providers of rehabilitation services or other appropriate services. RRTCs serve as centers of national excellence and national or regional resources for providers and individuals with disabilities and the parents, family members, guardians, advocates or authorized representatives of the individuals.

RRTCs conduct coordinated and advanced programs of research in rehabilitation targeted toward the production of new knowledge to improve rehabilitation methodology and service delivery systems, to alleviate or stabilize disabling conditions, and to promote maximum social and economic independence of individuals with disabilities.

RRTCs provide training, including graduate, pre-service, and in-service training, to assist individuals to more effectively provide rehabilitation services. They also provide training including graduate, pre-service, and in-service training, for rehabilitation research personnel and other rehabilitation personnel.

RRTCs serve as informational and technical assistance resources to providers, individuals with disabilities, and the parents, family members, guardians, advocates, or authorized representatives of these individuals through conferences, workshops, public education programs, in-service training programs and similar activities.

NIDRR encourages all Centers to involve individuals with disabilities and minorities as recipients in research training, as well as clinical training.

Applicants have considerable latitude in proposing the specific research and related projects they will undertake to achieve the designated outcomes; however, the regulatory selection criteria for the program (34 CFR 352.31) state that the Secretary reviews the extent to which applicants justify their choice of research projects in terms of the relevance to the priority and to the needs of individuals with disabilities. The Secretary also reviews the extent to which applicants present a scientific methodology that includes reasonable hypotheses, methods of data collection and analysis, and a means to evaluate the extent to which project objectives have been achieved.

The Department is particularly interested in ensuring that the expenditure of public funds is justified by the execution of intended activities and the advancement of knowledge and, thus, has built this accountability into the selection criteria. Not later than three years after the establishment of any RRTC, NIDRR will conduct one or more reviews of the activities and achievements of the Center. In accordance with the provisions of 34 CFR 75.253(a), continued funding depends at all times on satisfactory performance and accomplishment.

General

The following requirements apply to these RRTCs pursuant to the priorities unless noted otherwise:

Each RRTC must conduct an integrated program of research to develop solutions to problems confronted by individuals with disabilities.

Each RRTC must conduct a coordinated and advanced program of training in rehabilitation research, including training in research methodology and applied research experience, that will contribute to the number of qualified researchers working in the area of rehabilitation research.

Each RRTC must disseminate and encourage the use of new rehabilitation knowledge. They must publish all

materials for dissemination or training in alternate formats to make them accessible to individuals with a range of disabling conditions.

Each RRTC must involve individuals with disabilities and, if appropriate, their family members, as well as rehabilitation service providers, in planning and implementing the research and training programs, in interpreting and disseminating the research findings, and in evaluating the Center.

Priorities

Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet one of the following priorities. The Secretary will fund under these competitions only applications that meet one of these absolute priorities:

Priority 3: Effective Interventions for Children and Youth With Disabilities Who Exhibit Severe Problem Behaviors

Background

In recent years researchers have focused on the application of non-aversive approaches to reduce and eliminate severe problem behaviors (SPBs) exhibited by children and youth with disabilities. This has been the case because of ethical concerns about aversive interventions expressed by disability professionals, parents, and advocates, as well as research findings which indicate that aversive interventions are largely ineffective in eliminating or reducing SPBs over an extended period of time. Because of their disruptive nature, SPBs such as physical aggression, self-injury, violence, and property destruction are among the primary obstacles to full inclusion of children and youth with disabilities in age-appropriate community-based activities and regular education settings. School and community-based program personnel need effective methods to reduce and eliminate SPBs in order to provide these children and youth with disabilities with opportunities to learn, play, and work with their non-disabled peers.

Previous research in this area has improved our understanding of the early indicators of SPBs. For example, children with disabilities who display minor self-injurious behavior during the preschool years are strong candidates to exhibit more SPBs within two years (Hall, S., ''Early Intervention of Self-injurious Behavior in Young Children with Intellectual Disabilities: Naturalistic Observation,'' Presented at the Annual Meeting of the American Association of Mental Retardation, San Francisco, June, 1995). Further research is needed on how severe problem behavior patterns develop and whether early intervention efforts can reduce, and perhaps prevent, SPBs.

Preliminary research has also indicated that problem behaviors can be reduced by understanding the antecedents to and function of the behavior. Accordingly, children and youth with disabilities who exhibit SPBs may be able to learn to self-manage their problem behaviors.

While there are encouraging indications that non-aversive approaches can be effective in reducing and eliminating SPBs, there is a need to develop effective interventions that can be maintained over extended periods of time. Treatments of self-injurious behaviors are particularly problematic in regard to long-term effectiveness. Research has shown that children who exhibit self-injurious behaviors, even after intensive non-aversive treatment programs, may revert to self-injury at high rates within a few months of intervention (Durand, V.M., et al., ''The Course of Self-injurious Behavior Among People with Autism,'' Paper presented at the Annual Meeting of the Berkshire Association for Behavior Analysis and Therapy, Amherst, MA. 1995).

Information from functional assessments can be used to develop educational plans and address inappropriate behavior. Functional assessment is the general label assigned to describe a set of processes (e.g., interviews, rating, rating scales, direct observations, and systematic experimental analyses of specific situations) for defining the events in an environment that reliably predict and maintain behaviors. More research needs to be done in order to expand the application of functional assessments with children and youth with disabilities who exhibit severe problem behaviors.

Under normal circumstances, children and youth with disabilities who exhibit SPBs in school and the community are also exhibiting these behaviors at home. In order for non-aversive approaches to be implemented consistently across environments, parents and other caregivers must not only consent to the approach, but also be capable of implementing the approach effectively in the home environment. The non-aversive strategies that are developed must be compatible with the home environment, and take into account providing parents and guardians with the skills they need to implement the program effectively.

Priority 3

The Secretary will establish an RRTC for the purpose of providing school and community-based program personnel with effective methods to reduce and eliminate SPBs in children and youth with disabilities. The RRTC shall:

(1) Develop and evaluate non-aversive interventions that reduce and eliminate severe behavior problems exhibited by children and youth with disabilities;

(2) Investigate the etiology of SPBs for the purpose of developing prevention and early intervention strategies;

(3) Investigate the durability and maintenance of effective non-aversive interventions;

(4) Investigate the effectiveness of self-management strategies;

(5) Develop and evaluate functional assessments to address SPBs in educational and community-based settings;

(6) Develop materials and provide training to educators, community-based program personnel, parents, and caregivers who address SPBs; and

(7) Develop and disseminate informational materials and provide technical assistance to local and State educational agencies to address SPBs.

In carrying out the purposes of the priority, the RRTC shall disseminate materials and coordinate training activities with related projects supported by the Office of Special Education Programs, including the Regional Resource Centers and Parent Information Centers.

Priority 4: Aging With Spinal Cord Injury

Background

While the mortality rate of persons who experience a spinal cord injury (SCI) and related conditions has improved markedly, life expectancy estimates are still well below normal (DeVivo, M. and Stover, S., ''Long-term Survival and Causes of Death,'' in *Spinal Cord Injury: Clinical Outcomes from the Model Systems,* Aspen Publications, Gaithersburg, Maryland, 1995). Estimates of spinal cord injury prevalence in America range from 180,000 to 250,000 with between 7,000 and 10,000 new spinal cord injuries each year (National Spinal Cord Injury Statistical Center, The University of Alabama at Birmingham, 1995). One of four individuals who previously sustained a spinal cord injury is now at least 20 years post-onset. The average age of a SCI survivor is now about 48 years and about 20 percent of SCI survivors are over age 60.

Many SCI survivors develop new medical, functional, and psychological

problems that threaten their independence. In addition, many experience job loss, barriers to accessing proper health maintenance and caregiver/personal assistance services, loss of financial assistance, and economic hardship. Persons aging with SCI are susceptible to multiple health maintenance problems including, but not limited to, cardiovascular problems, urinary tract infections, pressure sores, hypertension, fractures, blood in the urine or bowel problems, and diabetes (Whiteneck, G.(Ed.), *Aging with a Spinal Cord Injury,* 1992). The leading medical cause of death and further disability that affects people with SCI is now premature cardiovascular disease of the atherosclerotic kind. Whiteneck, using data from England, found that cardiovascular disease is now tied with genito-urinary problems as the leading cause of death in people aging with SCI.

Individuals aging with a SCI also experience complications as a result of osteoporosis and lower extremity fractures (Garland, D.E., ''Bone Mineral Density about the Knee in SCI Patients with Pathological Fractures,'' *Contemporary Orthopaedics,* 1992 and Garland, D.E., ''Osteoporosis Following SCI,'' *Journal of Orthopaedic Research,* 1992). Garland discovered a high prevalence of carpal tunnel syndrome, which increased with the length of time after injury. In addition, Sie found an increased prevalence of general upper extremity pain and shoulder pain with time since injury in both paraplegic and tetraplegia individuals (Sie, I., ''Upper Extremity Pain in the Post-Rehabilitation SCI Injured Patient,'' *Archives of Physical Medicine and Rehabilitation,* 1992). Shoulder pain occurs in about 50 percent of people with paraplegia secondary to prolonged wheelchair use. Pain, fatigue and weakness are also commonly reported but accommodations for them are poorly understood.

The 1996 SCI Model Systems Annual report shows employment peaking at 39 percent at fifteen years after injury and at 38.4 percent at 20 years after injury. Interventions are needed to maintain the employment status of people aging with SCI and prevent job loss due to premature aging effects. In addition, further research is needed to determine the changes in functional ability to perform activities of daily living (ADL) and work.

As people age and their functioning changes, the need for assistance from others (i.e., family, friends, and paid caregivers) increases. Strategies to best assist the caregiver, in turn, to help the person who is aging with SCI need to be developed. Moreover, there is no ''typical'' caregiver; some are spouses, some are parents, and some are children. Fifty percent of people with SCI receive help exclusively from their families, and an additional 19 percent receive substantial help from their families. Living with family is the most frequently reported living situation, occurring in over 90 percent of cases (Nosek, M.A., ''Personal Assistance: Key to Maintaining Ability of Persons with Physical Disabilities,'' *Applied Rehabilitation Counselor,* Vol. 21, 1990).

Declining or unstable support systems for people aging with SCI are also a major concern. Since parents of aging SCI individuals are often elderly, they are also at risk of poor health or death. Spousal support providers may experience ''burn-out'' and stress, or develop health problems. There are few alternatives to the informal support system. As individuals with SCI age, access to proper health care, especially with the growing trend toward managed care, is becoming a bigger problem. There is need for research on maintaining independence in the community for people aging with SCI through both the informal and formal systems of care.

Psychological well-being for individuals aging with SCI is also of major concern. Depression is a very important issue requiring additional study because of its bearing on quality of life, its importance for overall health, and its relationship to suicide (Schulz, R., ''Long Term Adjustment to Physical Disability: The Role of Social Support Service of Control and Self Blame,'' *Journal of Personality and Social Psychology,* 5, pgs. 1162–1172, 1985). The research indicates that over 40 percent of people who have sustained functional changes as a consequence of aging with SCI show high levels of distress and depression. Pilot data on treatment are available from the NIDRR-funded centers, but a full treatment procedure for stress and depression needs to be developed.

A significant trend over time has been observed in the racial distribution of persons in the SCI Model Systems database. Among persons injured between 1973 and 1978, 77.5 percent of persons in the database were Caucasian, 13.6 percent were African-American, and 6 percent were Hispanic. Among those injured since 1990, 55.2 percent were Caucasian, 29 percent were African-American, and 12.8 percent were Hispanic (''Spinal Cord Injury, Facts and Figures at a Glance,'' National Spinal Cord Injury Statistical Center, University of Alabama at Birmingham, July, 1996). This increase in incidence of SCI among persons from minority backgrounds is accompanied by research at the current RRTC on Aging with SCI indicating that people from minority backgrounds experience different long-term consequences from SCI.

Priority 4

The Secretary will establish an RRTC for the purpose of conducting research on rehabilitation techniques that assist individuals aging with SCI to maintain employment and independence in the community. The RRTC shall:

(1) Identify, develop, and evaluate interventions to address health maintenance issues, and prevent and treat secondary conditions for individuals aging with SCI;

(2) Identify, develop, and evaluate rehabilitation techniques that will assist individuals aging with SCI to maintain employment and to cope with changes in functional abilities and ADL;

(3) Investigate how formal and informal systems of care could be improved to address the impact of problems associated with long-term care givers and personal service assistants;

(4) Develop a better understanding of the natural course of SCI as persons age and develop regimens to minimize or take account of the impacts of aging with SCI; and

(5) Develop materials and a program of information dissemination and training for individuals aging with SCI, their families, service providers and educators that will assist them to understand the natural course of SCI as persons age.

In carrying out the purposes of the priority, the RRTC shall:

- Emphasize the needs of persons from minority backgrounds; and
- Coordinate with all other relevant SCI research and demonstration activities, including those sponsored by the National Center on Medical Rehabilitation Research, the Rehabilitation Services Administration, Paralyzed Veterans of America, National Spinal Cord Injury Association and NIDRR-funded SCI projects.

Knowledge Dissemination and Utilization Projects

Authority for the D&U program of NIDRR is contained in sections 202 and 204(a) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760–762). Under this program the Secretary makes awards to public and private organizations, including institutions of higher education and Indian tribes or tribal organizations. Under the regulations for this program (see 34 CFR 355.32), the Secretary may establish

research priorities by reserving funds to support particular research activities.

Priority

Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet the following priority. The Secretary will fund under this competition only applications that meet this absolute priority:

Priority 5: Improving the Utilization of Existing and Emerging Rehabilitation Technology in the State Vocational Rehabilitation Program

Background

One of the more persistent issues in the rehabilitation of individuals with disabilities has been maximizing the use of existing and emerging rehabilitation technology in the service settings of the State Vocational Rehabilitation (VR) programs. As defined in Section 7(13) of the Rehabilitation Act, as amended (Act), rehabilitation technology means ''the systematic application of technologies, engineering methodologies, or scientific principles to meet the needs of and address the barriers confronted by individuals with disabilities in areas which include education, rehabilitation, employment, transportation, independent living and recreation'' and includes ''rehabilitation engineering, assistive technology devices, and assistive technology services.'' Under Section 101(a)(5)(C) of the Act, designated VR agencies must describe in their State plan how the State will provide a broad range of rehabilitation technology services at each stage of the rehabilitation process. As appropriate, rehabilitation technology services are provided to individuals with disabilities served by State VR programs under an Individualized Written Rehabilitation Program.

Rehabilitation technology, and information about rehabilitation technology, is generated by a variety of sources including, but not limited to, NIDRR-funded Rehabilitation Engineering and Research Centers, the Assistive Technology program funded under the Technology-Related Assistance for Individuals with Disabilities Act of 1988, ABLEDATA, the Department of Veteran's Affairs Research and Development projects, and manufacturers in the private sector. While many of these sources may undertake dissemination activities, too often rehabilitation counselors and related vocational rehabilitation service providers are unaware of existing or emerging rehabilitation technologies, resulting in a number of problems for clients of the State vocational rehabilitation system.

The provision of inappropriate rehabilitation technology can result in nonuse. The nonuse of a device may lead to decreases in functional abilities, freedom, and independence. On a service delivery level, device abandonment represents ineffective use of limited funds by Federal, State, and local government agencies, insurers, and other provider organizations (Phillips, B. and Hongxin, Z., ''Predictors of Assistive Technology Abandonment,'' *Assistive Technology*, Vol. 5, No. 1, pg. 36, 1993).

If vocational rehabilitation personnel are unfamiliar with an emerging technology, their clients are disadvantaged by not having access to recent developments in the field. These developments may be more effective and economical than existing rehabilitation technology. Because of the costs that can be involved, the decision to utilize a particular rehabilitation technology, even if the technology is outdated, can be difficult to reverse or modify.

Information barriers related to rehabilitation technology also apply to secondary students with disabilities who increasingly complete their education with the help of assistive devices (Everson, J., ''Using Person-centered Planning Concepts to Enhance School-to-Adult Life Transition Planning,'' *Journal of Vocational Rehabilitation*, Vol. 6, 1996). In order to ensure their continued access to technical accommodation as part of their transition to employment and independent living, special education and vocational rehabilitation personnel involved in their transition must have proper training and access to current information.

Assigning inappropriate or outdated rehabilitation technology to consumers can be avoided if vocational rehabilitation personnel are provided with comprehensive and current information on existing and emerging rehabilitation technology. Rehabilitation counselors and related vocational rehabilitation service providers gain access to information about rehabilitation technology from various sources including, but not limited to, their pre-service and in-service training, memberships in professional organizations, conferences, and more recently through the information superhighway. Because the field of rehabilitation technology is developing rapidly, and because it is a technically diverse and complex field, it has been a challenge for rehabilitation personnel development programs to keep pace with rehabilitation technology. There is a growing need for dissemination of information about rehabilitation technology, including the development of pre-service and in-service resources, in order to promote improved rehabilitation professional training on rehabilitation technology.

Priority 5

The Secretary will establish a knowledge dissemination and utilization project for the purpose of improving the ability of rehabilitation professionals to more effectively use rehabilitation technology in providing services to individuals through the State VR Services program. The D&U project must:

(1) Evaluate the pre-service and in-service rehabilitation professional training materials that address rehabilitation technology and identify strengths and deficiencies in those materials;

(2) Based on this evaluation, develop training materials that will improve the ability of rehabilitation counselors and related professionals to utilize existing and emerging rehabilitation technology;

(3) Disseminate these materials to pre-service and in-service rehabilitation professional training programs;

(4) As needed, provide technical assistance to these pre-service and in-service training programs to maximize the use of the materials; and

(5) Using a variety of strategies, disseminate information about existing and emerging rehabilitation technology to rehabilitation counselors, special educators involved with the transition of secondary students, and related rehabilitation professionals.

In carrying out the purposes of the priority, the D&U project must:

- Coordinate with the Assistive Technology projects to avoid duplication of effort;
- Develop information about existing and emerging rehabilitation technology from a wide variety of sources; and
- On a regular basis, update the information and materials that are developed.

APPLICABLE PROGRAM REGULATIONS: 34 CFR Parts 350, 351, and 352. Program Authority: 29 U.S.C. 760–762.

(Catalog of Federal Domestic Assistance Numbers: 84.133A, Research and Demonstration Projects, 84.133B, Rehabilitation Research and Training Center Program, 84.133D, Knowledge Dissemination and Utilization Program)

Dated: May 6, 1997.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 97–12259 Filed 5–8–97; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA Nos.: 84.133A, 84.133B, and 84.133D]

Office of Special Education and Rehabilitative Services, National Institute on Disability and Rehabilitation Research; Notice Inviting Applications for New Awards Under Certain Programs for Fiscal Year 1997

NOTE TO APPLICANTS: This notice is a complete application package. Together with the statute authorizing the programs and applicable regulations governing the programs, including the Education Department General Administrative Regulations (EDGAR), this notice contains information, application forms, and instructions needed to apply for a grant under these competitions.

These programs support the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

The estimated funding levels in this notice do not bind the Department of Education to make awards in any of these categories, or to any specific number of awards or funding levels, unless otherwise specified in statute.

Applicable Regulations:

The Education Department General Administrative Regulations (EDGAR), 34 CFR Parts 74, 75, 77, 80, 81, 82, 85, and 86; and the following program regulations:

(a) *Research and Demonstration Projects (R&D)*—34 CFR Parts 350 and 351;

(b) *Knowledge Dissemination and Utilization Program (D&U)*—34 CFR Parts 350 and 355; and

(c) *Rehabilitation Research and Training Centers (RRTCs)*—34 CFR Parts 350 and 352.

Program Title: Research and Demonstration Projects

CFDA Number: 84.133A

Purpose of Program: The Research and Demonstration Projects program is designed to support discrete research, demonstration, training, and related projects to develop methods, procedures, and technology that maximize the full inclusion and integration into society, independent living, employment, family support, and economic and social self-sufficiency of individuals with disabilities, especially those with the most severe disabilities. In addition, the R&D program supports discrete research, demonstration, and training projects that specifically address the implementation of Titles I, III, VI, VII, and VIII of the Rehabilitation Act, with emphasis on projects to improve the effectiveness of these programs and to meet the needs described in State Plans submitted to the Rehabilitation Services Administration by State vocational rehabilitation agencies.

Eligible Applicants

Parties eligible to apply for grants under this program are public and private nonprofit and for-profit agencies and organizations, including institutions of higher education and Indian tribes and tribal organizations.

Program Authority: 29 U.S.C. 761a and 762.

Program Title: Knowledge Dissemination and Utilization Program

CFDA Number: 84.133D

Purpose of Program: The Knowledge Dissemination and Utilization is designed to support activities that will ensure that rehabilitation knowledge generated from projects and centers funded by NIDRR and from other sources is fully utilized to improve the lives of individuals with disabilities and their families.

Eligible Applicants: Parties eligible to apply for grants under this program are public and private nonprofit and for-profit agencies and organizations, including institutions of higher education and Indian tribes and tribal organizations.

Program Authority: 29 U.S.C. 761a and 762.

APPLICATION NOTICE FOR FISCAL YEAR 1997—RESEARCH AND DEMONSTRATION PROJECTS, CFDA NO. 84.133A, KNOWLEDGE DISSEMINATION AND UTILIZATION PROGRAM, CFDA NO. 84.133D

Funding priority	Deadline for transmittal of applications	Estimated number of awards	Maximum award amount (per year in dollars)*	Project period (months)
Burn Injury Rehabilitation Model System 84.133A	6/23/97	4	295,000	60
Traumatic Brain Injury Model Systems 84.133A	6/23/97	5	345,000	Up to 60**
Improving the Utilization of Rehabilitation Technology in Rehabilitation 84.133D	6/23/97	1	500,000	60

Applications Available: May 9, 1997.

* Note 1: The Secretary will reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount (See 34 CFR 75.104(b)).

** Note 2: Applicants should submit proposals covering a 60 month project period. The Secretary will assess, during the third year of the project period, whether the model as described in the TBI Model Systems Priority is the most appropriate approach and whether revisions are needed in the model. Based on this determination the Secretary will determine whether there is a continuing need to provide funding beyond 36 months.

Research and Demonstration Projects and Knowledge Dissemination and Utilization Program Selection Criteria

The Secretary uses the following selection criteria to evaluate applications under the R&D and D&U programs.

(a) *Potential Impact of Outcomes: Importance of Program* (Weight 3.0).

The Secretary reviews each application to determine to what degree—

(1) The proposed activity relates to the announced priority;

(2) The research is likely to produce new and useful information (research activities only);

(3) The need and target population are adequately defined;

(4) The outcomes are likely to benefit the defined target population;

(5) The training needs are clearly defined (training activities only);

(6) The training methods and developed subject matter are likely to meet the defined need (training activities only); and

(7) The need for information exists (utilization activities only).

(b) *Potential Impact of Outcomes: Dissemination/Utilization* (Weight 3.0). The Secretary reviews each application to determine to what degree—

(1) The research results are likely to become available to others working in the field (research activities only);

(2) The means to disseminate and promote utilization by others are defined;

(3) The training methods and content are to be packaged for dissemination and use by others (training activities only);

(4) The utilization approach is likely to address the defined need (utilization activities only); and

(5) There is likely to be widespread dissemination of the results, in a usable and effective manner, to all appropriate target populations, including individuals with disabilities and their family members.

(c) *Probability of Achieving Proposed Outcomes; Program/ Project Design* (Weight 5.0). The Secretary reviews each application to determine to what degree—

(1) The objectives of the project(s) are clearly stated;

(2) The hypothesis is sound and based on evidence (research activities only);

(3) The project design/methodology is likely to achieve the objectives;

(4) The measurement methodology and analysis is sound (research and development/demonstration activities only);

(5) The conceptual model (if used) is sound (development/ demonstration activities only);

(6) The sample populations are correct and significant (research and development/demonstration activities only);

(7) The human subjects are sufficiently protected (research and development/demonstration activities only);

(8) The device(s) or model system is to be developed in an appropriate environment;

(9) The training content is comprehensive and at an appropriate level (training activities only);

(10) The training methods are likely to be effective (training activities only);

(11) The new materials (if developed) are likely to be of high quality and uniqueness (training activities only);

(12) The target populations are linked to the project (utilization activities only);

(13) The format of the dissemination medium is the best to achieve the desired result (utilization activities only); and

(14) The materials to be used in the project and the materials to be disseminated are likely to be in formats that are accessible to the appropriate populations.

(d) *Probability of Achieving Proposed Outcomes: Key Personnel* (Weight 4.0). The Secretary reviews each application to determine to what degree—

(1) The principal investigator and other key staff have adequate training and/or experience and demonstrate appropriate potential to conduct the proposed research, demonstration, training, development, or dissemination activity;

(2) The principal investigator and other key staff are familiar with pertinent literature and/or methods;

(3) All required disciplines are effectively covered;

(4) Commitments of staff time are adequate for the project; and

(5) The applicant is likely, as part of its non-discriminatory employment practices, to encourage applications for employment from persons who are members of groups that traditionally have been underrepresented, such as—

(i) Members of racial or ethnic minority groups;

(ii) Women;

(iii) Handicapped persons; and

(iv) The elderly.

(e) *Probability of Achieving Proposed Outcomes: Evaluation Plan* (Weight 1.0). The Secretary reviews each application to determine to what degree—

(1) There is a mechanism to evaluate plans, progress and results;

(2) The evaluation methods and objectives are likely to produce data that are quantifiable; and

(3) The evaluation results, where relevant, are likely to be assessed in a service setting.

(f) *Program/Project Management: Plan of Operation* (Weight 2.0). The Secretary reviews each application to determine to what degree—

(1) There is an effective plan of operation that insures proper and efficient administration of the project(s);

(2) The applicant's planned use of its resources and personnel is likely to achieve each objective;

(3) Collaboration between institutions, if proposed, is likely to be effective; and

(4) There is a clear description of how the applicant will include eligible project participants who have been traditionally underrepresented, such as—

(i) Members of racial or ethnic minority groups;

(ii) Women;

(iii) Handicapped persons; and

(iv) The elderly.

(g) *Program/Project Management: Adequacy of Resources* (Weight 1.0). The Secretary reviews each application to determine to what degree—

(1) The facilities planned for use are adequate;

(2) The equipment and supplies planned for use are adequate; and

(3) The commitment of the applicant to provide administrative support and adequate facilities is evident.

(h) *Program/Project Management: (Budget and Cost Effectiveness* (Weight 1.0). The Secretary reviews each application to determine to what degree—

(1) The budget for the project(s) is adequate to support the activities;

(2) The costs are reasonable in relation to the objectives of the projects(s); and

(3) The budget for subcontracts (if required) is detailed and appropriate.

Program Title: Rehabilitation Research and Training Centers

CFDA Number: 84.133B

Purpose of Program: RRTCs conduct coordinated and advanced programs of research on disability and rehabilitation that will produce new knowledge that will improve rehabilitation methods and service delivery systems, alleviate or stabilize disabling conditions, and promote maximum social and economic independence for individuals with disabilities. RRTCs provide training to service providers at the pre-service, in-service training, undergraduate, and graduate levels, to improve the quality and effectiveness of rehabilitation services. They also provide advanced research training to individuals with disabilities and those from minority backgrounds, engaged in research on disability and rehabilitation. RRTCs serve as national and regional technical assistance resources, and provide training for service providers, individuals with disabilities and families and representatives, and rehabilitation researchers.

APPLICATION NOTICE FOR FISCAL YEAR 1997 REHABILITATION RESEARCH AND TRAINING CENTERS CFDA NO. 84.133B

Funding priority	Deadline for transmittal of applications	Estimated number of awards	Maximum award amount (per year in dollars)*	Project period (months)
Effective Interventions for Children and Youth Who Exhibit Severe Problem Behaviors	6/23/97	1	600,000	60
Aging with Spinal Cord Injury	6/23/97	1	650,000	60

Applications Available: May 9, 1997.

*Note: The Secretary will reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount (See 34 CFR 75.104(b)).

Selection Criteria

The Secretary uses the following selection criteria to evaluate applications under this program.

(a) *Relevance and importance of the research program* (20 points). The Secretary reviews each application to determine to what degree—

(1) The proposed activities are responsive to a priority established by the Secretary and address a significant need of a disabled target population and rehabilitation service providers;

(2) The overall research program of the Center includes appropriate interdisciplinary and collaborative research activities, is likely to lead to new and useful knowledge in the priority area, and is likely to become a nationally recognized source of scientific knowledge; and

(3) The applicant demonstrates that all component activities of the Center are related to the overall objective of the Center, and will build upon and complement each other to enhance the likelihood of solving significant rehabilitation problems.

(b) *Quality of the research design* (35 points). The Secretary reviews each application to determine to what degree—

(1) The applicant proposes a comprehensive research program for the entire project period, including at least three interrelated research projects;

(2) The research design and methodology of each proposed activity are meritorious in that—

(i) The literature review is appropriate and indicates familiarity with current research in the field;

(ii) The research hypotheses are important and scientifically relevant;

(iii) The sample populations are appropriate and significant;

(iv) The data collection and measurement techniques are appropriate and likely to be effective;

(v) The data analysis methods are appropriate; and

(vi) The applicant assures that human subjects, animals, and the environment are adequately protected; and

(3) The application discusses the anticipated research results and demonstrates how those results would satisfy the original hypotheses and could be used for planning future research, including generation of new hypotheses where applicable.

(c) *Quality of the training and dissemination program* (25 points). The Secretary reviews each application to determine the degree to which—

(1) The proposed plan for training and dissemination provides evidence that research results will be effectively disseminated and utilized based on the identification of appropriate and accessible target groups; the proposed training materials and methods are appropriate; the proposed activities are relevant to the regional and national needs of the rehabilitation field; and the training materials and dissemination packages will be developed in alternate media that are usable by people with various types of disabilities.

(2) The proposed plan for training and dissemination provides for—

(i) Advanced training in rehabilitation research;

(ii) Training rehabilitation service personnel and other appropriate individuals to improve practitioner skills based on new knowledge derived from research;

(iii) Training packages that make research results available to service providers, researchers, educators, individuals with disabilities, parents, and others;

(iv) Technical assistance or consultation that is responsive to the concerns of service providers and consumers;

(v) Dissemination of research findings through publication in professional journals, textbooks, and consumer and other publications, and through other appropriate media such as audiovisual materials and telecommunications.

(vi) Widespread dissemination of findings and other appropriate materials to providers of rehabilitation and other relevant services to individuals with disabilities, family members of individuals with disabilities, and other authorized representatives, advocates, and organizations that provide information and support to individuals with disabilities and their families; and

(vii) Dissemination of research findings and other materials in appropriate formats and accessible media for use by individuals with various disabilities.

(d) *Quality of the organization and management* (20 points). The Secretary reviews each application to determine the degree to which—

(1) The staffing plan for the Center provides evidence that the project director, research director, training director, principal investigators, and other personnel have appropriate training and experience in disciplines required to conduct the proposed activities; the commitment of staff time is adequate to conduct all proposed activities; and the Center, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or handicapping conditions;

(2) The budgets for the Center and for each component project are reasonable, adequate, and cost-effective for the proposed activities;

(3) The facilities, equipment, and other resources are adequate and are appropriately accessible to persons with disabilities;

(4) The plan of operations is adequate to accomplish the Center's objectives and to ensure proper and efficient management of the Center;

(5) The proposed relationships with Federal, State, and local rehabilitation service providers and consumer organizations are likely to ensure that the Center program is relevant and applicable to the needs of consumers and service providers;

(6) The past performance and accomplishments of the applicant indicate an ability to complete successfully the proposed scope of work;

(7) The application demonstrates appropriate commitment and support by

the host institution and opportunities for interdisciplinary activities and collaboration with other institutions and organizations; and

(8) The plan for evaluation of the Center provides for an annual assessment of the outcomes of the research, the impact of the training and dissemination activities on the target populations, and the extent to which the overall objectives have been accomplished.

Eligible Applicants

Institutions of higher education and public or private agencies and organizations collaborating with institutions of higher education, including Indian tribes and tribal organizations, are eligible to apply for awards under this program.

Program Authority: 29 U.S.C. 762.

Instructions for Application Narrative

The Secretary strongly recommends that applicants include a one-page abstract in their application. The Secretary strongly recommends that the narrative for Research and Demonstration Projects applications and Knowledge Dissemination and Utilization Program applications be limited to no more than 50 double-spaced, typed pages (on one side only), not including appendices. The Secretary strongly recommends that the narrative for Rehabilitation Research and Training Center applications be limited to no more than 100 double-spaced, typed pages (on one side only), not including appendices. These recommended page limits apply only to the narrative and not to the abstract, application forms, assurances, certifications and attachments to those forms, assurances, and certifications.

Instructions for Transmittal of Applications

(a) If an applicant wants to apply for a grant, the applicant shall—

(1) Mail the original and two copies of the application on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # [Applicant must insert number and letter]), Washington, DC. 20202–4725, or

(2) Hand deliver the original and two copies of the application by 4:30 p.m. [Washington, DC time] on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # [Applicant must insert number and letter]), Room #3633, Regional Office Building #3, 7th and D Streets, SW., Washington, DC.

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Notes: (1) The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

(2) An applicant wishing to know that its application has been received by the Department must include with the application a stamped self-addressed postcard containing the CFDA number and title of this program.

(3) The applicant *must* indicate on the envelope and—if not provided by the Department—in Item 10 of the Application for Federal Assistance (Standard Form 424) the CFDA number—and letter, if any—of the competition under which the application is being submitted.

Application Forms and Instructions

The appendix to this application is divided into four parts. These parts are organized in the same manner that the submitted application should be organized. These parts are as follows:

PART I: Application for Federal Assistance (Standard Form 424 (Rev. 4–88)) and instructions.

PART II: Budget Form—Non-Construction Programs (Standard Form 524A) and instructions.

PART III: Application Narrative.

Additional Materials

Estimated Public Reporting Burden.

Assurances—Non-Construction Programs (Standard Form 424B).

Certification Regarding Lobbying, Debarment, Suspension, and Other Responsibility Matters: and Drug-Free Work-Place Requirements (ED Form 80–0013).

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED Form 80–0014) and instructions.

Note: ED Form GCS–014 is intended for the use of primary participants and should not be transmitted to the Department.

Disclosure of Lobbying Activities (Standard Form LLL (if applicable) and instructions; and Disclosure Lobbying Activities Continuation Sheet (Standard Form LLL–A).

An applicant may submit information on a photostatic copy of the application and budget forms, the assurances, and the certifications. However, the application form, the assurances, and the certifications must each have an *original signature*. No grant may be awarded unless a completed application form has been received.

FOR APPLICATIONS CONTACT: The Grants and Contracts Service Team, Department of Education, 600 Independence Avenue S.W., Switzer Building, 3317, Washington, D.C. 20202, or call (202) 205–8207. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–9860. The preferred method for requesting information is to FAX your request to (202) 205–8717.

Information about the Department's funding opportunities, including copies of application notices for discretionary grant competitions, can be viewed on the Department's electronic bulletin board (ED Board), telephone (202) 260–9950; on the Internet Gopher Server (at gopher://gcs.ed.gov); or on the World Wide Web (at http://gcs.ed.gov). However, the official application notice for a discretionary grant competition is the notice published in the **Federal Register**.

Program Authority: 29 U.S.C. 760–762.

Dated: May 6, 1997.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

Appendix

Application Forms and Instructions

Applicants are advised to reproduce and complete the application forms in this Section. Applicants are required to submit an original and two copies of each application as provided in this Section.

Frequent Questions

1. CAN I GET AN EXTENSION OF THE DUE DATE?

No! On rare occasions the Department of Education may extend a closing date for all applicants. If that occurs, a notice of the revised due date is published in the **Federal Register**. However, there are no extensions or exceptions to the due date made for individual applicants.

2. WHAT SHOULD BE INCLUDED IN THE APPLICATION?

The application should include a project narrative, vitae of key personnel, and a budget, as well as the Assurances forms included in this package. Vitae of staff or consultants should include the individual's title and role in the proposed project, and other information that is specifically pertinent to this proposed project. The budgets for both the first year and all subsequent project years should be included.

If collaboration with another organization is involved in the proposed activity, the application should include assurances of participation by the other parties, including written agreements or assurances of cooperation. It is *not* useful to include general letters of support or endorsement in the application.

If the applicant proposes to use unique tests or other measurement instruments that are not widely known in the field, it would be helpful to include the instrument in the application.

Many applications contain voluminous appendices that are not helpful and in many cases cannot even be mailed to the reviewers. It is generally not helpful to include such things as brochures, general capability statements of collaborating organizations, maps, copies of publications, or descriptions of other projects completed by the applicant.

3. WHAT FORMAT SHOULD BE USED FOR THE APPLICATION?

NIDRR generally advises applicants that they may organize the application to follow the selection criteria that will be used. The specific review criteria vary according to the specific program, and are contained in this Consolidated Application Package.

4. MAY I SUBMIT APPLICATIONS TO MORE THAN ONE NIDRR PROGRAM COMPETITION OR MORE THAN ONE APPLICATION TO A PROGRAM?

Yes, you may submit applications to any program for which they are responsive to the program requirements. You may submit the same application to as many competitions as you believe appropriate. You may also submit more than one application in any given competition.

5. WHAT IS THE ALLOWABLE INDIRECT COST RATE?

The limits on indirect costs vary according to the program and the type of application.

An applicant for a project in the R&D or D&U grant programs is limited to the organization's approved indirect cost rate. If the organization does not have an approved indirect cost rate, the application should include an estimated actual rate.

An applicant for a project in the RRTC program is limited to an indirect cost rate of 15 percent.

6. CAN PROFITMAKING BUSINESSES APPLY FOR GRANTS?

Yes. However, for-profit organizations will not be able to collect a fee or profit on the grant, and in some programs will be required to share in the costs of the project.

7. CAN INDIVIDUALS APPLY FOR GRANTS?

No. Only organizations are eligible to apply for *grants* under NIDRR programs. However, individuals are the only entities eligible to apply for fellowships.

8. CAN NIDRR STAFF ADVISE ME WHETHER MY PROJECT IS OF INTEREST TO NIDRR OR LIKELY TO BE FUNDED?

No. NIDRR staff can advise you of the requirements of the program in which you propose to submit your application. However, staff cannot advise you of whether your subject area or proposed approach is likely to receive approval.

9. HOW DO I ASSURE THAT MY APPLICATION WILL BE REFERRED TO THE MOST APPROPRIATE PANEL FOR REVIEW?

Applicants should be sure that their applications are referred to the correct competition by clearly including the competition title and CFDA number, including alphabetical code, on the Standard Form 424, and including a project title that describes the project.

10. HOW SOON AFTER SUBMITTING MY APPLICATION CAN I FIND OUT IF IT WILL BE FUNDED?

The time from closing date to grant award date varies from program to program. Generally speaking, NIDRR endeavors to have awards made within five to six months of the closing date.

Unsuccessful applicants generally will be notified within that time frame as well. For the purpose of estimating a project start date, the applicant should estimate approximately six months from the closing date, but no later than the following September 30.

11. CAN I CALL NIDRR TO FIND OUT IF MY APPLICATION IS BEING FUNDED?

No. When NIDRR is able to release information on the status of grant applications, it will notify applicants by letter. The results of the peer review cannot be released except through this formal notification.

12. IF MY APPLICATION IS SUCCESSFUL, CAN I ASSUME I WILL GET THE REQUESTED BUDGET AMOUNT IN SUBSEQUENT YEARS?

No. Funding in subsequent years is subject to availability of funds and project performance.

13. WILL ALL APPROVED APPLICATIONS BE FUNDED?

No. It often happens that the peer review panels approve for funding more applications than NIDRR can fund within available resources. Applicants who are approved but not funded are encouraged to consider submitting similar applications in future competitions.

BILLING CODE 4000–01–P

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

1. TYPE OF SUBMISSION: *Application* ☐ Construction ☐ Non-Construction; *Preapplication* ☐ Construction ☐ Non-Construction	2. DATE SUBMITTED	Applicant Identifier
	3. DATE RECEIVED BY STATE	State Application Identifier
	4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address *(give city, county, state, and zip code)*:	Name and telephone number of the person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER (EIN):

☐☐ – ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify): _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other *(specify)*:

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐.☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(cities, counties, states, etc.)*:

13. PROPOSED PROJECT: Start Date	Ending Date	14. CONGRESSIONAL DISTRICTS OF: a. Applicant	b. Project

15. ESTIMATED FUNDING:	
a. Federal	$ .00
b. Applicant	$ .00
c. State	$ .00
d. Local	$ .00
e. Other	$ .00
f. Program Income	$ .00
g. TOTAL	$ .00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE_____

b NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item: Entry:

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. if more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

Item: Entry:

12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

U.S. DEPARTMENT OF EDUCATION

BUDGET INFORMATION

NON-CONSTRUCTION PROGRAMS

OMB Control No. 1875-0102

Expiration Date: 9/30/98

Name of Institution/Organization

Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

SECTION A - BUDGET SUMMARY
U.S. DEPARTMENT OF EDUCATION FUNDS

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	**Total (f)**
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

ED FORM NO. 524

Name of Institution/Organization	Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

SECTION B - BUDGET SUMMARY
NON-FEDERAL FUNDS

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	Total (f)
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

SECTION C - OTHER BUDGET INFORMATION (see instructions)

ED FORM NO. 524

Public reporting burden for this collection of information is estimated to vary from 13 to 22 hours per response, with an average of 17.5 hours, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, Information Management and Compliance Division, Washington, D.C. 20202-4651; and the Office of Management and Budget, Paperwork Reduction Project 1875-0102, Washington, D.C. 20503.

INSTRUCTIONS FOR ED FORM NO. 524

General Instructions

This form is used to apply to individual U.S. Department of Education discretionary grant programs. Unless directed otherwise, provide the same budget information for each year of the multi-year funding request. Pay attention to applicable program specific instructions, if attached.

Section A - Budget Summary
U.S. Department of Education Funds

All applicants must complete Section A and provide a breakdown by the applicable budget categories shown in lines 1-11.

Lines 1-11, columns (a)-(e): For each project year for which funding is requested, show the total amount requested for each applicable budget category.

Lines 1-11, column (f): Show the multi-year total for each budget category. If funding is requested for only one project year, leave this column blank.

Line 12, columns (a)-(e): Show the total budget request for each project year for which funding is requested.

Line 12, column (f): Show the total amount requested for all project years. If funding is requested for only one year, leave this space blank.

Section B - Budget Summary
Non-Federal Funds

If you are required to provide or volunteer to provide matching funds or other non-Federal resources to the project, these should be shown for each applicable budget category on lines 1-11 of Section B.

Lines 1-11, columns (a)-(e): For each project year for which matching funds or other contributions are provided, show the total contribution for each applicable budget category.

Lines 1-11, column (f): Show the multi-year total for each budget category. If non-Federal contributions are provided for only one year, leave this column blank.

Line 12, columns (a)-(e): Show the total matching or other contribution for each project year.

Line 12, column (f): Show the total amount to be contributed for all years of the multi-year project. If non-Federal contributions are provided for only one year, leave this space blank.

Section C - Other Budget Information
Pay attention to applicable program specific instructions, if attached.

1. Provide an itemized budget breakdown, by project year, for each budget category listed in Sections A and B.

2. If applicable to this program, enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period. In addition, enter the estimated amount of the base to which the rate is applied, and the total indirect expense.

3. If applicable to this program, provide the rate and base on which fringe benefits are calculated.

4. Provide other explanations or comments you deem necessary.

BILLING CODE 4000–01–C

Public reporting burden for these collections of information is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of these collections of information, including suggestions for reducing this burden, to: the U.S. Department of Education, Information Management and Compliance Division, Washington, D.C. 20202–4651; and to the Office of Management and Budget, Paperwork Reduction Project 1820–0027, Washington, D.C. 20503.

Research and Demonstration Projects (CFDA No. 84.133A) 34 CFR Parts 350 and 351.

Rehabilitation Research and Training Center (CFDA No. 84.133B) 34 CFR Parts 350 and 352.

Knowledge Dissemination and Utilization Program (CFDA No. 84.133D) 34 CFR Parts 350 and 355.

Assurances—Non-Construction Programs

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728–4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88–352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681–1683, and 1685–1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101–6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92–255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91–616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290dd–3 and 290ee–3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91–646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501–1508 and 7324–7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a–7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327–333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93–234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) Institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91–190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93–523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93–205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a–1 et seq.).

14. Will comply with P.L. 93–348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89–544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

_____

Signature of Authorized Certifying Official

_____

Title

_____

Applicant Organization

_____

Date submitted

Certifications Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and Drug-Free Workplace Requirements

Applicants should refer to the regulations cited below to determine the certification to which they are required to attest. Applicants should also review the instructions for certification included in the regulations before completing this form. Signature of this form provides for compliance with certification requirements under 34 CFR Part 82, ''New Restrictions on Lobbying,'' and 34

CFR Part 85, ''Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants).'' The certifications shall be treated as a material representation of fact upon which reliance will be placed when the Department of Education determines to award the covered transaction, grant, or cooperative agreement.

1. Lobbying

As required by Section 1352, Title 31 of the U.S. Code, and implemented at 34 CFR Part 82, for persons entering into a grant or cooperative agreement over $100,000, as defined at 34 CFR Part 82, Sections 82.105 and 82.110, the applicant certifies that:

(a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement;

(b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form—LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions;

(c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all suberscripients shall certify and disclose accordingly.

2. Debarment, Suspension, and Other Responsibility Matters

As required by Executive Order 12549, Debarment and Suspension, and implemented at 34 CFR Part 85, for prospective participants in primary covered transactions, as defined at 34 CFR Part 85, Sections 85.105 and 85.110—

A. The applicant certifies that it and its principles:

(a) Are not presently debarred, suspended, proposed for debarment, declared intelligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this application been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicated for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application had one or more public transactions (Federal, State, or local) terminated for cause or default; and

B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.

3. Drug-Free Workplace (Grantees Other Than Individuals)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610—

A. The applicant certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an on-going drug-free awareness program to inform employees about—

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employees assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency, in writing, within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, SW., (Room 3124, GSA Regional Office Building No. 3), Washington, DC 20202–4571. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted—

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

_____

_____

_____

Check ☐ if there are workplaces on file that are not identified here.

Drug-Free Workplace (Grantees who are Individuals)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined in at 34 CFR Part 85, Sections 85.605 and 85.610—

A. As a condition of the grant, I certify that I will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant; and

B. If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, I will report the conviction, in writing, within 10 calendar days of the conviction, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, SW., (Room 3124, GSA Regional Office Building No. 3), Washington, DC 20202–4571. Notice shall include the identification number(s) of each affected grant.

As the duly authorized representative of the applicant, I hereby certify that the applicant will comply with the above certifications.

_____

Name of Applicant

_____

PR/Award Number and/or Project Name

_____

Printed Name and Title of Authorized Representative

_____

Signature

_____

Date

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions

This certification is required by the Department of Education regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, for all lower tier transactions meeting the

threshold and tier requirements stated at Section 85.110.

Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

4. The terms ''covered transaction,'' ''debarred,'' ''suspended,'' ''ineligible,'' ''lower tier covered transaction,'' ''participant,'' ''person,'' ''primary covered transaction,'' ''principal,'' ''proposal,'' and ''voluntarily excluded,'' as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled ''Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions,'' without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

Certification

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

_____

Name of Applicant

_____

PR/Award Number and/or Project Name

_____

Printed Name and Title of Authorized Representative

_____

Signature

_____

Date

BILLING CODE 4000–01–P

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:
☐ a. contract
b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

2. Status of Federal Action:
☐ a. bid/offer/application
b. initial award
c. post-award

3. Report Type:
☐ a. initial filing
b. material change

For Material Change Only:
year _____ quarter ____
date of last report _____

4. Name and Address of Reporting Entity:
☐ Prime ☐ Subawardee
Tier _____, *if known:*

Congressional District, *if known:*

5. If Reporting Entity in No.4 is Subawardee, Enter Name and Address of Prime:

Congressional District, *if known:*

6. Federal Department/Agency:

7. Federal Program Name/Description:

CFDA Number, *if applicable*: _____

8. Federal Action Number, *if known:*

9. Award Amount, *if known:*

$

10. a. Name and Address of Lobbying ~~Entity~~ Registrant
(if individual, last name, first name, MI):

b. Individuals Performing Services *(including address if different from No. 10a)*
(last name, first name, MI):

~~11. Amount of Payment *(check all that apply):*~~

~~$ _____ ☐ actual ☐ planned~~

~~12. Form of Payment *(check all that apply):*~~

~~☐ a. cash~~
~~☐ b. in-kind; specify: nature _____~~
~~value _____~~

~~13. Type of Payment *(Check all that apply):*~~

~~☐ a. retainer~~
~~☐ b. one-time fee~~
~~☐ c. commission~~
~~☐ d. contingent fee~~
~~○ e. deferred~~
~~☐ f. other; specify: _____~~

~~14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11:~~

~~*(attach Continuation Sheet(s) SF-LLL-A, if necessary)*~~

~~15. Continuation Sheet(s) SF-LLL attached: ☐ Yes ☐ No~~

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____

Print Name: _____

Title: _____

Telephone No.: _____ Date: _____

Federal Use Only

Authorized for Local Reproduction
Standard Form - LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. ~~Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate.~~ Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and conract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee" then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number, grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state, and zip code of the ~~lobbying entity~~ registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a). Enter Last Name, First Name, and Middle Initial (MI).

~~11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this a material change report, enter the cumulative amount of payment made or planned to be made.~~

~~12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of in-kind payment.~~

~~13. Check the appropriate box(es). Check all boxes that apply. If other specify nature.~~

~~14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.~~

~~15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.~~

16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

[FR Doc. 97–12258 Filed 5–8–97; 8:45 am]
BILLING CODE 4000–01–C

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0007]

Proposed Collection; Comment Request Entitled Summary Subcontract Support

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding a revision of an existing OMB clearance (9000–0007).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision of a currently approved information collection requirement concerning Summary Subcontract Report.

DATES: Comment Due Date: July 8, 1997.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat, 1800 F Street, NW, Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000–0007, Summary Subcontract Report, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Victoria Moss, Office of Federal Acquisition Policy, GSA (202) 501–4764.

SUPPLEMENTARY INFORMATION:

A. Purpose

The proposed rule contemplates revisions to the FAR to implement the Department of Justice (DOJ) proposal to reform affirmative action in Federal procurement. DOJ's proposal is designed to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand Constructors, Inc.* v. *Pena,* 115 S.Ct. 2097 (1995). In *Adarand*, the Supreme Court extended strict judicial scrutiny to Federal affirmative action programs that use racial or ethnic criteria as a basis for decisionmaking. In Federal procurement, this means that any use of race in the decision to award a contract is subject to strict scrutiny. Under strict scrutiny, any Federal programs that make race a basis for contract decisionmaking must be narrowly tailored to serve a compelling government interest.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *16.77* hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents, *4,253*; responses per respondent, *1.66*; total annual responses, *7,098*; preparation hours per response, *16.77*; and total response burden hours, *119,070*.

Obtaining Copies of Justifications

Requester may obtain a copy of the justification from the General Services Administration, FAR Secretariat (MVRS), Room 4037, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0007, Summary Subcontract Support, in all correspondence.

Dated: April 22, 1997.

Sharon A. Kiser,

FAR Secretariat.

[FR Doc. 97–12266 Filed 5–8–97; 8:45 am]

BILLING CODE 6820–EP–U

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[FAR Case 97–004]

Comment Request; Proposed Collection Entitled Reform of Affirmative Action in Federal Procurement

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding a new information collection requirement.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat plans to submit to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement concerning Reform of Affirmative Action in Federal Procurement (FAR Case 97–004).

DATES: Comment Due Date: July 8, 1997.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat, 1800 F Street, NW, Room 4037, Washington, DC 20405. Please cite FAR case 97–004, Reform of Affirmative Action in Federal Procurement, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Ms. Victoria Moss, Office of Federal Acquisition Policy, GSA (202) 501–4764.

SUPPLEMENTARY INFORMATION:

A. Purpose

The proposed rule contemplates revisions to the FAR to implement the Department of Justice (DOJ) proposal to reform affirmative action in Federal procurement. DOJ's proposal is designed to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand Constructors, Inc.* v. *Pena,* 115 S.Ct. 2097. In *Adarand*, the Supreme Court extended strict judicial scrutiny to Federal affirmative action programs that use racial or ethnic criteria as a basis for decisionmaking. In Federal procurement, this means any use of race in the decision to award a contract is subject to strict scrutiny. Under strict scrutiny, any Federal programs that make race a basis for contract decisionmaking must be narrowly tailored to serve a compelling Government interest.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *2.09* hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents *20,430*; responses per respondent, *8.97*; total annual responses, *182,470*; preparation hours per response, *2.09*; and total response burden hours, *381,305*.

Obtaining Copies of Justifications

Requester may obtain a copy of the justification from the General Services

Administration, FAR Secretariat (MVRS), Room 4037, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite FAR case 97–004, Reform of Affirmative Action in Federal Procurement, in all correspondence.

Dated: April 17, 1997.

Sharon A. Kiser,

FAR Secretariat.

[FR Doc. 97–12265 Filed 5–8–97; 8:45 am]

BILLING CODE 6820–EP–U

federal register

Friday
May 9, 1997

Part II

Department of Health and Human Services

Food and Drug Administration

International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline; Notice of Availability

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0219]

International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guideline entitled ''Good Clinical Practice: Consolidated Guideline.'' The guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guideline is intended to define ''Good Clinical Practice'' and to provide a unified standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. The guideline also describes the minimum information that should be included in an Investigator's Brochure (IB) and provides a suggested format. In addition, the guideline describes the essential documents that individually and collectively permit evaluation of the conduct of a clinical study and the quality of the data produced.

DATES: Effective May 9, 1997. Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Good Clinical Practice: Consolidated Guideline'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. The ''Good Clinical Practice: Consolidated Guideline'' and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Bette L. Barton, Center for Drug Evaluation and Research (HFD–344), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1032.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of August 17, 1995 (60 FR 42948), FDA published a draft tripartite guideline entitled ''Good Clinical Practice.'' In the **Federal Register** of August 9, 1994, FDA published draft tripartite guidelines entitled ''Guideline for the Investigator's Brochure'' (59 FR 40772) and ''Guideline for Essential Documents for the Conduct of a Clinical Study'' (59 FR 40774). The notices gave interested persons an opportunity to submit comments.

After consideration of the comments received and revisions to the guidelines, the three guidelines were consolidated into one guideline on good clinical practice. The consolidated guideline was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies at the ICH meeting held on April 30, 1996.

The guideline defines ''Good Clinical Practice'' and provides a unified standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with Good Clinical Practice provides public assurance that the rights, well-being, and confidentiality of trial subjects are protected and that trial data are credible. The guideline should be followed when generating clinical data that are intended to be submitted to regulatory authorities. The principles established in this guideline should also be applied to other investigations that involve therapeutic intervention in, or observation of, human subjects.

The guideline also describes the minimum information that should be included in an IB, such as information on the drug's physical, chemical, and pharmaceutical properties, and its effect in humans; a suggested format for the IB is also provided. The guideline also describes the purpose of essential documents in a clinical study and explains whether the documents should be filed in the investigator's files or the sponsor's files.

This guideline represents the agency's current thinking on good clinical practices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

As with all of FDA's guidelines, the public is encouraged to submit written comments with new data or other new information pertinent to this guideline. The comments in the docket will be periodically reviewed, and, where appropriate, the guideline will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guideline. 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. A copy of the guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this guideline is available via Internet. Type http://www.fda.gov/cder and go to the ''Regulatory Guidance'' section.

The text of the guideline follows:

Good Clinical Practice: Consolidated Guideline

Table of Contents

Introduction

1. Glossary
2. The Principles of ICH CGP
3. Institutional Review Board/Independent Ethics Committee (IRB/IEC)
3.1 Responsibilities
3.2 Composition, Functions, and Operations
3.3 Procedures
3.4 Records
4. Investigator
4.1 Investigator's Qualifications and Agreements
4.2 Adequate Resources
4.3 Medical Care of Trial Subjects
4.4 Communication with IRB/IEC
4.5 Compliance with Protocol
4.6 Investigational Product(s)
4.7 Randomization Procedures and Unblinding
4.8 Informed Consent of Trial Subjects
4.9 Records and Reports
4.10 Progress Reports
4.11 Safety Reporting
4.12 Premature Termination or Suspension of a Trial
4.13 Final Report(s) by Investigator/Institution
5. Sponsor
5.1 Quality Assurance and Quality Control
5.2 Contract Research Organization (CRO)
5.3 Medical Expertise
5.4 Trial Design
5.5 Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring Committee
5.6 Investigator Selection
5.7 Allocation of Duties and Functions
5.8 Compensation to Subjects and Investigators
5.9 Financing
5.10 Notification/Submission to Regulatory Authority(ies)
5.11 Confirmation of Review by IRB/IEC
5.12 Information on Investigational Product(s)
5.13 Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)
5.14 Supplying and Handling Investigational Product(s)
5.15 Record Access
5.16 Safety Information
5.17 Adverse Drug Reaction Reporting
5.18 Monitoring
5.18.1 Purpose
5.18.2 Selection and Qualifications of Monitors
5.18.3 Extent and Nature of Monitoring
5.18.4 Monitor's Responsibilities
5.18.5 Monitoring Procedures
5.18.6 Monitoring Report
5.19 Audit
5.19.1 Purpose
5.19.2 Selection and Qualification of Auditors
5.19.3 Auditing Procedures
5.20 Noncompliance
5.21 Premature Termination or Suspension of a Trial
5.22 Clinical Trial/Study Reports
5.23 Multicenter Trials
6. Clinical Trial Protocol and Protocol Amendment(s)
6.1 General Information
6.2 Background Information
6.3 Trial Objectives and Purpose
6.4 Trial Design
6.5 Selection and Withdrawal of Subjects
6.6 Treatment of Subjects
6.7 Assessment of Efficacy
6.8 Assessment of Safety
6.9 Statistics
6.10 Direct Access to Source Data/Documents
6.11 Quality Control and Quality Assurance
6.12 Ethics
6.13 Data Handling and Recordkeeping
6.14 Financing and Insurance
6.15 Publication Policy
6.16 Supplements
7. Investigator's Brochure
7.1 Introduction
7.2 General Considerations
7.2.1 Title Page
7.2.2 Confidentiality Statement
7.3 Contents of the Investigator's Brochure
7.3.1 Table of Contents
7.3.2 Summary
7.3.3 Introduction
7.3.4 Physical, Chemical, and Pharmaceutical Properties and Formulation
7.3.5 Nonclinical Studies
7.3.6 Effects in Humans
7.3.7 Summary of Data and Guidance for the Investigator
7.4 Appendix 1
7.5 Appendix 2
8. Essential Documents for the Conduct of a Clinical Trial
8.1 Introduction
8.2 Before the Clinical Phase of the Trial Commences
8.3 During the Clinical Conduct of the Trial
8.4 After Completion or Termination of the Trial

Introduction

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries, and the World Health Organization (WHO).

This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

1. *Glossary*

1.1 *Adverse Drug Reaction (ADR)*

In the preapproval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase ''responses to a medicinal product'' means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

Regarding marketed medicinal products: A response to a drug that is noxious and unintended and that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.2 *Adverse Event (AE)*

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.3 *Amendment (to the protocol)*

See Protocol Amendment.

1.4 *Applicable Regulatory Requirement(s)*

Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products of the jurisdiction where a trial is conducted.

1.5 *Approval (in relation to Institutional Review Boards (IRB's))*

The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements.

1.6 *Audit*

A systematic and independent examination of trial-related activities and documents to

determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOP's), good clinical practice (GCP), and the applicable regulatory requirement(s).

1.7 *Audit Certificate*

A declaration of confirmation by the auditor that an audit has taken place.

1.8 *Audit Report*

A written evaluation by the sponsor's auditor of the results of the audit.

1.9 *Audit Trail*

Documentation that allows reconstruction of the course of events.

1.10 *Blinding/Masking*

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the subject(s) being unaware, and double blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

1.11 *Case Report Form (CRF)*

A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

1.12 *Clinical Trial/Study*

Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

1.13 *Clinical Trial/Study Report*

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports).

1.14 *Comparator (Product)*

An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

1.15 *Compliance (in relation to trials)*

Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.

1.16 *Confidentiality*

Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

1.17 *Contract*

A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

1.18 *Coordinating Committee*

A committee that a sponsor may organize to coordinate the conduct of a multicenter trial.

1.19 *Coordinating Investigator*

An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicenter trial.

1.20 *Contract Research Organization (CRO)*

A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

1.21 *Direct Access*

Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

1.22 *Documentation*

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

1.23 *Essential Documents*

Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see 8. ''Essential Documents for the Conduct of a Clinical Trial'').

1.24 *Good Clinical Practice (GCP)*

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

1.25 *Independent Data Monitoring Committee (IDMC) (Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee)*

An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

1.26 *Impartial Witness*

A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

1.27 *Independent Ethics Committee (IEC)*

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and nonmedical/nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The legal status, composition, function, operations, and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

1.28 *Informed Consent*

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

1.29 *Inspection*

The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

1.30 *Institution (medical)*

Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

1.31 *Institutional Review Board (IRB)*

An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

1.32 *Interim Clinical Trial/Study Report*

A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

1.33 *Investigational Product*

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

1.34 *Investigator*

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Subinvestigator.

1.35 *Investigator/Institution*

An expression meaning ''the investigator and/or institution, where required by the applicable regulatory requirements.''

1.36 *Investigator's Brochure*

A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the

investigational product(s) in human subjects (see 7. ''Investigator's Brochure'').

1.37 *Legally Acceptable Representative*

An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

1.38 *Monitoring*

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOP's), GCP, and the applicable regulatory requirement(s).

1.39 *Monitoring Report*

A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOP's.

1.40 *Multicenter Trial*

A clinical trial conducted according to a single protocol but at more than one site, and, therefore, carried out by more than one investigator.

1.41 *Nonclinical Study*

Biomedical studies not performed on human subjects.

1.42 *Opinion (in relation to Independent Ethics Committee)*

The judgment and/or the advice provided by an Independent Ethics Committee (IEC).

1.43 *Original Medical Record*

See Source Documents.

1.44 *Protocol*

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline, the term protocol refers to protocol and protocol amendments.

1.45 *Protocol Amendment*

A written description of a change(s) to or formal clarification of a protocol.

1.46 *Quality Assurance (QA)*

All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

1.47 *Quality Control (QC)*

The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

1.48 *Randomization*

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

1.49 *Regulatory Authorities*

Bodies having the power to regulate. In the ICH GCP guideline, the expression ''Regulatory Authorities'' includes the authorities that review submitted clinical data and those that conduct inspections (see 1.29). These bodies are sometimes referred to as competent authorities.

1.50 *Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)*

Any untoward medical occurrence that at any dose:

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity,

or

- Is a congenital anomaly/birth defect.

(See the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.)

1.51 *Source Data*

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

1.52 *Source Documents*

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

1.53 *Sponsor*

An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

1.54 *Sponsor-Investigator*

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

1.55 *Standard Operating Procedures (SOP's)*

Detailed, written instructions to achieve uniformity of the performance of a specific function.

1.56 *Subinvestigator*

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.

1.57 *Subject/Trial Subject*

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

1.58 *Subject Identification Code*

A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data.

1.59 *Trial Site*

The location(s) where trial-related activities are actually conducted.

1.60 *Unexpected Adverse Drug Reaction*

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product). (See the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.)

1.61 *Vulnerable Subjects*

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

1.62 *Well-being (of the trial subjects)*

The physical and mental integrity of the subjects participating in a clinical trial.

2. *The Principles of ICH GCP*

2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

2.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

2.6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favorable opinion.

2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.

2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

2.12 Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

2.13 Systems with procedures that assure the quality of every aspect of the trial should be implemented.

3. *Institutional Review Board/Independent Ethics Committee (IRB/IEC)*

3.1 *Responsibilities*

3.1.1 An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.

3.1.2 The IRB/IEC should obtain the following documents:

Trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may require to fulfill its responsibilities.

The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed, and the dates for the following:

- Approval/favorable opinion;
- Modifications required prior to its approval/favorable opinion;
- Disapproval/negative opinion; and
- Termination/suspension of any prior approval/favorable opinion.

3.1.3 The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.

3.1.4 The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

3.1.5 The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgment of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety, and/or well-being of the subjects.

3.1.6 When a nontherapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.

3.1.7 Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e., in emergency situations).

3.1.8 The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.

3.1.9 The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.

3.2 *Composition, Functions, and Operations*

3.2.1 The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:

(a) At least five members.

(b) At least one member whose primary area of interest is in a nonscientific area.

(c) At least one member who is independent of the institution/trial site.

Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

A list of IRB/IEC members and their qualifications should be maintained.

3.2.2 The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

3.2.3 An IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present.

3.2.4 Only members who participate in the IRB/IEC review and discussion should vote/provide their opinion and/or advise.

3.2.5 The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB/IEC or in the vote/opinion of the IRB/IEC.

3.2.6 An IRB/IEC may invite nonmembers with expertise in special areas for assistance.

3.3 *Procedures*

The IRB/IEC should establish, document in writing, and follow its procedures, which should include:

3.3.1 Determining its composition (names and qualifications of the members) and the authority under which it is established.

3.3.2 Scheduling, notifying its members of, and conducting its meetings.

3.3.3 Conducting initial and continuing review of trials.

3.3.4 Determining the frequency of continuing review, as appropriate.

3.3.5 Providing, according to the applicable regulatory requirements, expedited review and approval/favorable opinion of minor change(s) in ongoing trials that have the approval/favorable opinion of the IRB/IEC.

3.3.6 Specifying that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favorable opinion of the trial.

3.3.7 Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favorable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s)) (see 4.5.2).

3.3.8 Specifying that the investigator should promptly report to the IRB/IEC:

(a) Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects (see 3.3.7, 4.5.2, 4.5.4).

(b) Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial (see 4.10.2).

(c) All adverse drug reactions (ADR's) that are both serious and unexpected.

(d) New information that may affect adversely the safety of the subjects or the conduct of the trial.

3.3.9 Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:

(a) Its trial-related decisions/opinions.

(b) The reasons for its decisions/opinions.

(c) Procedures for appeal of its decisions/opinions.

3.4 *Records*

The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies).

The IRB/IEC may be asked by investigators, sponsors, or regulatory authorities to provide copies of its written procedures and membership lists.

4. *Investigator*

4.1 *Investigator's Qualifications and Agreements*

4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).

4.1.2 The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information, and in other information sources provided by the sponsor.

4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

4.1.4 The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom

the investigator has delegated significant trial-related duties.

4.2 *Adequate Resources*

4.2.1 The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

4.2.3 The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

4.3 *Medical Care of Trial Subjects*

4.3.1 A qualified physician (or dentist, when appropriate), who is an investigator or a subinvestigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

4.3.2 During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

4.3.3 It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

4.3.4 Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.

4.4 *Communication with IRB/IEC*

4.4.1 Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.

4.4.2 As part of the investigator's/institution's written application to the IRB/IEC, the investigator/institution should provide the IRB/IEC with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the IRB/IEC.

4.4.3 During the trial the investigator/institution should provide to the IRB/IEC all documents subject to its review.

4.5 *Compliance with Protocol*

4.5.1 The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and which was given approval/favorable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm their agreement.

4.5.2 The investigator should not implement any deviation from, or changes of, the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), change of telephone number(s)).

4.5.3 The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

4.5.4 The investigator may implement a deviation from, or a change in, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favorable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

(a) To the IRB/IEC for review and approval/favorable opinion;

(b) To the sponsor for agreement; and, if required,

(c) To the regulatory authority(ies).

4.6 *Investigational Product(s)*

4.6.1 Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.

4.6.2 Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

4.6.3 The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor.

4.6.4 The investigational product(s) should be stored as specified by the sponsor (see 5.13.2 and 5.14.3) and in accordance with applicable regulatory requirement(s).

4.6.5 The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.

4.6.6 The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product(s) to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.

4.7 *Randomization Procedures and Unblinding*

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

4.8 *Informed Consent of Trial Subjects*

4.8.1 In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB/IEC's written approval/favorable opinion of the written informed consent form and any other written information to be provided to subjects.

4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favorable opinion in advance of use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.

4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

4.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

4.8.5 The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information given approval/favorable opinion by the IRB/IEC.

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as nontechnical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

4.8.7 Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the

satisfaction of the subject or the subject's legally acceptable representative.

4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial, and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

(a) That the trial involves research.

(b) The purpose of the trial.

(c) The trial treatment(s) and the probability for random assignment to each treatment.

(d) The trial procedures to be followed, including all invasive procedures.

(e) The subject's responsibilities.

(f) Those aspects of the trial that are experimental.

(g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

(h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

(i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

(j) The compensation and/or treatment available to the subject in the event of trial-related injury.

(k) The anticipated prorated payment, if any, to the subject for participating in the trial.

(l) The anticipated expenses, if any, to the subject for participating in the trial.

(m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

(n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

(o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

(p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

(q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

(r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

(s) The expected duration of the subject's participation in the trial.

(t) The approximate number of subjects involved in the trial.

4.8.11 Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

4.8.12 When a clinical trial (therapeutic or nontherapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should assent, sign and personally date the written informed consent.

4.8.13 Except as described in 4.8.14, a nontherapeutic trial (i.e., a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written informed consent form.

4.8.14 Nontherapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

(a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally.

(b) The foreseeable risks to the subjects are low.

(c) The negative impact on the subject's well-being is minimized and low.

(d) The trial is not prohibited by law.

(e) The approval/favorable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/favorable opinion covers this aspect.

Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

4.8.15 In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject's legally acceptable representative is not available, enrollment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favorable opinion by the IRB/IEC, to protect the rights, safety, and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate (see 4.8.10) should be requested.

4.9 *Records and Reports*

4.9.1 The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRF's and in all required reports.

4.9.2 Data reported on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

4.9.3 Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections (see 5.18.4(n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRF's made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see 8.) and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents.

4.9.5 Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see 5.5.12).

4.9.6 The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.
4.9.7 Upon request of the monitor, auditor, IRB/IEC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.
4.10 *Progress Reports*
4.10.1 Where required by the applicable regulatory requirements, the investigator should submit written summaries of the trial's status to the institution. The investigator/institution should submit written summaries of the status of the trial to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC.
4.10.2 The investigator should promptly provide written reports to the sponsor, the IRB/IEC (see 3.3.8), and, where required by the applicable regulatory requirements, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.
4.11 *Safety Reporting*
4.11.1 All serious adverse events (SAE's) should be reported immediately to the sponsor except for those SAE's that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC.
4.11.2 Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
4.11.3 For reported deaths, the investigator should supply the sponsor and the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports).
4.12 *Premature Termination or Suspension of a Trial*

If the trial is terminated prematurely or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies). In addition:
4.12.1 If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution, where required by the applicable regulatory requirements, and the investigator/institution should promptly inform the sponsor and the IRB/IEC, and should provide the sponsor and the IRB/IEC a detailed written explanation of the termination or suspension.
4.12.2 If the sponsor terminates or suspends a trial (see 5.21), the investigator should promptly inform the institution, where required by the applicable regulatory requirements, and the investigator/institution should promptly inform the IRB/IEC and provide the IRB/IEC a detailed written explanation of the termination or suspension.
4.12.3 If the IRB/IEC terminates or suspends its approval/favorable opinion of a trial (see 3.1.2 and 3.3.9), the investigator should inform the institution, where required by the applicable regulatory requirements, and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.
4.13 *Final Report(s) by Investigator/Institution*

Upon completion of the trial, the investigator should, where required by the applicable regulatory requirements, inform the institution, and the investigator/institution should provide the sponsor with all required reports, the IRB/IEC with a summary of the trial's outcome, and the regulatory authority(ies) with any report(s) they require of the investigator/institution.
5. *Sponsor*
5.1 *Quality Assurance and Quality Control*
5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOP's to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
5.1.2 The sponsor is responsible for securing agreement from all involved parties to ensure direct access (see 1.21) to all trial-related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.
5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.
5.1.4 Agreements, made by the sponsor with the investigator/institution and/or with any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement.
5.2 *Contract Research Organization (CRO)*
5.2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.
5.2.2 Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.
5.2.3 Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.
5.2.4 All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial-related duties and functions of a sponsor.
5.3 *Medical Expertise*

The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on trial-related medical questions or problems. If necessary, outside consultant(s) may be appointed for this purpose.
5.4 *Trial Design*
5.4.1 The sponsor should utilize qualified individuals (e.g., biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRF's and planning the analyses to analyzing and preparing interim and final clinical trial/study reports.
5.4.2 For further guidance: Clinical Trial Protocol and Protocol Amendment(s) (see 6.), the ICH Guideline for Structure and Content of Clinical Study Reports, and other appropriate ICH guidance on trial design, protocol, and conduct.
5.5 *Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring Committee*
5.5.1 The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
5.5.2 The sponsor may consider establishing an independent data monitoring committee (IDMC) to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints at intervals, and to recommend to the sponsor whether to continue, modify, or stop a trial. The IDMC should have written operating procedures and maintain written records of all its meetings.
5.5.3 When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

(a) Ensure and document that the electronic data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e., validation).

(b) Maintain SOP's for using these systems.

(c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail).

(d) Maintain a security system that prevents unauthorized access to the data.

(e) Maintain a list of the individuals who are authorized to make data changes (see 4.1.5 and 4.9.3).

(f) Maintain adequate backup of the data.

(g) Safeguard the blinding, if any (e.g., maintain the blinding during data entry and processing).

5.5.4 If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data.
5.5.5 The sponsor should use an unambiguous subject identification code (see 1.58) that allows identification of all the data reported for each subject.
5.5.6 The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial. (See 8. ''Essential Documents for the Conduct of a Clinical Trial.'')
5.5.7 The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the sponsor intends to apply for approval(s).

5.5.8 If the sponsor discontinues the clinical development of an investigational product (i.e., for any or all indications, routes of administration, or dosage forms), the sponsor should maintain all sponsor-specific essential documents for at least 2 years after formal discontinuation or in conformance with the applicable regulatory requirement(s).

5.5.9 If the sponsor discontinues the clinical development of an investigational product, the sponsor should notify all the trial investigators/institutions and all the appropriate regulatory authorities.

5.5.10 Any transfer of ownership of the data should be reported to the appropriate authority(ies), as required by the applicable regulatory requirement(s).

5.5.11 The sponsor-specific essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirement(s) or if needed by the sponsor.

5.5.12 The sponsor should inform the investigator(s)/institution(s) in writing of the need for record retention and should notify the investigator(s)/institution(s) in writing when the trial-related records are no longer needed (see 4.9.5).

5.6 *Investigator Selection*

5.6.1 The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be qualified by training and experience and should have adequate resources (see 4.1, 4.2) to properly conduct the trial for which the investigator is selected. If a coordinating committee and/or coordinating investigator(s) are to be utilized in multicenter trials, their organization and/or selection are the sponsor's responsibility.

5.6.2 Before entering an agreement with an investigator/institution to conduct a trial, the sponsor should provide the investigator(s)/institution(s) with the protocol and an up-to-date Investigator's Brochure, and should provide sufficient time for the investigator/institution to review the protocol and the information provided.

5.6.3 The sponsor should obtain the investigator's/institution's agreement:

(a) To conduct the trial in compliance with GCP, with the applicable regulatory requirement(s), and with the protocol agreed to by the sponsor and given approval/favorable opinion by the IRB/IEC;

(b) To comply with procedures for data recording/reporting: and

(c) To permit monitoring, auditing, and inspection (see 4.1.4).

(d) To retain the essential documents that should be in the investigator/institution files (see 8.) until the sponsor informs the investigator/institution these documents are no longer needed (see 4.9.4, 4.9.5, and 5.5.12).

The sponsor and the investigator/institution should sign the protocol, or an alternative document, to confirm this agreement.

5.7 *Allocation of Duties and Functions*

Prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions.

5.8 *Compensation to Subjects and Investigators*

5.8.1 If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.

5.8.2 The sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s).

5.8.3 When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s).

5.9 *Financing*

The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

5.10 *Notification/Submission to Regulatory Authority(ies)*

Before initiating the clinical trial(s), the sponsor (or the sponsor and the investigator, if required by the applicable regulatory requirement(s)), should submit any required application(s) to the appropriate authority(ies) for review, acceptance, and/or permission (as required by the applicable regulatory requirement(s)) to begin the trial(s). Any notification/submission should be dated and contain sufficient information to identify the protocol.

5.11 *Confirmation of Review by IRB/IEC*

5.11.1 The sponsor should obtain from the investigator/institution:

(a) The name and address of the investigator's/institution's IRB/IEC.

(b) A statement obtained from the IRB/IEC that it is organized and operates according to GCP and the applicable laws and regulations.

(c) Documented IRB/IEC approval/favorable opinion and, if requested by the sponsor, a current copy of protocol, written informed consent form(s) and any other written information to be provided to subjects, subject recruiting procedures, and documents related to payments and compensation available to the subjects, and any other documents that the IRB/IEC may have requested.

5.11.2 If the IRB/IEC conditions its approval/favorable opinion upon change(s) in any aspect of the trial, such as modification(s) of the protocol, written informed consent form and any other written information to be provided to subjects, and/or other procedures, the sponsor should obtain from the investigator/institution a copy of the modification(s) made and the date approval/favorable opinion was given by the IRB/IEC.

5.11.3 The sponsor should obtain from the investigator/institution documentation and dates of any IRB/IEC reapprovals/reevaluations with favorable opinion, and of any withdrawals or suspensions of approval/favorable opinion.

5.12 *Information on Investigational Product(s)*

5.12.1 When planning trials, the sponsor should ensure that sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

5.12.2 The sponsor should update the Investigator's Brochure as significant new information becomes available. (See 7. ''Investigator's Brochure.'')

5.13 *Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)*

5.13.1 The sponsor should ensure that the investigational product(s) (including active comparator(s) and placebo, if applicable) is characterized as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labeled in a manner that protects the blinding, if applicable. In addition, the labeling should comply with applicable regulatory requirement(s).

5.13.2 The sponsor should determine, for the investigational product(s), acceptable storage temperatures, storage conditions (e.g., protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion, if any. The sponsor should inform all involved parties (e.g., monitors, investigators, pharmacists, storage managers) of these determinations.

5.13.3 The investigational product(s) should be packaged to prevent contamination and unacceptable deterioration during transport and storage.

5.13.4 In blinded trials, the coding system for the investigational product(s) should include a mechanism that permits rapid identification of the product(s) in case of a medical emergency, but does not permit undetectable breaks of the blinding.

5.13.5 If significant formulation changes are made in the investigational or comparator product(s) during the course of clinical development, the results of any additional studies of the formulated product(s) (e.g., stability, dissolution rate, bioavailability) needed to assess whether these changes would significantly alter the pharmacokinetic profile of the product should be available prior to the use of the new formulation in clinical trials.

5.14 *Supplying and Handling Investigational Product(s)*

5.14.1 The sponsor is responsible for supplying the investigator(s)/institution(s) with the investigational product(s).

5.14.2 The sponsor should not supply an investigator/institution with the investigational product(s) until the sponsor obtains all required documentation (e.g., approval/favorable opinion from IRB/IEC and regulatory authority(ies)).

5.14.3 The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

5.14.4 The sponsor should:

(a) Ensure timely delivery of investigational product(s) to the investigator(s).

(b) Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s). (See 8. ''Essential Documents for the Conduct of a Clinical Trial.'')

(c) Maintain a system for retrieving investigational products and documenting this retrieval (e.g., for deficient product recall, reclaim after trial completion, expired product reclaim).

(d) Maintain a system for the disposition of unused investigational product(s) and for the documentation of this disposition.

5.14.5 The sponsor should:

(a) Take steps to ensure that the investigational product(s) are stable over the period of use.

(b) Maintain sufficient quantities of the investigational product(s) used in the trials to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and characteristics. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

5.15 *Record Access*

5.15.1 The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) provide direct access to source data/documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection.

5.15.2 The sponsor should verify that each subject has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, audit, IRB/IEC review, and regulatory inspection.

5.16 *Safety Information*

5.16.1 The sponsor is responsible for the ongoing safety evaluation of the investigational product(s).

5.16.2 The sponsor should promptly notify all concerned investigator(s)/institution(s) and the regulatory authority(ies) of findings that could affect adversely the safety of subjects, impact the conduct of the trial, or alter the IRB/IEC's approval/favorable opinion to continue the trial.

5.17 *Adverse Drug Reaction Reporting*

5.17.1 The sponsor should expedite the reporting to all concerned investigator(s)/institutions(s), to the IRB(s)/IEC(s), where required, and to the regulatory authority(ies) of all adverse drug reactions (ADR's) that are both serious and unexpected.

5.17.2 Such expedited reports should comply with the applicable regulatory requirement(s) and with the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

5.17.3 The sponsor should submit to the regulatory authority(ies) all safety updates and periodic reports, as required by applicable regulatory requirement(s).

5.18 *Monitoring*

5.18.1 *Purpose.* The purposes of trial monitoring are to verify that:

(a) The rights and well-being of human subjects are protected.

(b) The reported trial data are accurate, complete, and verifiable from source documents.

(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

5.18.2 *Selection and Qualifications of Monitors.*

(a) Monitors should be appointed by the sponsor.

(b) Monitors should be appropriately trained, and should have the scientific and/or clinical knowledge needed to monitor the trial adequately. A monitor's qualifications should be documented.

(c) Monitors should be thoroughly familiar with the investigational product(s), the protocol, written informed consent form and any other written information to be provided to subjects, the sponsor's SOP's, GCP, and the applicable regulatory requirement(s).

5.18.3 *Extent and Nature of Monitoring.*

The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. In general there is a need for on-site monitoring, before, during, and after the trial; however, in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigators' training and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP. Statistically controlled sampling may be an acceptable method for selecting the data to be verified.

5.18.4 *Monitor's Responsibilities.*

The monitor(s), in accordance with the sponsor's requirements, should ensure that the trial is conducted and documented properly by carrying out the following activities when relevant and necessary to the trial and the trial site:

(a) Acting as the main line of communication between the sponsor and the investigator.

(b) Verifying that the investigator has adequate qualifications and resources (see 4.1, 4.2, 5.6) and these remain adequate throughout the trial period, and that the staff and facilities, including laboratories and equipment, are adequate to safely and properly conduct the trial and these remain adequate throughout the trial period.

(c) Verifying, for the investigational product(s):

(i) That storage times and conditions are acceptable, and that supplies are sufficient throughout the trial.

(ii) That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).

(iii) That subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s).

(iv) That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.

(v) That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor's authorized procedures.

(d) Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.

(e) Verifying that written informed consent was obtained before each subject's participation in the trial.

(f) Ensuring that the investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).

(g) Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.

(h) Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.

(i) Verifying that the investigator is enrolling only eligible subjects.

(j) Reporting the subject recruitment rate.

(k) Verifying that source data/documents and other trial records are accurate, complete, kept up-to-date, and maintained.

(l) Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.

(m) Checking the accuracy and completeness of the CRF entries, source data/documents, and other trial-related records against each other. The monitor specifically should verify that:

(i) The data required by the protocol are reported accurately on the CRF's and are consistent with the source data/documents.

(ii) Any dose and/or therapy modifications are well documented for each of the trial subjects.

(iii) Adverse events, concomitant medications, and intercurrent illnesses are reported in accordance with the protocol on the CRF's.

(iv) Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRF's.

(v) All withdrawals and dropouts of enrolled subjects from the trial are reported and explained on the CRF's.

(n) Informing the investigator of any CRF entry error, omission, or illegibility. The monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialed by the investigator or by a member of the investigator's trial staff who is authorized to initial CRF changes for the investigator. This authorization should be documented.

(o) Determining whether all adverse events (AE's) are appropriately reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, the applicable regulatory requirement(s), and indicated in the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

(p) Determining whether the investigator is maintaining the essential documents. (See 8. ''Essential Documents for the Conduct of a Clinical Trial.'')

(q) Communicating deviations from the protocol, SOP's, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

5.18.5 *Monitoring Procedures.*

The monitor(s) should follow the sponsor's established written SOP's as well as those procedures that are specified by the sponsor for monitoring a specific trial.

5.18.6 *Monitoring Report.*

(a) The monitor should submit a written report to the sponsor after each trial-site visit or trial-related communication.

(b) Reports should include the date, site, name of the monitor, and name of the investigator or other individual(s) contacted.

(c) Reports should include a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken, and/or actions recommended to secure compliance.

(d) The review and follow-up of the monitoring report by the sponsor should be documented by the sponsor's designated representative.

5.19 *Audit*

If or when sponsors perform audits, as part of implementing quality assurance, they should consider:

5.19.1 *Purpose.*

The purpose of a sponsor's audit, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOP's, GCP, and the applicable regulatory requirements.

5.19.2 *Selection and Qualification of Auditors.*

(a) The sponsor should appoint individuals, who are independent of the clinical trial/data collection system(s), to conduct audits.

(b) The sponsor should ensure that the auditors are qualified by training and experience to conduct audits properly. An auditor's qualifications should be documented.

5.19.3 *Auditing Procedures.*

(a) The sponsor should ensure that the auditing of clinical trials/systems is conducted in accordance with the sponsor's written procedures on what to audit, how to audit, the frequency of audits, and the form and content of audit reports.

(b) The sponsor's audit plan and procedures for a trial audit should be guided by the importance of the trial to submissions to regulatory authorities, the number of subjects in the trial, the type and complexity of the trial, the level of risks to the trial subjects, and any identified problem(s).

(c) The observations and findings of the auditor(s) should be documented.

(d) To preserve the independence and value of the audit function, the regulatory authority(ies) should not routinely request the audit reports. Regulatory authority(ies) may seek access to an audit report on a case-by-case basis, when evidence of serious GCP noncompliance exists, or in the course of legal proceedings or investigations.

(e) Where required by applicable law or regulation, the sponsor should provide an audit certificate.

5.20 *Noncompliance*

5.20.1 Noncompliance with the protocol, SOP's, GCP, and/or applicable regulatory requirement(s) by an investigator/institution, or by member(s) of the sponsor's staff should lead to prompt action by the sponsor to secure compliance.

5.20.2 If the monitoring and/or auditing identifies serious and/or persistent noncompliance on the part of an investigator/institution, the sponsor should terminate the investigator's/institution's participation in the trial. When an investigator's/institution's participation is terminated because of noncompliance, the sponsor should notify promptly the regulatory authority(ies).

5.21 *Premature Termination or Suspension of a Trial*

If a trial is terminated prematurely or suspended, the sponsor should promptly inform the investigators/institutions, and the regulatory authority(ies) of the termination or suspension and the reason(s) for the termination or suspension. The IRB/IEC should also be informed promptly and provided the reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s).

5.22 *Clinical Trial/Study Reports*

Whether the trial is completed or prematurely terminated, the sponsor should ensure that the clinical trial/study reports are prepared and provided to the regulatory agency(ies) as required by the applicable regulatory requirement(s). The sponsor should also ensure that the clinical trial/study reports in marketing applications meet the standards of the ICH Guideline for Structure and Content of Clinical Study Reports. (NOTE: The ICH Guideline for Structure and Content of Clinical Study Reports specifies that abbreviated study reports may be acceptable in certain cases.)

5.23 *Multicenter Trials*

For multicenter trials, the sponsor should ensure that:

5.23.1 All investigators conduct the trial in strict compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and given approval/favorable opinion by the IRB/IEC.

5.23.2 The CRF's are designed to capture the required data at all multicenter trial sites. For those investigators who are collecting additional data, supplemental CRF's should also be provided that are designed to capture the additional data.

5.23.3 The responsibilities of the coordinating investigator(s) and the other participating investigators are documented prior to the start of the trial.

5.23.4 All investigators are given instructions on following the protocol, on complying with a uniform set of standards for the assessment of clinical and laboratory findings, and on completing the CRF's.

5.23.5 Communication between investigators is facilitated.

6. *Clinical Trial Protocol and Protocol Amendment(s)*

The contents of a trial protocol should generally include the following topics. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as an Investigator's Brochure.

6.1 *General Information*

6.1.1 Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).

6.1.2 Name and address of the sponsor and monitor (if other than the sponsor).

6.1.3 Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.

6.1.4 Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.

6.1.5 Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

6.1.6 Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable) who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).

6.1.7 Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

6.2 *Background Information*

6.2.1 Name and description of the investigational product(s).

6.2.2 A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.

6.2.3 Summary of the known and potential risks and benefits, if any, to human subjects.

6.2.4 Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).

6.2.5 A statement that the trial will be conducted in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

6.2.6 Description of the population to be studied.

6.2.7 References to literature and data that are relevant to the trial, and that provide background for the trial.

6.3 *Trial Objectives and Purpose*

A detailed description of the objectives and the purpose of the trial.

6.4 *Trial Design*

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design should include:

6.4.1 A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.

6.4.2 A description of the type/design of trial to be conducted (e.g., double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures, and stages.

6.4.3 A description of the measures taken to minimize/avoid bias, including (for example):

(a) Randomization.
(b) Blinding.
6.4.4 A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labeling of the investigational product(s).
6.4.5 The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.
6.4.6 A description of the ''stopping rules'' or ''discontinuation criteria'' for individual subjects, parts of trial, and entire trial.
6.4.7 Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.
6.4.8 Maintenance of trial treatment randomization codes and procedures for breaking codes.
6.4.9 The identification of any data to be recorded directly on the CRF's (i.e., no prior written or electronic record of data), and to be considered to be source data.
6.5 *Selection and Withdrawal of Subjects*
6.5.1 Subject inclusion criteria.
6.5.2 Subject exclusion criteria.
6.5.3 Subject withdrawal criteria (i.e., terminating investigational product treatment/trial treatment) and procedures specifying:
(a) When and how to withdraw subjects from the trial/ investigational product treatment.
(b) The type and timing of the data to be collected for withdrawn subjects.
(c) Whether and how subjects are to be replaced.
(d) The follow-up for subjects withdrawn from investigational product treatment/trial treatment.
6.6 *Treatment of Subjects*
6.6.1 The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.
6.6.2 Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.
6.6.3 Procedures for monitoring subject compliance.
6.7 *Assessment of Efficacy*
6.7.1 Specification of the efficacy parameters.
6.7.2 Methods and timing for assessing, recording, and analyzing efficacy parameters.
6.8 *Assessment of Safety*
6.8.1 Specification of safety parameters.
6.8.2 The methods and timing for assessing, recording, and analyzing safety parameters.
6.8.3 Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.
6.8.4 The type and duration of the follow-up of subjects after adverse events.
6.9 *Statistics*
6.9.1 A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).
6.9.2 The number of subjects planned to be enrolled. In multicenter trials, the number of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
6.9.3 The level of significance to be used.
6.9.4 Criteria for the termination of the trial.
6.9.5 Procedure for accounting for missing, unused, and spurious data.
6.9.6 Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in the protocol and/or in the final report, as appropriate).
6.9.7 The selection of subjects to be included in the analyses (e.g., all randomized subjects, all dosed subjects, all eligible subjects, evaluate-able subjects).
6.10 *Direct Access to Source Data/Documents*
The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s) by providing direct access to source data/documents.
6.11 *Quality Control and Quality Assurance*
6.12 *Ethics*
Description of ethical considerations relating to the trial.
6.13 *Data Handling and Recordkeeping*
6.14 *Financing and Insurance*
Financing and insurance if not addressed in a separate agreement.
6.15 *Publication Policy*
Publication policy, if not addressed in a separate agreement.
6.16 *Supplements*
(NOTE: Since the protocol and the clinical trial/study report are closely related, further relevant information can be found in the ICH Guideline for Structure and Content of Clinical Study Reports.)
7. *Investigator's Brochure*
7.1 *Introduction*
The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration, and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial. The information should be presented in a concise, simple, objective, balanced, and nonpromotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial. For this reason, a medically qualified person should generally participate in the editing of an IB, but the contents of the IB should be approved by the disciplines that generated the described data.
This guideline delineates the minimum information that should be included in an IB and provides suggestions for its layout. It is expected that the type and extent of information available will vary with the stage of development of the investigational product. If the investigational product is marketed and its pharmacology is widely understood by medical practitioners, an extensive IB may not be necessary. Where permitted by regulatory authorities, a basic product information brochure, package leaflet, or labeling may be an appropriate alternative, provided that it includes current, comprehensive, and detailed information on all aspects of the investigational product that might be of importance to the investigator. If a marketed product is being studied for a new use (i.e., a new indication), an IB specific to that new use should be prepared. The IB should be reviewed at least annually and revised as necessary in compliance with a sponsor's written procedures. More frequent revision may be appropriate depending on the stage of development and the generation of relevant new information. However, in accordance with GCP, relevant new information may be so important that it should be communicated to the investigators, and possibly to the Institutional Review Boards (IRB's)/Independent Ethics Committees (IEC's) and/or regulatory authorities before it is included in a revised IB.
Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator(s) and the investigators are responsible for providing the up-to-date IB to the responsible IRB's/IEC's. In the case of an investigator-sponsored trial, the sponsor-investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor-investigator, then he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol that contains the minimum current information described in this guideline.
7.2 *General Considerations*
The IB should include:
7.2.1 *Title Page.* This should provide the sponsor's name, the identity of each investigational product (i.e., research number, chemical or approved generic name, and trade name(s) where legally permissible and desired by the sponsor), and the release date. It is also suggested that an edition number, and a reference to the number and date of the edition it supersedes, be provided. An example is given in Appendix 1.
7.2.2 *Confidentiality Statement.* The sponsor may wish to include a statement instructing the investigator/recipients to treat the IB as a confidential document for the sole information and use of the investigator's team and the IRB/IEC.
7.3 *Contents of the Investigator's Brochure.* The IB should contain the following sections, each with literature references where appropriate:
7.3.1 *Table of Contents.* An example of the Table of Contents is given in Appendix 2.
7.3.2 *Summary.* A brief summary (preferably not exceeding two pages) should be given, highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetic, metabolic,

and clinical information available that is relevant to the stage of clinical development of the investigational product.

7.3.3 *Introduction.* A brief introductory statement should be provided that contains the chemical name (and generic and trade name(s) when approved) of the investigational product(s), all active ingredients, the investigational product(s) pharmacological class and its expected position within this class (e.g., advantages), the rationale for performing research with the investigational product(s), and the anticipated prophylactic, therapeutic, or diagnostic indication(s). Finally, the introductory statement should provide the general approach to be followed in evaluating the investigational product.

7.3.4 *Physical, Chemical, and Pharmaceutical Properties and Formulation.* A description should be provided of the investigational product substance(s) (including the chemical and/or structural formula(e)), and a brief summary should be given of the relevant physical, chemical, and pharmaceutical properties.

To permit appropriate safety measures to be taken in the course of the trial, a description of the formulation(s) to be used, including excipients, should be provided and justified if clinically relevant. Instructions for the storage and handling of the dosage form(s) should also be given.

Any structural similarities to other known compounds should be mentioned.

7.3.5 *Nonclinical Studies.*

Introduction:

The results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies should be provided in summary form. This summary should address the methodology used, the results, and a discussion of the relevance of the findings to the investigated therapeutic and the possible unfavorable and unintended effects in humans.

The information provided may include the following, as appropriate, if known/available:

Species tested;

Number and sex of animals in each group;

Unit dose (e.g., milligram/kilogram (mg/kg));

Dose interval;

Route of administration;

Duration of dosing;

Information on systemic distribution;

Duration of post-exposure follow-up;

Results, including the following aspects:

- Nature and frequency of pharmacological or toxic effects;
- Severity or intensity of pharmacological or toxic effects;
- Time to onset of effects;
- Reversibility of effects;
- Duration of effects;
- Dose response.

Tabular format/listings should be used whenever possible to enhance the clarity of the presentation.

The following sections should discuss the most important findings from the studies, including the dose response of observed effects, the relevance to humans, and any aspects to be studied in humans. If applicable, the effective and nontoxic dose findings in the same animal species should be compared (i.e., the therapeutic index should be discussed). The relevance of this information to the proposed human dosing should be addressed. Whenever possible, comparisons should be made in terms of blood/tissue levels rather than on a mg/kg basis.

(a) Nonclinical Pharmacology

A summary of the pharmacological aspects of the investigational product and, where appropriate, its significant metabolites studied in animals should be included. Such a summary should incorporate studies that assess potential therapeutic activity (e.g., efficacy models, receptor binding, and specificity) as well as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect(s)).

(b) Pharmacokinetics and Product Metabolism in Animals

A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species studied should be given. The discussion of the findings should address the absorption and the local and systemic bioavailability of the investigational product and its metabolites, and their relationship to the pharmacological and toxicological findings in animal species.

(c) Toxicology

A summary of the toxicological effects found in relevant studies conducted in different animal species should be described under the following headings where appropriate:

Single dose;

Repeated dose;

Carcinogenicity;

Special studies (e.g., irritancy and sensitization);

Reproductive toxicity;

Genotoxicity (mutagenicity).

7.3.6 *Effects in Humans.*

Introduction:

A thorough discussion of the known effects of the investigational product(s) in humans should be provided, including information on pharmacokinetics, metabolism, pharmacodynamics, dose response, safety, efficacy, and other pharmacological activities. Where possible, a summary of each completed clinical trial should be provided. Information should also be provided regarding results from any use of the investigational product(s) other than in clinical trials, such as from experience during marketing.

(a) Pharmacokinetics and Product Metabolism in Humans

A summary of information on the pharmacokinetics of the investigational product(s) should be presented, including the following, if available:

Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination).

Bioavailability of the investigational product (absolute, where possible, and/or relative) using a reference dosage form.

Population subgroups (e.g., gender, age, and impaired organ function).

Interactions (e.g., product-product interactions and effects of food).

Other pharmacokinetic data (e.g., results of population studies performed within clinical trial(s)).

(b) Safety and Efficacy

A summary of information should be provided about the investigational product's/products' (including metabolites, where appropriate) safety, pharmacodynamics, efficacy, and dose response that were obtained from preceding trials in humans (healthy volunteers and/or patients). The implications of this information should be discussed. In cases where a number of clinical trials have been completed, the use of summaries of safety and efficacy across multiple trials by indications in subgroups may provide a clear presentation of the data. Tabular summaries of adverse drug reactions for all the clinical trials (including those for all the studied indications) would be useful. Important differences in adverse drug reaction patterns/incidences across indications or subgroups should be discussed.

The IB should provide a description of the possible risks and adverse drug reactions to be anticipated on the basis of prior experiences with the product under investigation and with related products. A description should also be provided of the precautions or special monitoring to be done as part of the investigational use of the product(s).

(c) Marketing Experience

The IB should identify countries where the investigational product has been marketed or approved. Any significant information arising from the marketed use should be summarized (e.g., formulations, dosages, routes of administration, and adverse product reactions). The IB should also identify all the countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.

7.3.7 *Summary of Data and Guidance for the Investigator.*

This section should provide an overall discussion of the nonclinical and clinical data, and should summarize the information from various sources on different aspects of the investigational product(s), wherever possible. In this way, the investigator can be provided with the most informative interpretation of the available data and with an assessment of the implications of the information for future clinical trials.

Where appropriate, the published reports on related products should be discussed. This could help the investigator to anticipate adverse drug reactions or other problems in clinical trials.

The overall aim of this section is to provide the investigator with a clear understanding of the possible risks and adverse reactions, and of the specific tests, observations, and precautions that may be needed for a clinical trial. This understanding should be based on the available physical, chemical, pharmaceutical, pharmacological, toxicological, and clinical information on the investigational product(s). Guidance should also be provided to the clinical investigator on the recognition and treatment of possible overdose and adverse drug reactions that is based on previous human experience and on

the pharmacology of the investigational product.

7.4 *Appendix 1:*

TITLE PAGE OF INVESTIGATOR'S BROCHURE (Example)

Sponsor's Name:

Product:

Research Number:

Name(s): Chemical, Generic (if approved)

Trade Name(s) (if legally permissible and desired by the sponsor)

Edition Number:

Release Date:

Replaces Previous Edition Number:

Date:

7.5 *Appendix 2:*

TABLE OF CONTENTS OF INVESTIGATOR'S BROCHURE (Example)

- Confidentiality Statement (optional)
- Signature Page (optional)

1. Table of Contents
2. Summary
3. Introduction
4. Physical, Chemical, and Pharmaceutical Properties and Formulation
5. Nonclinical Studies
5.1 Nonclinical Pharmacology
5.2 Pharmacokinetics and Product Metabolism in Animals
5.3 Toxicology
6. Effects in Humans
6.1 Pharmacokinetics and Product Metabolism in Humans
6.2 Safety and Efficacy
6.3 Marketing Experience
7. Summary of Data and Guidance for the Investigator

NB: References on

1. Publications
2. Reports

These references should be found at the end of each chapter.

Appendices (if any)

8. *Essential Documents for the Conduct of a Clinical Trial*

8.1 *Introduction*

Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements.

Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor, and monitor. These documents are also the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

The minimum list of essential documents that has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated: (1) Before the clinical phase of the trial commences, (2) during the clinical conduct of the trial, and (3) after completion or termination of the trial. A description is given of the purpose of each document, and whether it should be filed in either the investigator/institution or sponsor files, or both. It is acceptable to combine some of the documents, provided the individual elements are readily identifiable.

Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the appropriate files.

Any or all of the documents addressed in this guideline may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

8.2 *Before the Clinical Phase of the Trial Commences*

During this planning stage the following documents should be generated and should be on file before the trial formally starts.

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.2.1	Investigator's brochure	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X
8.2.2	Signed protocol and amendments, if any, and sample case report form (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF	X	X
8.2.3	Information given to trial subject - Informed consent form (Including all applicable translations)	To document the informed consent	X	X
	- Any other written information	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent	X	X
	- Advertisement for subject recruitment (if used)	To document that recruitment measures are appropriate and not coercive	X	
8.2.4	Financial aspects of the trial	To document the financial agreement between the investigator/institution and the sponsor for the trial	X	X
8.2.5	Insurance statement (where required)	To document that compensation to subject(s) for trial-related injury will be available	X	X
8.2.6	Signed agreement between involved parties, e.g.:	To document agreements		
	- Investigator/institution and sponsor		X	X
	- Investigator/institution and CRO		X	X (Where required)
	- Sponsor and CRO			X
	- Investigator/institution and authority(ies) (Where required)		X	X

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.2.7	Dated, documented approval/favorable opinion of IRB/IEC of the following: - Protocol and any amendments - CRF (if applicable) - Informed consent form(s) - Any other written information to be provided to the subject(s) - Advertisement for subject recruitment (if used) - Subject compensation (if any) - Any other documents given approval/favorable opinion	To document that the trial has been subject to IRB/IEC review and given approval/favorable opinion. To identify the version number and date of the document(s).	X	X
8.2.8	Institutional review board/independent ethics committee composition	To document that the IRB/IEC is constituted in agreement with GCP	X	X (where required)
8.2.9	Regulatory authority(ies) authorization/approval/notification of protocol (where required)	To document appropriate authorization/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	X (where required)	X (where required)
8.2.10	Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and subinvestigators	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	X	X
8.2.11	Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol	To document normal values and/or ranges of the tests	X	X
8.2.12	Medical/laboratory/technical procedures/tests - Certification or - Accreditation or - Established quality control and/or external quality assessment or - Other validation (where required)	To document competence of facility to perform required test(s), and support reliability of results	X (where required)	X
8.2.13	Sample of label(s) attached to investigational product container(s)	To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects	X	X
8.2.14	Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or Investigator's Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of investigational products and trial-related materials	X	X
8.2.15	Shipping records for investigational product(s) and trial-related materials	To document shipment dates, batch numbers, and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability.	X	X
8.2.16	Certificate(s) of analysis of investigational product(s) shipped	To document identity, purity, and strength of investigational products to be used in the trial.		X
8.2.17	Decoding procedures for blinded trials	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment	X	X (third party if applicable)
8.2.18	Master randomization list	To document method for randomization of trial population		X (third party if applicable)
8.2.19	Pretrial monitoring report	To document that the site is suitable for the trial (may be combined with 8.2.20)		X
8.2.20	Trial initiation monitoring report	To document that trial procedures were reviewed with the investigator and investigator's trial staff (may be combined with 8.2.19)	X	X

8.3 *During the Clinical Conduct of the Trial*

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.3.1	Investigator's Brochure updates	To document that investigator is informed in a timely manner of relevant information as it becomes available	X	X
8.3.2	Any revisions to: - Protocol/amendment(s) and CRF - Informed consent form - Any other written information provided to subjects - Advertisement for subject recruitment (if used)	To document revisions of these trial-related documents that take effect during trial	X	X
8.3.3	Dated, documented approval/favorable opinion of institutional review board (IRB)/independent ethics committee (IEC) of the following: - Protocol amendment(s) - Revision(s) of: - Informed consent form - Any other written information to be provided to the subject - Advertisement for subject recruitment (if used) - Any other documents given approval/favorable opinion - Continuing review of trial (see 3.1.4)	To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favorable opinion. To identify the version number and date of the document(s)	X	X
8.3.4	Regulatory authority(ies) authorizations/approvals/notifications where required for: - Protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements	X (where required)	X
8.3.5	Curriculum vitae for new investigator(s) and/or subinvestigators	(See 8.2.10)	X	X
8.3.6	Updates to normal value(s)/range(s) for medical laboratory/technical procedure(s)/test(s) included in the protocol	To document normal values and ranges that are revised during the trial (see 8.2.11)	X	X
8.3.7	Updates of medical/laboratory/technical procedures/tests - Certification or - Accreditation or - Established quality control and/or external quality assessment or - Other validation (where required)	To document that tests remain adequate throughout the trial period (see 8.2.12)	X (where required)	X
8.3.8	Documentation of investigational product(s) and trial-related materials shipment	(See 8.2.15)	X	X
8.3.9	Certificate(s) of analysis for new batches of investigational products	(See 8.2.16)		X
8.3.10	Monitoring visit reports	To document site visits by, and findings of, the monitor		X
8.3.11	Relevant communications other than site visits - Letters - Meeting notes - Notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	X	X
8.3.12	Signed informed consent forms	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission (see 8.2.3)	X	
8.3.13	Source documents	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject	X	
8.3.14	Signed, dated, and completed case report forms (CRF's)	To document that the investigator or authorized member of the investigator's staff confirms the observations recorded	X (copy)	X (original)

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.3.15	Documentation of CRF corrections	To document all changes/additions or corrections made to CRF after initial data were recorded	X (copy)	X (original)
8.3.16	Notification by originating investigator to sponsor of serious adverse events and related reports	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with 4.11	X	X
8.3.17	Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s)/IEC(s) of unexpected serious adverse drug reactions and of other safety information	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions in accordance with 5.17 and 4.11.1 and of other safety information in accordance with 4.11.2 and 5.16.2	X (where required)	X
8.3.18	Notification by sponsor to investigators of safety information	Notification by sponsor to investigators of safety information in accordance with 5.16.2	X	X
8.3.19	Interim or annual reports to IRB/IEC and authority(ies)	Interim or annual reports provided to IRB/IEC in accordance with 4.10 and to authority(ies) in accordance with 5.17.3	X	X (where required)
8.3.20	Subject screening log	To document identification of subjects who entered pretrial screening	X	X (where required)
8.3.21	Subject identification code list	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject	X	
8.3.22	Subject enrollment log	To document chronological enrollment of subjects by trial number	X	
8.3.23	Investigational product(s) accountability at the site	To document that investigational products(s) have been used according to the protocol	X	X
8.3.24	Signature sheet	To document signatures and initials of all persons authorized to make entries and/or corrections on CRF's	X	X
8.3.25	Record of retained body fluids/tissue samples (if any)	To document location and identification of retained samples if assays need to be repeated	X	X

8.4 *After Completion or Termination of the Trial*

After completion or termination of the trial, all of the documents identified in sections 8.2 and 8.3 should be in the file together with the following:

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.4.1	Investigational product(s) accountability at site	To document that the investigational product(s) have been used according to the protocol. To document the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor	X	X
8.4.2	Documentation of investigational product(s) destruction	To document destruction of unused investigational product(s) by sponsor or at site	X (if destroyed at site)	X
8.4.3	Completed subject identification code list	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time	X	
8.4.4	Audit certificate (if required)	To document that audit was performed (if required) (see 5.19.3(e))		X
8.4.5	Final trial close-out monitoring report	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files		X

	Title of Document	Purpose	Located in Files of	
			Investigator/Institution	Sponsor
8.4.6	Treatment allocation and decoding documentation	Returned to sponsor to document any decoding that may have occurred		X
8.4.7	Final report by investigator/institution to IRB/IEC where required, and where applicable, to the regulatory authority(ies) (see 4.13)	To document completion of the trial	X	
8.4.8	Clinical study report (see 5.22)	To document results and interpretation of trial	X (if applicable)	X

Dated: April 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12138 Filed 5–8–97; 8:45 am]

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federal register

Friday
May 9, 1997

Part III

Department of Health and Human Services

Food and Drug Administration

International Conference on Harmonisation; Draft Guideline on Statistical Principles for Clinical Trials; Notice of Availability

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0174]

International Conference on Harmonisation; Draft Guideline on Statistical Principles for Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline entitled ''Statistical Principles for Clinical Trials.'' The draft guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline is intended to provide recommendations to sponsors and scientific experts regarding statistical principles and methodology which, when applied to clinical trials for marketing applications, will facilitate the general acceptance of analyses and conclusions drawn from the trials.

DATES: Written comments by June 23, 1997.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the draft guideline are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the draft guideline may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448 or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Robert T. O'Neill, Center for Drug Evaluation and Research (HFD–700), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3195.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

On January 17, 1997, the ICH Steering Committee agreed that a draft guideline entitled ''Statistical Principles for Clinical Trials'' should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the other regulatory agency members of the Efficacy Expert Working Group.

The draft guideline addresses principles of statistical methodology applied to clinical trials for marketing applications. The draft guideline provides recommendations to sponsors in the design, conduct, analysis, and evaluation of clinical trials of an investigational product in the context of its overall clinical development. The draft guideline also provides guidance to scientific experts in preparing application summaries or assessing evidence of efficacy and safety, principally from late Phase II and Phase III clinical trials. Application of the principles of statistical methodology is intended to facilitate the general acceptance of analyses and conclusions drawn from clinical trials.

This draft guideline represents the agency's current thinking on statistical principles for clinical trials of drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before June 23, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guideline. 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. The draft guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this draft guideline is available on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cder/guidance.htm) or through the CBER home page (http://www.fda.gov/cber/cberftp.html).

The text of the draft guideline follows:

Statistical Principles for Clinical Trials

Note: A Glossary of terms and definitions is provided as an annex to this guideline.

Table of Contents

I. Introduction
1.1 Background and Purpose
1.2 Scope and Direction
II. Considerations for Overall Clinical Development
2.1 Study Context
2.1.1 Development Plan
2.1.2 Confirmatory Trial
2.1.3 Exploratory Trial
2.2 Study Scope
2.2.1 Population
2.2.2 Primary and Secondary Variables
2.3 Design Techniques to Avoid Bias
2.3.1 Blinding
2.3.2 Randomization
III. Study Design Considerations
3.1 Study Configuration
3.1.1 Parallel Group Design
3.1.2 Cross-Over Design
3.1.3 Factorial Designs

3.2 Multicenter Trials
3.3 Type of Comparison
3.3.1 Trials to Show Superiority
3.3.2 Trials to Show Equivalence or Non-inferiority
3.3.3 Dose-Response Designs
3.4 Group Sequential Designs
3.5 Sample Size
3.6 Data Capture and Processing
IV. Study Conduct
4.1 Trial Monitoring
4.2 Changes in Inclusion and Exclusion Criteria
4.3 Accrual Rates
4.4 Sample Size Adjustment
4.5 Interim Analysis and Early Stopping
4.6 Role of Independent Data Monitoring Committee (IDMC)
V. Data Analysis
5.1 Prespecified Analysis Plan
5.2 Analysis Sets
5.2.1 All Randomized Subjects
5.2.2 Per Protocol Subjects
5.2.3 Roles of the All Randomized Subjects Analysis and the Per Protocol Analysis
5.3 Missing Values and Outliers
5.4 Data Transformation/Modification
5.5 Estimation, Confidence Intervals and Hypothesis Testing
5.6 Adjustment of Type I Error and Confidence Levels
5.7 Subgroups, Interactions and Covariates
5.8 Integrity of Data and Computer Software
VI. Evaluation of Safety and Tolerability
6.1 Scope of Evaluation
6.2 Choice of Variables and Data Collection
6.3 Set of Subjects to be Evaluated and Presentation of Data
6.4 Statistical Evaluation
6.5 Single Study versus Integrated Summary
VII. Reporting
7.1 Evaluation and Reporting
7.2 Summarizing the Clinical Database
7.2.1 Efficacy Data
7.2.2 Safety Data
Annex 1 Glossary

I. Introduction

1.1 Background and Purpose

The efficacy and safety of medicinal products should be demonstrated by clinical trials that follow the guidance in ''Good Clinical Practice: Consolidated Guideline (E6)'' adopted by the ICH, May 1, 1996. The role of statistics in clinical trial design and analysis is acknowledged as essential in that ICH guideline. The proliferation of statistical research in the area of clinical trials coupled with the critical role of clinical research in the drug approval process and health care in general necessitate a succinct document on statistical issues related to clinical trials. This guideline is written primarily to attempt to harmonize the principles of statistical methodology applied to clinical trials for marketing applications submitted in Europe, Japan, and the United States.

As a starting point, this guideline utilized the CPMP (Committee for Proprietary Medicinal Products) Note for Guidance entitled ''Biostatistical Methodology in Clinical Trials in Applications for Marketing Authorizations for Medicinal Products'' (December 1994). It was also influenced by ''Guidelines on the Statistical Analysis of Clinical Studies'' (March 1992) from the Japanese Ministry of Health and Welfare and the U.S. FDA document entitled ''Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications'' (July 1988). Some topics related to statistical principles and methodology are also embedded within other ICH guidelines, particularly those listed below. The specific guideline that contains related text will be identified in various sections of this document.

E1: The Extent of Population Exposure to Assess Clinical Safety

E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

E2B: Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

E2C: Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs

E3: Structure and Content of Clinical Study Reports

E4: Dose-Response Information to Support Drug Registration

E5: Ethnic Factors in the Acceptability of Foreign Clinical Data

E6: Good Clinical Practice: Consolidated Guideline

E7: Studies in Support of Special Populations: Geriatrics

E8: General Considerations for Clinical Trials

E10: Choice of Control Group in Clinical Trials

M1: Standardization of Medical Terminology for Regulatory Purposes

M3: Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals

This guideline is intended to give direction to sponsors in the design, conduct, analysis, and evaluation of clinical trials of an investigational product in the context of its overall clinical development. The document will also assist scientific experts charged with preparing application summaries or assessing evidence of efficacy and safety, principally from late Phase II and Phase III clinical trials.

1.2 Scope and Direction

The focus of this guideline is on statistical principles. It does not address the use of specific statistical procedures or methods. Specific procedural steps to ensure that principles are implemented properly are the responsibility of the sponsor. Integration of data across clinical trials is discussed, but is not a primary focus of this guideline. Selected principles and procedures related to data management or clinical trial monitoring activities are covered in other ICH guidelines and are not addressed here.

This guideline should be of interest to individuals from a broad range of scientific disciplines. However, it is assumed that the actual responsibility for all statistical work associated with clinical trials will lie with an appropriately qualified and experienced statistician, as indicated in the ''ICH Guideline for Good Clinical Practice.'' The involvement of the statistician, in collaboration with other clinical trial professionals, is to ensure that statistical principles are applied appropriately in clinical trials supporting drug development. Thus, the statistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guideline.

All important details of the design, conduct, and proposed analysis of each clinical trial contributing to a marketing application should be clearly specified in a protocol written before the trial begins. The extent to which the procedures in the protocol are followed and the primary analysis is planned a priori will contribute to the degree of confidence in the final results and conclusions of the trial. The protocol and subsequent amendments should be approved by the responsible personnel, including the trial statistician. The trial statistician should ensure that the protocol and any amendments cover all relevant statistical issues clearly and accurately, using technical terminology as appropriate.

The principles outlined in this guideline are primarily relevant to clinical trials conducted in the later phases of development, many of which are confirmatory trials of efficacy. In addition to efficacy, confirmatory trials may have as their primary variable a safety variable (e.g., an adverse event, a clinical laboratory variable, or an electrocardiographic measure) or a pharmacodynamic or pharmacokinetic variable (as in a confirmatory bioequivalence trial). Furthermore, some confirmatory findings may be derived from data integrated across studies, and selected principles in this guideline are applicable in this situation. Finally, although the early phases of drug development consist mainly of clinical trials that are exploratory in nature, statistical principles are also relevant to these clinical trials. Hence, the substance of this document should be applied as far as possible to all phases of clinical development.

Many of the principles delineated in this guideline deal with minimizing bias and maximizing precision. As used in this guideline, the term ''bias'' describes the systematic tendency of any factors associated with the design, conduct, analysis, and interpretation of the results of clinical trials to make the estimate of a treatment effect deviate from its true value. It is important to identify potential sources of bias to the extent possible so that attempts to limit such bias may be made. The presence of bias may seriously compromise the ability to draw valid conclusions from clinical studies.

Some sources of bias arise from the design of the trial, for example an assignment of treatments such that subjects at lower risk are systematically assigned to one treatment. Other sources of bias arise during the conduct and analysis of a clinical trial. For example, protocol violations and exclusion of subjects from analysis based upon knowledge of subject outcomes are possible sources of bias that may affect the accurate assessment of treatment effect. Because bias can occur in subtle or unknown ways and its effect is not measurable directly, it is important to evaluate the robustness of the results and

primary conclusions of the trial. Robustness is a concept that refers to the sensitivity of the overall conclusions to various limitations of the data, assumptions, and analytic approaches to data analysis. Robustness implies that, if a variety of analyses of the data that take into account changing assumptions were to be performed, the treatment effect and primary conclusions of the trial would be consistent. The interpretation of statistical measures of uncertainty of the treatment effect and treatment comparisons should involve consideration of the potential contribution of bias to the p-value, confidence interval, or inference.

This guideline largely refers to the use of frequentist methods when discussing hypothesis testing and/or confidence intervals. However, the use of Bayesian or other approaches may be considered when the reasons for their use are clear and when the resulting conclusions are sufficiently robust compared to alternative assumptions.

II. Considerations for Overall Clinical Development

2.1 Study Context

2.1.1 Development Plan

The broad aim of the process of clinical development of a new drug is to find out whether there is a dose range and schedule at which the drug can be shown to be simultaneously safe and effective, to the extent that the risk-benefit relationship is acceptable. The particular subjects who may benefit from the drug and the specific indications for its use also need to be defined.

Satisfying these broad aims usually requires an ordered program of clinical trials, each with its own specific objectives. This should be specified in a clinical plan, or a series of plans, with appropriate decision points and flexibility to allow modification as knowledge accumulates. A marketing application should clearly describe the main content of such plans, and the contribution made by each trial. Interpretation and assessment of the evidence from the total program of trials involves synthesis of the evidence from the individual trials (see section 7.2). This is facilitated by ensuring that common standards are adopted for a number of features of the trials, such as dictionaries of medical terms, definition and timing of the main measurements, handling of protocol deviations, and so on. A statistical overview or meta-analysis may be informative when medical questions are addressed in more than one trial. Where possible, this should be envisaged in the plan so that the relevant trials are clearly identified and any necessary common features of their designs are specified in advance. Other major statistical issues (if any) that are expected to affect a number of trials in a common plan should be addressed in that plan.

2.1.2 Confirmatory Trial

A confirmatory trial is a controlled trial in which a hypothesis is stated in advance and evaluated. As a rule, confirmatory trials are necessary to provide firm evidence of efficacy or safety. In such trials, the key hypothesis of interest follows directly from the trial's primary objective, is always predefined, and is the hypothesis that is subsequently tested when the trial is complete. In a confirmatory trial, it is equally important to estimate with due precision the size of the effects attributable to the treatment of interest and to relate these effects to their clinical significance.

Confirmatory trials are intended to provide firm evidence in support of claims. Therefore, adherence to their planned design and procedures is particularly important; unavoidable changes should be explained and documented, and their effect examined. A justification of the design of each such trial and of all other statistical aspects, such as the planned analysis, should be set out in the protocol. Each trial should address only a limited number of questions.

Firm evidence in support of claims requires that the results of the confirmatory trials demonstrate that the investigational product under test has clinical benefits. The confirmatory trials should therefore be sufficient to answer each key clinical question relevant to the efficacy or safety claim clearly and definitively. In addition, it is important that the basis for generalization to the intended patient population is understood and explained; this may also influence the number and type of centers and/or trials needed. The results of the confirmatory trial(s) should be robust. In some circumstances, the weight of evidence from a single confirmatory trial may be sufficient.

2.1.3 Exploratory Trial

The rationale and design of confirmatory trials nearly always rests on earlier clinical work carried out in a series of exploratory studies. Like all clinical trials, these exploratory studies should have clear and precise objectives. However, in contrast to confirmatory trials, their objectives may not always lead to simple tests of predefined hypotheses. In addition, exploratory trials may sometimes require a more flexible approach to design so that changes can be made in response to accumulating results. Their analysis may entail data exploration; tests of hypothesis may be carried out, but the choice of hypothesis may be data dependent. Such trials cannot be the basis of the formal proof of efficacy, although they may contribute to the total body of relevant evidence.

Any individual trial may have both confirmatory and exploratory aspects. For example, in most confirmatory trials the data are also subjected to exploratory analyses which serve as a basis for explaining or supporting their findings and for suggesting further hypotheses for later research. The protocol should make a clear distinction between the aspects of a trial that will be used for confirmatory proof and the aspects that will provide data for exploratory analysis.

2.2 Study Scope

2.2.1 Population

In the earlier phases of drug development, the choice of subjects for a clinical trial may be heavily influenced by the wish to maximize the chance of observing specific clinical effects of interest. Hence, they may come from a very narrow subgroup of the total patient population for which the drug may eventually be indicated. However, by the time the confirmatory trials are undertaken, the subjects in the trials should more closely mirror the intended users. In these trials, it is generally helpful to relax the inclusion and exclusion criteria as much as possible within the target indication, while maintaining sufficient homogeneity to permit a successful trial to be carried out. No individual clinical trial can be expected to be totally representative of future users because of the possible influences of geographical location, the time when it is conducted, the medical practices of the particular investigator(s) and clinics, and so on. However, the influence of such factors should be reduced wherever possible and subsequently discussed during the interpretation of the trial results.

2.2.2 Primary and Secondary Variables

The primary variable (''target'' variable, primary endpoint) should be the variable capable of providing the most clinically relevant and convincing evidence directly related to the primary objective of the trial. There should generally be only one primary variable. This will usually be an efficacy variable, because the primary objective of most confirmatory trials is to provide strong scientific evidence regarding efficacy. Safety/tolerability may sometimes be the primary variable, and will always be an important consideration. Measurements relating to quality of life and health economics are further potential primary variables. The selection of the primary variable should reflect the accepted norms and standards in the relevant field of research. The use of a reliable and validated variable with which experience has been gained either in earlier studies or in published literature is recommended. There should be sufficient evidence that the primary variable can provide a valid and reliable measure of some clinically relevant and important treatment benefit in the subject population described by the inclusion and exclusion criteria. The primary variable should generally be the one used when estimating the sample size (see section 3.5).

In many cases, and especially when treatment is directed at a chronic rather than an acute process, the approach to assessing subject outcome may not be straightforward and should be carefully defined. For example, it is inadequate to specify mortality as a primary variable without further clarification; mortality may be assessed by comparing proportions alive at fixed points in time, or by comparing overall distributions of survival times over a specified interval. Another common example is a recurring outcome. The measure of treatment effect may again be a simple dichotomous variable (any occurrence during a specified interval), time to first occurrence, or rate of occurrence (events per time units of observation), to give a few possibilities. The assessment of functional status over time in studying treatment for chronic disease presents other challenges in selection of the primary variable. There are many possible

approaches, such as comparisons of the assessments done at the beginning and end of the interval of observation, comparison of slopes calculated from all assessments throughout the interval, or comparisons of the proportions of subjects exceeding or declining beyond a prespecified threshold. To avoid multiplicity concerns, it is critical to specify in the protocol the precise definition of the primary variable as it will be used in the statistical analysis. In addition, the clinical relevance of the specific primary variable selected and the validity of the associated measurement procedures will generally need to be addressed and justified in the protocol.

The primary variable should be specified in the protocol, along with the rationale for its selection. Redefinition of the primary variable after unblinding will almost always be unacceptable, since the biases this introduces are difficult to assess. When relevant, the validity and reliability of the primary variable should be described. Secondary variables are either supportive measurements related to the primary objective or measurements of effects related to the secondary objectives. Their predefinition in the protocol is also important, as well as an explanation of their relative importance and roles in interpretation of trial results. When the clinical effect defined by the primary objective is to be measured in more than one way, the protocol should identify one of the measurements as the primary variable on the basis of clinical relevance, importance, objectivity, and/or other relevant characteristics, whenever such selection is feasible. Another strategy that may be useful in some situations is to integrate or combine the multiple measurements into a single or ''composite'' variable, using a predefined algorithm. Indeed, the primary variable sometimes arises as a combination of multiple clinical measurements (e.g., the rating scales used in arthritis, psychiatric disorders, and elsewhere). This approach addresses the multiplicity problem without requiring adjustment for multiple comparisons. The method of combining the multiple measurements should be specified in the protocol, and an interpretation of the resulting scale should be provided in terms of the size of a clinically relevant benefit. When composite variables are used as primary variables, the individual components of these variables are often analyzed separately. When a rating scale is used as a primary variable, it is especially important to address factors such as content validity, inter- and intrarater reliability, and sensitivity for discriminating different medical conditions.

In some cases, ''global assessment'' variables are developed to measure the overall safety, overall efficacy, and/or overall usefulness of a treatment. This type of variable integrates objective variables and the investigator's overall impression about the state or change in the state of the subject, and is usually a scale of ordered categorical ratings. Global assessments of overall effectiveness are well established in many therapeutic areas, especially psychotropic drugs and nonsteroidal anti-inflammatory drugs.

Global assessment variables generally have a subjective component. When a global assessment scale is used as a primary or secondary variable, fuller details should be included in the protocol with respect to:

(1) The relevance of the global scale to the primary objective of the trial;

(2) The basis for the validity of the scale;

(3) How to utilize the data collected on an individual subject to assign him/her to a unique category of the global assessment scale;

(4) How to uniquely categorize subjects with missing data.If objective variables are considered by the investigator when making a global assessment, then those objective variables should be considered additional primary or, at least, important secondary variables.

Overall usefulness integrates components of both benefit and risk and reflects the decisionmaking process of the treating physician, who must weigh benefit and risk in making product use decisions. A problem with global usefulness scales is that their use could in some cases lead to the result of two products being declared equivalent despite having very different profiles of beneficial and adverse effects. For example, judging the global usefulness of a treatment as equivalent or superior to an alternative may mask the fact that it has little or no efficacy but fewer adverse effects. Therefore, if usefulness is used as a primary variable, it is important to consider specific efficacy and safety outcomes separately as additional primary variables.

It may sometimes be desirable to use more than one primary variable, each of which (or a subset of which) could be a sufficient basis for marketing approval, to cover the range of effects of the therapies. The planned manner of interpretation of this type of evidence should be carefully spelled out. For example, it should be clear whether an impact on any of the variables, some minimum number of them, or all of them, would be considered necessary for approval. The primary hypothesis or hypotheses should be clearly stated with respect to the primary variables identified and the approach to testing the hypotheses described. This should include specification of the statistical parameters being tested (e.g., mean, percentage, distribution). The effect on the Type I error should be explained because of the potential for multiple comparison problems (see section 5.6); the method of controlling Type I error should be given in the protocol. The extent of intercorrelation among the proposed primary variables may be considered in evaluating the impact on Type I error. If the success of the trial depends upon demonstrating effects on all of the designated primary variables, then there is no need for adjustment of the Type I error, but the impact on Type II error and sample size needs should be carefully considered.

When direct assessment of the clinical benefit to the subject through observing actual clinical efficacy is not practical, indirect criteria (surrogate variables) may be considered. Commonly accepted surrogate variables are used in a number of indications where they are believed to be reliable predictors of clinical benefit. There are two principal concerns with the introduction of any proposed surrogate variable. First, it may not be a true predictor of the clinical outcome of interest. For example, it may measure treatment activity along one particular pathway, but may not provide full information on the range of actions and ultimate effects of the treatment, whether positive or negative. There have been many instances where treatments showing a highly positive effect on a proposed surrogate have ultimately been shown to be detrimental to the subjects' clinical status; conversely, there are cases of treatments conferring clinical benefit without measurable impact on proposed surrogates. Additionally, proposed surrogate variables may not yield a quantitative measure of clinical benefit that can be weighed directly against adverse effects. Statistical criteria for validating surrogate variables have been proposed, but the experience with their use is relatively limited. In practice, the strength of the evidence for surrogacy depends upon the biological plausibility of the relationship, the demonstration in epidemiological studies of the prognostic value of the surrogate for the clinical outcome, and evidence from clinical trials that treatment effects on the surrogate correspond to effects on the clinical outcome. Relationships between clinical and surrogate variables for one product do not necessarily apply to a product with a different mode of action for treating the same disease.

Dichotomization or other categorization of continuous or ordinal variables may sometimes be desirable. Criteria of ''success'' and ''response'' are common examples of dichotomies that should be specified precisely in terms of, for example, a minimum percentage improvement (relative to baseline) in a continuous variable or a ranking categorized as at or above some threshold level (e.g., ''good'') on an ordinal rating scale. The reduction of diastolic blood pressure below 90 mmHg is a common dichotomization. Categorizations are most useful when they have clear clinical relevance. The criteria for categorization should be predefined and specified in the protocol, as knowledge of trial results could easily bias the choice of such criteria. Because categorization normally implies a loss of information, a consequence will be a loss of power in the analysis; this should be accounted for in the sample size calculation.

2.3 Design Techniques to Avoid Bias

The two most important design techniques for avoiding bias in clinical trials are blinding and randomization, and these should be a normal feature of most controlled clinical trials intended to be included in a marketing application. Most such trials follow a double-blind approach in which treatments are prepacked in accordance with a suitable randomization schedule and supplied to the trial center(s) labeled only with the subject number and the treatment period, so that no one involved in the conduct of the trial is aware of the specific treatment allocated to any particular subject, not even as a code letter. This approach will be assumed in section 2.3.1 and most of section 2.3.2, exceptions being considered at the end. The protocol should also specify

procedures aimed at minimizing any anticipated irregularities in study conduct that might impair a satisfactory analysis, including various types of protocol violations, withdrawals, and missing values. The protocol should consider ways both to reduce frequency of such problems and to handle the problems that do occur in the analysis of data.

2.3.1 Blinding

Blinding is intended to limit the occurrence of conscious and unconscious bias in the conduct and interpretation of a clinical trial arising from the influence that knowledge of treatment may have on the recruitment and allocation of subjects, their subsequent care, the attitudes of subjects to the treatments, the assessment of end points, the handling of withdrawals, the exclusion of data from analysis, and so on. The essential aim is to prevent identification of the treatments until all such opportunities for bias have passed.

A double-blind trial is one in which neither the subject nor any of the investigator or sponsor staff involved in the treatment or clinical evaluation of the subjects is aware of the treatment received. This includes anyone determining subject eligibility, evaluating endpoints, or assessing compliance with the protocol. This level of blinding is maintained throughout the conduct of the trial; only when the data are cleaned to an acceptable level of quality will appropriate personnel be unblinded. If any of the sponsor staff who are not involved in the treatment or clinical evaluation of the subjects are required to be unblinded to the treatment code (e.g., bioanalytical scientists, auditors, those involved in serious adverse event reporting), the sponsor should have adequate standard operating procedures (SOP's) to guard against inappropriate dissemination of treatment codes. In a single-blind trial the investigator and/or his staff are aware of the treatment but not the subject. In an open-label trial the identity of treatment is known to all. The double-blind trial is the optimal approach. This requires that the treatments to be applied during the trial cannot be distinguished in any way (appearance, taste, etc.) either before or during administration, and that the blind is maintained appropriately during the whole trial.

Difficulties in achieving the double-blind ideal can arise because: (1) The treatments may be of a completely different nature, for example, surgery and drug therapy; (2) two drugs may have different formulations and, although they could be made indistinguishable by the use of capsules, changing the formulation might also change the pharmacokinetic and/or pharmacodynamic properties, so that bioequivalence of the formulations may need to be established; (3) the daily pattern of administration of two treatments may differ. One way of achieving double-blind conditions under these circumstances is to use a ''double dummy'' technique. This technique may sometimes force an administration scheme that is sufficiently unusual to influence adversely the motivation and compliance of the subjects. Ethical difficulties may also interfere with its use when, for example, it entails dummy operative procedures. Nevertheless, extensive efforts should be made to overcome these difficulties.

In some clinical trials, although double blinding is planned, it may be partially compromised by apparent treatment induced effects. In such cases, blinding may be improved by blinding investigators to certain test results (e.g., selected clinical laboratory measures). Similar approaches (see below) to minimizing bias in open-label trials should be considered in trials where unique or specific treatment effects may lead to unblinding individual patients.

If a double-blind trial is not feasible, then the single-blind option should be considered. In some cases only an open-label trial is practically or ethically possible. Single-blind and open-label trials provide additional flexibility, but it is particularly important that the investigator's knowledge of the next treatment should not influence the decision to enter the subject; this decision should precede knowledge of the randomized treatment. Also, under either of these circumstances, clinical assessments should be made by medical staff who are not involved in treating the subjects and who remain blind to treatment. In single-blind or open-label trials, every effort should be made to minimize the various known sources of bias and primary variables should be as objective as possible. The reasons for the degree of blinding adopted, as well as steps taken to minimize bias by other means, should be explained in the protocol.

Breaking the blind (for a single subject) should be considered only when knowledge of the treatment assignment is deemed essential by the subject's physician for the subject's care. Any intentional or unintentional breaking of the blind should be reported and explained at the end of the trial, irrespective of the reason for its occurrence. The procedure and timing for revealing the treatment assignments should be documented.

In this document, the blind review of data refers to the checking of data during the period of time between trial completion (the last observation on the last subject) and the breaking of the blind. If specific sponsor staff need to be unblinded during this period to ensure the integrity of the database or the suitability of statistical assumptions, appropriate SOP's should be developed to describe how the treatment code will be protected from broader dissemination.

2.3.2 Randomization

Randomization introduces a deliberate element of chance into the assignment of treatments to subjects in a clinical trial. During subsequent analysis of the trial data, it provides a sound statistical basis for the quantitative evaluation of the evidence relating to treatment effects. It also tends to produce treatment groups in which the distributions of prognostic factors (known and unknown) are similar. In combination with blinding, randomization helps to avoid possible bias in the selection and allocation of subjects arising from the predictability of treatment assignments.

The randomization schedule of a clinical trial documents the random allocation of treatments to subjects. In the simplest situation, it is a sequential list of treatments (or treatment sequences in a crossover trial) or corresponding codes by subject number. The logistics of some trials, such as those with a screening phase, may make matters more complicated, but the unique preplanned assignment of treatment, or treatment sequence, to subject should be clear. Different trial designs should have different procedures for generating randomization schedules. The randomization schedule should be capable of being reproduced (if the need arises). Whenever possible, this should be accomplished through the use of the same random number table, or the same computer routine and seed for its random number generator.

Although unrestricted randomization is an acceptable approach, some advantages can generally be gained by randomizing subjects in blocks. This helps to increase the comparability of the treatment groups particularly when subject characteristics may change over time, as a result, for example, of changes in recruitment policy. It also provides a better guarantee that the treatment groups will be of nearly equal size. In cross-over trials, it provides the means of obtaining balanced designs with their greater efficiency and easier interpretation. Care should be taken to choose block lengths that are sufficiently short to limit possible imbalance, but long enough to avoid predictability towards the end of the sequence in a block. Investigators should generally be blind to the block length; the use of two or more block lengths, randomly selected for each block, can achieve the same purpose. (Theoretically, in a double-blind trial predictability does not matter, but the pharmacological effects of drugs often provide the opportunity for intelligent guesswork.)

In multicenter trials, the randomization procedures should be organized centrally. It is advisable to have a separate random scheme for each center, i.e., to stratify by center or to allocate several whole blocks to each center. More generally, stratification by important prognostic factors measured at baseline (e.g., severity of disease, age, sex, etc.) may sometimes be valuable in order to promote balanced allocation within strata; this has greater potential benefit in small trials. The use of more than two or three stratification factors is rarely necessary, is less successful at achieving balance, and is logistically troublesome. Where it is necessary, the use of a dynamic allocation procedure (see below) may help to achieve balance across all factors simultaneously, provided the rest of the trial procedures can be adjusted to accommodate an approach of this type.

The next subject to be randomized into a study should always receive the treatment corresponding to the next free number in the appropriate randomization schedule (in the respective stratum, if randomization is stratified). The appropriate number and associated treatment for the next subject should only be allocated when entry of that subject to the randomized part of the trial has been confirmed. These tasks will normally be carried out by staff at the investigator's center, who will then dispense the relevant blinded trial supplies. Details of the

randomization which facilitate predictability (e.g., block length) should not be contained in the study protocol. The randomization schedule itself should be filed securely by the sponsor or an independent party in a manner that ensures that blindness is properly maintained throughout the trial. Access to the randomization schedule during the trial should take into account the possibility that, in an emergency, the blind may have to be broken for any subject, either partially or completely. The procedure to be followed, the necessary documentation, and the subsequent treatment and assessment of the subject should all be described in the protocol.

Dynamic allocation is an alternative randomization procedure in which the allocation of treatment to a subject is influenced by the current balance of allocated treatments and, in a stratified trial, by the stratum to which the subject belongs and the balance within that stratum. Every effort should be made to retain the double-blind status of the trial. For example, knowledge of the treatment code may be restricted to a central trial office from where the dynamic allocation is controlled, generally through telephone contact. This in turn permits additional checks of eligibility criteria and establishes entry into the trial, features that can be valuable in certain types of multicenter trials. The usual system of prepacking and labeling drug supplies for double-blind trials can then be followed, but the order of their use is no longer sequential. It is desirable to use appropriate computer algorithms to keep personnel at the central trial office blind to the treatment code. The complexity of the logistics and potential impact on the analysis should be carefully evaluated when considering dynamic allocation.

III. Study Design Considerations

3.1 Study Configuration

3.1.1 Parallel Group Design

The most common clinical trial design for confirmatory trials is the parallel group design in which subjects are randomized to one of two or more arms, each arm being allocated a different treatment. These treatments will include the investigational product at one or more doses, and one or more control treatments, such as placebo and/or an active comparator. The assumptions underlying this design are less complex than for most other designs. However, there may be additional features of the design which complicate the analysis and interpretation (e.g., covariates, repeated measurements over time, interactions between design factors, protocol violations, dropouts, and withdrawals).

3.1.2 Cross-Over Design

In the cross-over design, each subject is randomized to a sequence of two or more treatments and hence acts as his own control for treatment comparisons. This simple maneuver is attractive primarily because it reduces the number of subjects and, usually, the number of assessments needed to achieve a specific power, sometimes to a marked extent. In the simplest 2x2 cross-over design, each subject receives each of two treatments in randomized order in two successive treatment periods, often separated by a washout period. The most common extension of this entails comparing n(>2) treatments in n periods, each subject receiving all n treatments. Numerous variations exist, such as designs in which each subject receives a subset of n(>2) treatments, or designs in which treatments are repeated within a subject.

Cross-over designs have a number of problems which can invalidate their results. The chief difficulty concerns carryover, that is, the residual influence of treatments in subsequent treatment periods. In an additive model, the effect of unequal carryover will be to bias direct treatment comparisons. In the 2x2 design, the relevant contrast cannot be statistically distinguished from the interaction between treatment and period, and the test for either of these lacks power because it is a ''between subject'' contrast. This problem is less acute in higher order designs, but cannot be entirely dismissed.

Therefore, when the cross-over design is used, it is important to avoid carryover. This is best done by selective and careful use of the design on the basis of adequate knowledge of both the disease area and the new medication. The disease under study should be chronic and stable. The relevant effects of the medication should develop fully within the treatment period. The washout periods should be sufficiently long for complete reversibility of drug effect. The fact that these conditions are likely to be met should be established in advance of the trial by means of prior information and data.

A common, and generally satisfactory, use of the 2x2 cross-over design is to demonstrate the bioequivalence of two formulations of the same medication. In this particular application in healthy volunteers, carryover effects on the relevant pharmacokinetic variable are rather unlikely to occur if the wash-out time between the two periods is sufficiently long. However, it is still important to check this assumption during analysis on the basis of the data obtained, for example, by demonstrating that no drug is detectable at the start of each period.

There are additional problems that need careful attention in cross-over trials. The most notable of these are the complications of analysis and interpretation arising from the loss of subjects. Also, the potential for carryover leads to difficulties in assigning adverse events that occur in later treatment periods to the appropriate treatment. These and other issues are described in the ICH E4 topic on ''Dose-Response Information to Support Drug Registration.'' The cross-over design should generally be restricted to situations where losses of subjects from the trial are expected to be small.

3.1.3 Factorial Designs

In a factorial design, two or more treatments are evaluated simultaneously in the same set of subjects through the use of varying combinations of the treatments. The simplest example is the 2x2 factorial design in which subjects are randomly allocated to one of the four possible combinations of two treatments, A and B. These are: A alone; B alone; both A and B; neither A nor B. In many cases this design is used for the specific purpose of examining the interaction of A and B. The statistical test of interaction is model dependent and may lack power to detect an interaction if the sample size was calculated based on the test for main effects. This consideration is important when this design is used for examining the joint effects of A and B, in particular, if the treatments are likely to be used together.

Another important use of the factorial design is to establish the dose-response characteristics of a combination product, e.g., one combining treatments C and D, especially when the efficacy of each monotherapy has been established at some dose in prior studies. A number, m, of doses of C is selected, usually including a zero dose (placebo), and a similar number, n, of doses of D. The full design then consists of mn treatment groups, each receiving a different combination of doses of C and D. The resulting estimate of the response surface may then be used to help identify an appropriate combination of doses of C and D for clinical use.

In some cases, the 2x2 design may be used to make efficient use of clinical trial subjects by evaluating the efficacy of the two treatments with the same number of subjects as would be required to evaluate the efficacy of either one alone. This strategy has proved to be particularly valuable for very large mortality studies. The efficiency of this approach depends upon the absence of interaction between treatments A and B so that the effects of A and B on the primary efficacy variables follow an additive model, hence the effect of A is virtually identical whether or not it is additional to the effect of B. As for the cross-over trial, evidence that this condition is likely to be met should be established in advance of the trial by means of prior information and data.

3.2 Multicenter Trials

Multicenter trials are carried out for two main reasons. First, a multicenter trial is an accepted way of evaluating a new medication more efficiently; under some circumstances, it may present the only practical means of accruing sufficient subjects to satisfy the trial objective within a reasonable timeframe. Multicenter trials of this nature may, in principle, be carried out at any stage of clinical development. They may have several centers with a large number of subjects per center or, in the case of a rare disease, they may have a large number of centers with very few subjects per center.

Second, a trial may be designed as a multicenter (and multi-investigator) trial primarily to provide a better basis for the subsequent generalization of its findings. This arises from the possibility of recruiting the subjects from a wider population and of administering the medication in a broader range of clinical settings, thus presenting an experimental situation that is more typical of future use. In this case, the involvement of a number of investigators also gives the potential for a wider range of clinical judgement concerning the value of the medication. Such a trial would be a confirmatory trial in the later phases of drug development and would be likely to involve a large number of investigators and centers.

It might sometimes be conducted in a number of different countries to facilitate generalizability even further.

If a multicenter trial is to be meaningfully interpreted and extrapolated, then the manner in which the protocol is implemented should be clear and similar at all centers. Furthermore, the usual sample size and power calculations depend upon the assumption that the differences between the compared treatments in the centers are unbiased estimates of the same quantity. It is important to design the common protocol and to conduct the trial with this background in mind. Procedures should be standardized as completely as possible. Variation of evaluation criteria and schemes can be reduced by investigator meetings, by the training of personnel in advance of the study, and by careful monitoring during the study. Good design should generally aim to achieve the same distribution of subjects to treatments within each center and good management should maintain this design objective. Trials which avoid excessive variation in the numbers of subjects per center and trials which avoid a few very small centers have advantages if it is later found necessary to examine the heterogeneity of the treatment effect from center to center, because they reduce the differences between different weighted estimates of the treatment effect. (This point does not apply to trials in which all centers are very small and in which center does not feature in the analysis.) Failure to take these precautions, combined with doubts about the homogeneity of the results, may, in severe cases, reduce the value of a multicenter trial to such a degree that it cannot be regarded as giving convincing evidence for the sponsor's claims.

In the simplest multicenter trial, each investigator will be responsible for the subjects recruited at one hospital, so that ''center'' is identified uniquely by either investigator or hospital. In many trials, however, the situation is more complex. One investigator may recruit subjects from several hospitals; one investigator may represent a team of clinicians (subinvestigators) who all recruit subjects from their own clinics at one hospital or at several associated hospitals. Whenever there is room for doubt about the definition of center in a statistical model, the statistical section of the protocol (see section 5.1) should clearly define the term (e.g., by investigator, location, or region) in the context of the particular trial. In most instances, centers can be satisfactorily defined through the investigators. (ICH Guideline E6 provides relevant guidance in this respect.) In cases of doubt, the aim should be to define centers to achieve homogeneity in the important factors affecting the measurements of the primary variables and the influence of the treatments. Any rules for combining centers in the analysis should be justified and specified prospectively in the protocol where possible, but in any case decisions concerning this approach should always be taken blind to treatment, for example, at the time of the blind review. It is sometimes possible to characterize the centers by historical measures of response to the control treatment or to other standard treatments, and this information may help to support decisions concerning the combination of centers for analysis.

The statistical model to be adopted for the comparison of treatments should be described in the protocol. The main treatment effect may be investigated first using a model that allows for center differences, but does not include a term for center by treatment interaction. In the absence of a true center by treatment interaction, the routine inclusion of interaction terms in the model reduces the efficiency of the test for the main effects. In the presence of a true center by treatment interaction, the interpretation of the main treatment effect is controversial.

In some studies, for example, some large mortality studies with very few subjects per center, there may be no reason to expect the centers to have any influence on the primary or secondary variables because they are unlikely to represent influences of clinical importance. In other studies, it may be recognized from the start that the limited numbers of subjects per center will make it impracticable to include the center effects in the statistical model. In these cases, it is not appropriate to include a term for center in the model, because in this situation randomization is rarely stratified by center.

If positive treatment effects are found in a trial with appreciable numbers of subjects per center, there should generally be a subsequent exploration of treatment by center interaction, as this may affect the generalizability of the conclusions. Marked treatment by center interaction may be identified by graphical display of the results of individual centers or by analytical methods, such as a significance test of the interaction. When using such a statistical significance test, it is important to recognize that this generally has low power in a trial designed to detect the main effect of treatment.

If a treatment by center interaction is found, this should be interpreted with care and vigorous attempts should be made to find an explanation in terms of other features of trial management or subject characteristics. Such an explanation will usually define the appropriate further analysis and interpretation. In the absence of an explanation, marked quantitative interactions imply that alternative estimates of the treatment effect may be needed, giving different weights to the centers, in order to substantiate the robustness of the estimates of treatment effect. It is even more important to understand the basis of any marked qualitative interactions, and failure to find an explanation may necessitate further clinical trials before the treatment effect can be reliably predicted.

3.3 Type of Comparison

3.3.1 Trials to Show Superiority

Scientifically, efficacy is most convincingly established by demonstrating superiority to placebo in a placebo-controlled trial, by showing superiority to an active control treatment, or by demonstrating a dose-response relationship. This type of trial is referred to as a ''superiority'' trial (see section 5.2.3). In this guideline, superiority trials are generally assumed unless explicitly stated otherwise.

For serious illnesses, when a therapeutic treatment that has been shown to be efficacious by superiority trial(s) exists, a placebo-controlled trial may be considered unethical. In that case, the scientifically sound use of the active control should be considered. The appropriateness of placebo control versus active control should be considered on a study-by-study basis.

3.3.2 Trials to Show Equivalence or Noninferiority

In some cases, an investigational product is compared to a reference treatment without the objective of showing superiority. This type of trial is divided into two major categories according to its objective; one is an ''equivalence'' trial and the other is a ''noninferiority'' trial.

Bioequivalence trials fall into the former category. In some situations, clinical equivalence trials are also undertaken for other regulatory reasons, such as demonstrating the clinical equivalence of a generic product to the marketed product when the compound is not absorbed and therefore not present in the blood stream.

Many active control trials are designed to show that the efficacy of an investigational product is no worse than that of the active comparator, and hence fall into the latter category. Another possibility is a ''relative potency assay,'' which is a study where multiple doses of the investigational drug are compared with the recommended dose or multiple doses of the standard drug.

Active control equivalence or noninferiority trials may also incorporate a placebo, thus pursuing multiple goals in one trial, for example, establishing superiority to placebo, thereby validating the study design and evaluating the degree of similarity of efficacy and safety to the active comparator. There are well-known limitations associated with the use of the active control equivalence (or noninferiority) trials that do not incorporate a placebo. These relate to the implicit lack of any measure of internal validity (in contrast to superiority trials), thus making external validation necessary. The equivalence (or noninferiority) trial is not conservative in nature, so many flaws in the design or conduct of the trial will tend to bias the results towards a conclusion of equivalence. For these reasons, the design features of such trials should receive special attention.

Active comparators should be chosen with care. An example of a suitable active comparator would be a widely used therapy whose efficacy in the relevant indication has been clearly established and quantified in well-designed and well-documented superiority trial(s) and that can be reliably expected to exhibit similar efficacy in the contemplated active control study. To this end, the new trial should have the same important design features (primary variables, the dose of the active comparator, eligibility criteria, etc.) as the previously conducted superiority trials in which the active comparator clearly demonstrated clinically relevant efficacy.

It is vital that the protocol of a trial designed to demonstrate equivalence or

noninferiority contain a clear statement that this is its explicit intention. An equivalence margin should be specified in the protocol; this margin is the largest difference which can be judged as being clinically acceptable. For the active control equivalence trial, both the upper and the lower equivalence margins are needed, while for the active control non-inferiority trial, only the lower margin is needed. There should be clinical justification for the choice of equivalence margins.

Statistical analysis is generally based on the use of confidence intervals (see section 5.5). For equivalence trials, the two-sided 1–2α (alpha) confidence limits should be used. Equivalence is inferred when the entire confidence interval falls within the equivalence margins. This is equivalent to the method of using two simultaneous one-sided tests to test the (composite) null hypothesis that the treatment difference is outside of the equivalence margins versus the (composite) alternative that the treatment difference is within the limits. With this method, the Type I error is controlled at a level of α. For noninferiority trials, the one-sided 1-α interval should be used. The confidence interval approach has a one-sided hypothesis test counterpart testing the null hypothesis that the treatment difference (investigational product minus control) is equal to the lower equivalence margin versus the alternative that the treatment difference is greater than the lower equivalence margin. Sample size calculations should be based on these methods (see section 3.5). The choice of α should be a consideration separate from the choice of a one-sided or two-sided test.

It is inappropriate to conclude equivalence or noninferiority based on observing a nonsignificant test result of the null hypothesis that there is no difference between the investigational product and the active comparator.

There are also special issues in the choice of analysis sets. Subjects who withdraw or drop out of the treatment group or the comparator group will tend to have a lack of response, hence the analysis of all randomized subjects may be biased toward demonstrating equivalence (see section 5.2.3).

3.3.3 Dose-Response Designs

How response is related to the dose of a new investigational product is a question to which answers may be obtained in all phases of development and by a variety of approaches (see ICH E4). Dose-response studies may serve a number of objectives, among which the following are of particular importance: The confirmation of efficacy; the investigation of the shape and location of the dose-response curve; the estimation of an appropriate starting dose; the identification of optimal strategies for individual dose adjustments; the determination of a maximal dose beyond which additional benefit would be unlikely to occur. These objectives should be addressed using the data collected at a number of doses under investigation, including a placebo (zero dose) wherever appropriate. For this purpose, the application of estimation procedures, including the construction of confidence intervals and of graphical methods is as important as the use of statistical tests. The hypothesis tests that are used may need to be tailored to the natural ordering of doses or to particular questions regarding the shape of the dose-response curve (e.g., monotonicity). The details of the planned statistical procedures should be given in the protocol.

3.4 Group Sequential Designs

Group sequential designs are used to facilitate the conduct of interim analysis (see section 4.5). While group sequential designs are not the only acceptable types of designs permitting interim analysis, they are the most commonly applied because it is more practicable to assess grouped subject outcomes at periodic intervals during the trial than on a continuous basis as data from each subject become available. The statistical methods should be fully specified in advance of the availability of information on treatment outcomes and subject treatment assignments (i.e., blind breaking, see section 4.5). An independent data monitoring committee (IDMC) may be used to conduct the interim analysis of data arising from a group sequential design (see section 4.6). While the design has been most widely and successfully used in large, long-term trials of mortality or major nonfatal endpoints, its use is growing in other circumstances. In particular, it is recognized that safety must be monitored in all trials, therefore, the need for formal procedures to cover early stopping for safety reasons should always be considered.

3.5 Sample Size

The number of subjects in a clinical trial should always be large enough to provide a reliable answer to the questions addressed. This number is usually determined by the primary objective of the trial. If the sample size is determined on some other basis, this should be made clear and justified. For example, a trial sized on the basis of safety questions or requirements may need larger numbers of subjects than one sized on the basis of efficacy questions. (See, for example, ICH E1A ''Population Exposure: The Extent of Population Exposure to Assess Clinical Safety.'')

When determining the appropriate sample size, the following items should be specified: A primary variable; the test statistic; the null hypothesis; the alternative (''working'') hypothesis at the chosen dose(s) (embodying consideration of the treatment difference to be detected or rejected at the dose and in the subject population selected); the probability of erroneously rejecting the null hypothesis (the Type I error) and the probability of erroneously failing to reject the null hypothesis (the Type II error); as well as the approach to dealing with treatment withdrawals and protocol violations. In some instances, the event rate is of primary interest for evaluating power, and assumptions should be made to extrapolate from the required number of events to the eventual sample size for the trial.

The method by which the sample size is calculated should be given in the protocol, together with the estimates of any quantities used in the calculations (such as variances, mean values, response rates, event rates, difference to be detected). The basis of these estimates should also be given. It is important to investigate the sensitivity of the sample size estimate to a variety of deviations from these assumptions and this may be facilitated by providing a range of sample sizes appropriate for a reasonable range of deviations from assumptions. In confirmatory studies, assumptions should normally be based on published data or on the results of earlier studies. The treatment difference to be detected may be based on a judgement concerning the minimal effect that has clinical relevance in the management of patients or on a judgement concerning the anticipated effect of the new treatment, where this is larger. Conventionally, the probability of Type I error is set at 5 percent or less or as dictated by any adjustments made necessary for multiplicity considerations; the precise choice is influenced by the prior plausibility of the hypothesis under test and the desired impact of the results. The probability of Type II error is conventionally set at 20 percent or less; it is in the sponsor's interest to keep this figure as low as feasible, especially in the case of studies that are difficult or impossible to repeat.

Sample size calculations should refer to the number of subjects required for the primary analysis. If this is the ''all randomized subjects'' set, estimates about the effect size may need to be reduced compared to the per protocol set. This is due to the diluting effect of the inclusion of treatment withdrawals. The assumptions of variability may also need to be revised.

The sample size of an equivalence trial or a noninferiority trial (see section 3.3.2) should normally be based on the objective of obtaining a confidence interval for the treatment difference that shows that the treatments differ at most by a clinically acceptable difference. For equivalence trials, the power is usually assessed at a true difference of zero but can be underestimated if the true difference is not zero. For noninferiority trials, the power is usually assessed at an expected (nonzero) difference, but can be underestimated if the true difference is less than expected. The choice of a ''clinically acceptable'' difference needs justification, and may be smaller than the ''clinically relevant'' difference referred to above in the context of superiority trials designed to establish that a difference exists.

The sample size in a group sequential trial cannot be fixed in advance because it depends upon the play of chance in combination with the chosen stopping rule and the true treatment difference. The design of the stopping rule should take into account the consequent distribution of the sample size, usually embodied in the expected and maximum sample sizes.

When event rates are lower than anticipated or variability is larger than expected, methods for sample size reestimation are available without unblinding data or making treatment comparisons (see section 4.4).

3.6 Data Capture and Processing

The collection of data and transfer of data from the investigator to the sponsor can take place through a variety of media, including paper case record forms, remote site

monitoring systems, medical computer systems, and electronic transfer. Whatever data capture instrument is used, the form and content of the information collected should be in full accordance with the protocol and should be established in advance of the conduct of the clinical trial. It should focus on the data necessary to implement the analysis plan, including the context information (such as timing assessments relative to dosing) necessary to confirm protocol compliance or identify important protocol deviations. ''Missing values'' should be distinguishable from the ''value zero'' or ''characteristic absent.''

The process of data capture, through to database finalization, should be carried out in accordance with good clinical practice (GCP) (see ICH E6, section 5). Specifically, timely and reliable processes for recording data and rectifying errors and omissions are necessary to ensure delivery of a quality database and the achievement of the trial objectives through the implementation of the analysis plan.

IV. Study Conduct

4.1 Trial Monitoring

Careful conduct of a clinical trial according to the protocol has a major impact on the credibility of the results. Careful monitoring can ensure that difficulties are noticed early and their occurrence or recurrence minimized.

There are two distinct types of monitoring that generally characterize confirmatory clinical trials sponsored by the pharmaceutical industry. Both types of trial monitoring, in addition to entailing different staff responsibilities, involve access to different types of study data and information, thus different principles apply for the control of potential statistical and operational bias.

One type of monitoring concerns the oversight of the quality of the trial, including whether the protocol is being followed, acceptability of data being accrued, success of planned accrual targets, checking the design assumptions, etc. (see sections 4.2 to 4.4). This type of monitoring does not require access to information on comparative treatment effects, nor unblinding of data, and therefore has no impact on Type I error. The monitoring of a trial for this purpose is the responsibility of the sponsor and can be carried out by the sponsor or an independent group selected by the sponsor. The period for this type of monitoring usually starts with the selection of the study sites and ends with the collection and cleaning of the last subject's data.

The other type of trial monitoring involves breaking the blind to make treatment comparisons. It therefore involves the accruing of comparative treatment results, which requires that a protocol (or appropriate amendments prior to a first analysis) contain statistical plans to prevent certain types of bias. This type of trial monitoring involves unblinded (i.e., key breaking) access to treatment group assignment (actual treatment assignment or identification of group assignment) and comparative treatment group summary information. This type of monitoring is discussed in sections 4.5 and 4.6.

4.2 Changes in Inclusion and Exclusion Criteria

Inclusion and exclusion criteria should remain constant, as specified in the protocol, throughout the period of subject recruitment. Occasionally, however, changes may be appropriate; in long-term studies, for example, growing medical knowledge either from outside the trial or from interim analyses may suggest a change of entry criteria. Changes may also result from the discovery by monitoring staff that regular violations of the entry criteria are occurring, or that seriously low recruitment rates are due to over-restrictive criteria. Changes should be made without breaking the blind and should always be described by a protocol amendment that should cover any statistical consequences, such as sample size adjustments arising from different event rates, or modifications to the analysis plan, such as stratifying the analysis according to modified inclusion/exclusion criteria.

4.3 Accrual Rates

In studies with a long time-scale for the accrual of subjects, the rate of accrual should be monitored; if it falls appreciably below the projected level, the reasons should be identified and remedial actions taken to protect the power of the trial and allay concerns about selective entry and other aspects of quality. In a multicenter trial, these considerations apply to the individual centers.

4.4 Sample Size Adjustment

In long-term trials, there will usually be an opportunity to check the assumptions which underlie the original design and sample size calculations. This may be particularly important if the trial specifications have been made on preliminary and/or uncertain information. An interim check conducted on the blinded data may reveal that overall response variances, event rates, or survival experience are not as anticipated. A revised sample size may then be calculated using suitably modified assumptions, and should be justified and documented in a protocol amendment and in the final report. The steps taken to preserve blindness and the consequences, if any, for the Type I error and the width of confidence intervals should be explained. The potential need for reestimation of the sample size should be envisaged in the protocol whenever possible (see section 3.5).

4.5 Interim Analysis and Early Stopping

Any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to formal completion of a trial is an interim analysis. Because the number, methods, and consequences of these comparisons affect the interpretation of the trial, all interim analyses should be carefully planned in advance and described in the protocol, or otherwise specified in amendments prior to unblinded access to treatment comparison data. When an interim analysis is planned with the intention of deciding whether or not to terminate a trial, this is usually accomplished by the use of a group sequential design that employs statistical monitoring schemes as guidelines (see section 3.4). The goal of such an interim analysis is to stop the trial early if the superiority of the treatment under study is clearly established, if the demonstration of a relevant treatment difference has become unlikely, or if unacceptable adverse effects are apparent. Generally, boundaries for monitoring efficacy require more evidence to terminate a trial early (i.e., more conservative) than do boundaries to terminate a trial for safety reasons. When the trial design and monitoring objective involve multiple endpoints, then this aspect of multiplicity may also need to be taken into account.

The schedule of interim analyses, or at least the considerations which will govern its generation, should be stated in the protocol or a protocol amendment before the time of the first interim analysis; as flexible statistical methods are available to conduct interim analyses according to a variety of needs (early or late in a trial), the stopping guidelines and their properties should be clearly stated in the protocol or amendments. This material should be written or approved by the data monitoring committee, when the study has one (see section 4.6). Deviations from the planned procedure always bear the potential of invalidating the study results. If it becomes necessary to make changes to the trial, any consequent changes to the statistical procedures should be specified in an amendment to the protocol at the earliest opportunity, especially discussing the impact on any analysis and inferences that such changes may cause. The procedures selected should always ensure that the overall probability of Type I error is controlled.

The execution of an interim analysis should be a completely confidential process because unblinded data and results are potentially involved. All staff involved in the conduct of the trial should remain blind to the results of such analyses because of the possibility that their attitudes to the trial will be modified and cause changes in recruitment patterns or biases in treatment comparisons. This principle applies to the investigators and their staff and to staff employed by the sponsor that come into contact with clinic staff or subjects. Investigators should be informed only about the decision to continue or to discontinue the trial, or to implement modifications to trial procedures.

Most clinical trials intended to support the efficacy and safety of an investigational product should proceed to full completion of planned sample size accrual; trials should be stopped early only for ethical reasons or if the power is no longer acceptable. However, it is recognized that drug development plans involve the need for sponsor access to comparative treatment data for a variety of reasons, such as planning other studies or when only a subset of trials will involve the study of serious life-threatening outcomes or mortality which may need sequential monitoring of accruing comparative treatment effects for ethical reasons. In either of these situations, plans for interim statistical analysis should be in place in the protocol or in protocol amendments prior to the unblinded access to comparative treatment data in order to deal with the

potential statistical and operational bias that may be introduced.

For many clinical trials of investigational products, especially those that have major public health significance, the responsibility for monitoring comparisons of efficacy and/or safety outcomes should be assigned to an external, independent group, often called an independent data monitoring committee (IDMC), a data and safety monitoring board, or a data monitoring committee, whose responsibilities should be clearly described.

When a sponsor assumes the role of monitoring efficacy or safety comparisons and therefore has access to unblinded comparative information, particular care should be taken to protect the integrity of the trial and the sharing of information. The sponsor should ensure and document that the internal monitoring committee has complied with written SOP's and that minutes of decisionmaking meetings are maintained.

Any interim analysis that is not planned in the protocol or specified in an amendment to the protocol prior to unblinding the data (with or without the consequences of stopping the trial early) may flaw the results of a trial and possibly weaken confidence in the conclusions drawn. Therefore, such analyses should be avoided. If unplanned interim analysis is conducted, the study report should explain why it was necessary and the degree to which blindness had to be broken, and provide an assessment of the potential magnitude of bias introduced and the impact on the interpretation of the results.

4.6 Role of Independent Data Monitoring Committee (IDMC)

(see sections 1.25 and 5.5.2 of ICH Guideline E6)

An IDMC may be established by the sponsor to assess at intervals the progress of a clinical trial, safety data, and critical efficacy variables and recommend to the sponsor whether to continue, modify, or terminate a trial. The IDMC should have written operating procedures and maintain records of its meetings. The independence of the IDMC is intended to control the sharing of important comparative information and to protect the integrity of the clinical trial from adverse impact resulting from access to trial information. The IDMC is a separate entity from an institutional review board (IRB) or an ethics board, and its composition should include clinical trial scientists knowledgeable in the appropriate disciplines, including statistics.

When there are sponsor representatives on the IDMC, their role should be clearly defined in the operating procedures of the committee (for example, covering whether or not they can vote on key issues). Since these sponsor staff would have access to unblinded information, the procedures should also address the control of dissemination of interim trial results within the sponsor organization.

V. Data Analysis

5.1 Prespecified Analysis Plan

When designing a clinical trial, the principal features of the eventual statistical analysis of the data should be described in the statistical section of the protocol. This section should include all features of the proposed confirmatory analysis of the primary variable(s) and the way in which anticipated analysis problems will be handled. In the case of exploratory trials, this section could describe more general principles and directions.

Subsequently, a statistical analysis plan may be written as a separate document. In this document, a more technical and detailed elaboration of the principal features stated in the protocol may be included. The statistical analysis plan is usually an internal document and may include detailed procedures for executing the statistical analysis. The statistical analysis plan should be reviewed and possibly updated as a result of the blind review of the data (see section 7.1 for definition).

If the blind review suggests changes to the principal features stated in the protocol, these should be documented in a protocol amendment. Otherwise, it will suffice to update the statistical analysis plan with the considerations suggested from the blind review. Only results from analyses envisaged in the protocol (including amendments) can be regarded as confirmatory.

The statistical methodology, including when in the clinical trial process methodology decisions were made, should be clearly described in the statistical section of the clinical study report (see ICH E3).

5.2 Analysis Sets

The set of subjects whose data are to be included in the main analyses should be defined in the statistical section of the protocol. In addition, documentation for all subjects for whom study procedures (e.g., run-in period) were initiated may be useful. The content of this subject documentation depends on detailed features of the particular trial, but at least demographic and baseline data on disease status should be collected whenever possible.

If all subjects randomized into a clinical trial satisfied all entry criteria, followed all trial procedures perfectly with no losses to followup, and provided complete data records, then the set of subjects to be included in the analysis would be self-evident. The design and conduct of a trial should aim to approach this ideal as closely as possible, but, in practice, it is doubtful if it can ever be fully achieved. Hence, the statistical section of the protocol should address any anticipated problems prospectively in terms of how these affect the subjects and data to be analyzed. The protocol should also specify procedures aimed at minimizing any anticipated irregularities in study conduct that might impair a satisfactory analysis, including various types of protocol violations, withdrawals, and missing values. The protocol should consider ways both to reduce the frequency of such problems and to handle the problems that occur in the analysis of data. The blind review of data to identify possible amendments to the analysis plan due to the protocol violations should be carried out before unblinding. It is desirable to identify any important protocol violation with respect to the time when it occurred, its cause, and its influence on the trial result. The frequency and type of protocol violations, missing values, and other problems should be documented in the study report and their potential influence on the trial results should be described (see ICH E3).

Decisions concerning the analysis set should be guided by the following principles: (1) To minimize bias and (2) to avoid inflation of Type I error.

5.2.1 All Randomized Subjects

The intention-to-treat principle implies that the primary analysis should include all randomized subjects. In practice, this ideal may be difficult to achieve, for reasons to be described. Hence, analysis sets referred to as ''all randomized subjects'' may not, in fact, include every subject. For example, it is common practice to exclude from the all randomized set any subject who failed to take at least one dose of trial medication or any subject without data post randomization. No analysis is complete unless the potential biases arising from these exclusions are addressed and can be reasonably dismissed.

In many clinical trials, the ''all randomized subjects'' approach is conservative and also gives estimates of treatment effects that are more likely to mirror those observed in subsequent practice. Randomization prevents biased allocation of subjects to treatments and provides the foundation of statistical tests. The problems associated with the analysis of all randomized subjects lie in the handling of protocol violations and the subtleties that this can involve.

There are two types of major protocol violations. One is violation of entry criteria. The second is violation of the protocol after randomization. Subjects who fail to satisfy an objective entry criterion measured prior to randomization, but who enter the trial, may be excluded from analysis without introducing bias into the treatment comparison, assuming all subjects receive equal scrutiny for eligibility violations. (This may be difficult to ensure if the data are unblinded.) Not all entry criteria are sufficiently objective for this to be done satisfactorily. Reasons for excluding subjects from the analysis of all randomized subjects should be justified.

Other problems occur after randomization (error in treatment assignment, use of excluded medications, poor compliance, loss to followup, missing data, and other protocol violations). These problems are especially difficult when their occurrence is related to treatment assignment. It is good practice to assess the pattern of such problems with respect to frequency and time to occurrence among treatment groups. Subjects withdrawn from treatment may introduce serious bias and, if they have provided no data after withdrawal, there is no obvious solution. Severe protocol violation, such as use of excluded medication, may also introduce serious bias into measurements after such a violation. The necessary inclusion of such subjects in the analysis may require some redefinition of the primary variable or some assumptions about the subjects' outcomes.

Measurements of primary variables made at the time of the loss to followup of a subject for any reason or at the time of a severe

protocol violation, or subsequently collected in accordance with the protocol, are valuable in the context of all randomized subjects analysis. Their use in analysis should be described and justified in the statistical section of the protocol and their collection described elsewhere in the protocol. However, the use of imputation techniques can lead to biased estimates of treatment effects, particularly when the likelihood of the loss of a subject is related to treatment or response. Any other methods to be employed to ensure the availability of measurements of primary variables for every subject in the all randomized subjects analysis should be described.

Because of the unpredictability of some problems, it may sometimes be preferable to defer detailed consideration of the manner of dealing with irregularities until the blind review of the data at the end of the study and, if so, this should be stated in the protocol.

5.2.2 Per Protocol Subjects

The ''per protocol'' set of subjects, sometimes described as the ''valid cases,'' the ''efficacy'' sample, or the ''evaluable subjects'' sample, defines a subset of the data used in the all randomized subjects analysis and is characterized by the following criteria:

(i) The completion of a certain prespecified minimal exposure to the treatment regimen;

(ii) The availability of measurements of the primary variable(s);

(iii) The absence of any major protocol violations, including the violation of entry criteria where the nature of and reasons for these protocol violations should be defined and documented before breaking the blind.

This set may maximize the opportunity for a new treatment to show additional efficacy in the analysis, and most closely reflects the scientific model underlying the protocol. However, it may or may not be conservative, depending on the study, and may be subject to bias (possibly severe) because the subjects adhering most diligently to the study protocol may not be representative of the entire study population.

5.2.3 Roles of the All Randomized Subjects Analysis and the Per Protocol Analysis

In general, it is advantageous to demonstrate a lack of sensitivity of the principal trial results to alternative choices of the set of subjects analyzed. In confirmatory trials, it is usually appropriate to plan to conduct both all randomized subjects and per protocol analyses, so that any differences between them can be the subject of explicit discussion and interpretation. In some cases, it may be desirable to plan further exploration of the sensitivity of conclusions to the choice of the set of subjects analyzed. When the all randomized subjects and the per protocol analyses come to essentially the same conclusions, confidence in the study results is increased, bearing in mind, however, that the need to exclude a substantial proportion of subjects from the per protocol analysis throws some doubt on the overall validity of the study.

All randomized subjects and per protocol analyses play different roles in superiority trials (which seek to show the investigational product to be superior) and in equivalence or noninferiority trials (which seek to show the investigational product to be comparable, see section 3.3.2). In superiority studies, the all randomized subjects analysis usually tends to avoid the optimistic estimate of efficacy which may result from a per protocol analysis, since the noncompliers included in an all randomized subjects analysis will generally diminish the overall treatment effect. However, in an equivalence or noninferiority trial, the all randomized subjects analysis is no longer conservative and its role should be considered very carefully.

5.3 Missing Values and Outliers

Missing values represent a potential source of bias in a clinical trial. Hence, every effort should be undertaken to fulfill all the requirements of the protocol concerning the collection and management of data. However, in reality there will almost always be some missing data. A study may be regarded as valid, nonetheless, provided the methods of dealing with missing values are sensible, particularly if those methods are predefined in the analysis plan of the protocol. Predefinition of methods may be facilitated by updating this aspect of the analysis plan during the blind review. Unfortunately, no universally applicable methods of handling missing values can be recommended. An investigation should be made concerning the sensitivity of the results of analysis to the method of handling missing values, especially if the number of missing values is substantial.

A similar approach should be adopted to exploring the influence of outliers, the statistical definition of which is, to some extent, arbitrary. Clear identification of a particular value as an outlier is most convincing when justified medically as well as statistically, and the medical context will then often define the appropriate action. Any outlier procedure set out in the protocol should not favor any treatment group a priori. Once again, this aspect of the analysis plan can be usefully updated during blind review. If no procedure for dealing with outliers was foreseen in the study protocol, one analysis with the actual values and at least one other analysis eliminating or reducing the outlier effect should be performed and differences between their results discussed.

5.4 Data Transformation/Modification

The decision to transform key variables prior to analysis is best made during the design of the trial on the basis of similar data from earlier clinical trials. Transformations (e.g., square root, logarithm) should be specified in the protocol and a rationale provided, especially for the primary variable(s). The general principles guiding the use of transformations to ensure that the assumptions underlying the statistical methods are met are to be found in standard texts; conventions for particular variables have been developed in a number of specific clinical areas. The decision on whether and how to transform a variable should be influenced by the preference for a scale that facilitates clinical interpretation.

Similar considerations apply to other data modifications sometimes used to create a variable for analysis, such as the use of change from baseline, percentage change from baseline, the ''area under the curve'' of repeated measures, or the ratio of two different variables. Subsequent clinical interpretation should be carefully considered, and the modification should be justified in the protocol. Closely related points are made in section 2.2.2.

5.5 Estimation, Confidence Intervals, and Hypothesis Testing

The statistical section of the protocol should specify the hypotheses that are to be tested and/or the treatment effects that are to be estimated to satisfy the objectives of the trial. The statistical methods to be used to accomplish these tasks should be described for the primary (and preferably the secondary) variables, and the underlying statistical model should be made clear. Estimates of treatment effects should be accompanied by confidence intervals, whenever possible, and the way in which these will be calculated should be identified. The plan should also describe any intentions to use baseline data to improve precision and to adjust estimates for potential baseline differences, for example, by means of analysis of covariance. The reporting of precise p-values (e.g., ''P=0.034'') should be envisaged in the plan, rather than exclusive reference to critical values (e.g., ''P<0.05''). It is important to clarify whether one- or two-sided tests of statistical significance will be used and, in particular, to justify prospectively the use of one-sided tests. If formal hypothesis tests are not considered appropriate, then the alternative process for arriving at statistical conclusions should be given.

The particular statistical model chosen should reflect the current state of medical and statistical knowledge about the variables to be analyzed. All effects to be fitted in the analysis (for example, in analysis of variance models) should be fully specified and the manner, if any, in which this set of effects might be modified in response to preliminary results should be explained. The same considerations apply to the set of covariates fitted in an analysis of covariance. (See also section 5.7.). In the choice of statistical methods, due attention should be paid to the statistical distribution of both primary and secondary variables. When making this choice, it is important to bear in mind the need to provide statistical estimates of the size of treatment effects together with confidence intervals (in addition to significance tests), as this may influence the choice when there is any doubt about the appropriateness of the method.

The primary analysis of the primary variable should be clearly distinguished from supporting analyses of the primary or secondary variables. Within the statistical section of the protocol there should also be an outline of the way in which data other than the primary and secondary variables will be summarized and reported. This should include a reference to any approaches adopted for the purpose of achieving consistency of analysis across a range of studies, for example, for safety data.

5.6 Adjustment of Type I Error and Confidence Levels

When multiplicity is present, the usual frequentist approach to the analysis of clinical trial data may necessitate an adjustment to the Type I error. Multiplicity may arise, for example, from multiple primary variables (see section 2.2.2), multiple comparisons of treatments, repeated evaluation over time, and/or interim analyses (see section 4.6). Methods to avoid or reduce multiplicity are sometimes preferable when available, such as the identification of the key primary variable (multiple variables), the choice of a critical treatment contrast (multiple comparisons), the use of a summary measure such as ''area under the curve'' (repeated measures). In confirmatory analyses, any aspects of multiplicity that remain after steps of this kind have been taken should be identified in the protocol; adjustment should always be considered and the details of any adjustment procedure or an explanation of why adjustment is not thought to be necessary should be set out in the analysis plan.

5.7 Subgroups, Interactions, and Covariates

The primary variable(s) is often systematically related to other influences apart from treatment. For example, there may be relationships to covariates such as age and sex, or there may be differences between specific subgroups of subjects, such as those treated at the different centers of a multicenter trial. In some instances, an adjustment for the influence of covariates or for subgroup effects is an integral part of the analysis plan and hence should be set out in the protocol. Prestudy deliberations should identify those covariates and factors expected to have an important influence on the primary variable(s), and should consider how to account for these in the analysis to improve precision and to compensate for any lack of balance between treatment groups. When the potential value of an adjustment is in doubt, it is often advisable to nominate the unadjusted analysis as the one for primary attention, the adjusted analysis being supportive. Special attention should be paid to center effects and to the role of baseline measurements of the primary variable. It is not advisable to adjust the main analyses for covariates measured after randomization because they may be affected by the treatments.

The treatment effect itself may also vary with subgroup or covariate—for example, the effect may decrease with age or may be larger in a particular diagnostic category of subjects. In some cases such interactions are anticipated, hence a subgroup analysis or a statistical model including interactions is part of the confirmatory analysis plan. In most cases, however, subgroup or interaction analyses are exploratory and should be clearly identified as such; they should explore the uniformity of any treatment effects found overall. In general, such analyses should proceed first through the addition of interaction terms to the statistical model in question, complemented by additional exploratory analysis within relevant subgroups of subjects, or within strata defined by the covariates. When exploratory, these analyses should be interpreted cautiously; any conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses are unlikely to be accepted.

5.8 Integrity of Data and Computer Software

The credibility of the numerical results of the analysis depends on the quality and validity of the methods and software used both for data management (data entry, storage, verification, correction, and retrieval) and for processing the data statistically. Data management activities should therefore be based on thorough and effective SOP's. The computer software used for data management and statistical analysis should be reliable, and documentation of appropriate software testing procedures should be available.

VI. Evaluation of Safety and Tolerability

6.1 Scope of Evaluation

In all clinical trials, evaluation of safety and tolerability constitutes an important element. In early phases, this evaluation is mostly of an exploratory nature and is only sensitive to frank expressions of toxicity, whereas in later phases, the establishment of the safety and tolerability profile of a drug can be characterized more fully in larger samples of subjects. Later phase controlled trials represent an important means of exploring, in an unbiased manner, any new potential adverse effects, even if such trials generally lack power in this respect.

Certain studies may be designed with the purpose of making specific claims about superiority or equivalence with regard to safety and tolerability compared to another drug or to another dose of the investigational drug. Such specific claims should be supported by relevant evidence from confirmatory studies, similar to that necessary for corresponding efficacy claims.

6.2 Choice of Variables and Data Collection

In any clinical trial, the methods and measurements chosen to evaluate the safety and tolerability of a drug will depend on a number of factors, including knowledge of the adverse effects of closely related drugs, information from nonclinical and earlier clinical studies, and possible consequences of the pharmacodynamic/pharmacokinetic properties of the particular drug, the mode of administration, the type of subjects to be studied, and the duration of the study. Laboratory tests concerning clinical chemistry and hematology, vital signs, and clinical adverse events (diseases, signs, and symptoms) usually form the main body of the safety and tolerability data. The occurrence of serious adverse events and treatment discontinuations due to adverse events are particularly important to register (see ICH E2A and ICH E3).

Furthermore, it is recommended that a consistent methodology be used for the data collection and evaluation throughout a clinical trial program to facilitate the combining of data from different trials. The use of a common adverse event dictionary is particularly important. This dictionary has a structure that makes it possible to summarize the adverse event data on three different levels: System-organ class, preferred term, or included term. The preferred term is the level on which adverse events usually are summarized, and preferred terms belonging to the same system-organ class could then be brought together in the descriptive presentation of data (see ICH E2B).

6.3 Set of Subjects to be Evaluated and Presentation of Data

For the overall safety and tolerability assessment, the set of subjects to be summarized is usually defined as those subjects who received at least one dose of the investigational drug. Safety and tolerability variables should be collected as comprehensively as possible from these subjects, including type of adverse event, severity, onset, and duration (see ICH E2B). Additional safety and tolerability evaluations may be needed in specific subpopulations, such as females, the elderly (see ICH E7), the severely ill, or those who have a common concomitant treatment. These evaluations may need to address more specific issues (see ICH E3).

All safety and tolerability variables need attention during evaluation, and the broad approach should be indicated in the protocol. All adverse events should be reported, whether or not they are considered to be related to treatment. All available data in the study population should be accounted for in the evaluation. Definitions of measurement units and reference ranges of laboratory variables should be made with care; if different units or different reference ranges appear in the same trial (e.g., if more than one laboratory is involved), then measurements should be appropriately standardized to allow a unified evaluation. Use of a toxicity grading scale should be prespecified and justified.

The incidence of a certain adverse event is usually expressed in the form of a proportion relating number of subjects experiencing events to number of subjects at risk. However, it is not always self-evident how to assess incidence. For example, depending on the situation, the number of exposed subjects or the extent of exposure (in person-years) could be considered for the denominator. Whether the purpose of the calculation is to estimate a risk or to make a comparison between treatment groups, it is important that the definition is given in the protocol. This is especially important if long-term treatment is planned and a substantial proportion of treatment withdrawals or deaths are expected. For such situations, survival analysis methods should be considered and cumulative adverse event rates calculated in order to avoid the risk of underestimation.

Methods to account for situations where there is a substantial background noise of signs and symptoms (e.g., in psychiatric trials) should be considered in the estimation of risk for different adverse events. One such method is to make use of the ''treatment emergent'' concept in which adverse events are recorded only if they emerge or worsen relative to pretreatment baseline.

Other methods to reduce the background noise may also be appropriate, such as ignoring adverse events of mild severity or requiring that an event should have been

observed at repeated visits to qualify for inclusion in the numerator. Such methods should be explained and justified in the protocol.

6.4 Statistical Evaluation

The investigation of safety and tolerability is a multidimensional problem. Although some specific adverse effects can usually be anticipated and specifically monitored for any drug, the range of possible adverse effects is very large, and new and unforeseeable effects are always possible. Further, an adverse event experienced after a protocol violation, such as use of an excluded medication, may introduce a bias. This background underlies the statistical difficulties associated with the analytical evaluation of safety and tolerability of drugs, and means that confirmatory information from Phase III clinical trials is the exception rather than the rule.

In most trials, the safety and tolerability implications are best addressed by applying descriptive statistical methods to the data, supplemented by calculation of confidence intervals wherever this aids interpretation. It is also valuable to make use of graphical presentations in which patterns of adverse events are displayed both within treatment groups and within subjects.

The calculation of p-values is sometimes useful, either as an aid to evaluating a specific difference of interest or as a ''flagging'' device applied to a large number of safety and tolerability variables to highlight differences worthy of further attention. This is particularly useful for laboratory data, which otherwise can be difficult to summarize appropriately. It is recommended that laboratory data be subjected to both a quantitative analysis, e.g., evaluation of treatment means, and a qualitative analysis, where counting of numbers above or below certain thresholds are calculated.

If hypothesis tests are used, statistical adjustments for multiplicity to quantitate the Type I error are appropriate, but the Type II error is usually of more concern. Care should be taken when interpreting putative statistically significant findings when there is no multiplicity adjustment.

In the majority of studies, investigators are seeking to establish that there are no clinically unacceptable differences in safety and tolerability compared with either a comparator drug or a placebo. As is the case for noninferiority or equivalence evaluation of efficacy, the use of confidence intervals is preferred to hypothesis testing in this situation. In this way, the considerable imprecision often arising from low frequencies of occurrence is clearly demonstrated.

6.5 Single Study versus Integrated Summary

The safety and tolerability properties of a drug are commonly summarized across studies continuously during an investigational product's development and, in particular, for the submission of a marketing application. The usefulness of this summary, however, is dependent on adequate and well-controlled individual studies with high data quality.

The overall usefulness of a drug is always a question of balance between risk and benefit; in a single trial, such a perspective could also be considered even if the assessment of risk/benefit usually is performed in the summary of the entire clinical trial program. (See section 7.1.2.)

For more details of safety and tolerability reports, see section 12 of the ICH Guideline E3 on ''Clinical Study Reports: Structure and Content.''

VII. Reporting

7.1 Evaluation and Reporting

As stated in the introduction, the structure and content of clinical reports is the subject of ICH Guideline E3. That ICH guideline fully covers the reporting of statistical work, appropriately integrated with clinical and other material. The current section is therefore relatively brief.

During the planning phase of a trial, the principal features of the analysis should have been specified in the protocol as described in section 5. When the conduct of the trial is over and the data are assembled and available for preliminary inspection, it is valuable to carry out the blind review of the planned analysis also described in section 5. This preanalysis review, blinded to treatment, should: (1) Cover decisions concerning the exclusion of subjects or data from the analysis sets; (2) check possible transformations and define outliers; (3) add to the model important covariates identified in other recent research; (4) reconsider the use of parametric or nonparametric methods. Decisions made at this time should be described in the report and should be distinguished from those made after the statistician has had access to the treatment codes, as blind decisions will generally introduce less potential for bias.

Many of the more detailed aspects of presentation and tabulation should be finalized at or about the time of the blind review so that, by the time of the actual analysis, full plans exist for all its aspects including subject selection, data selection and modification, data summary and tabulation, estimation and hypothesis testing. Once data validation is complete, the analysis should proceed according to the predefined plans; the more these plans are adhered to, the greater the credibility of the results. Particular attention should be paid to any differences between the planned analysis and the actual analysis as described in the protocol, the protocol amendments, or the updated statistical analysis plan based on a blind review of data. A careful explanation should be provided for deviations from the planned analysis.

All subjects who entered the trial should be accounted for in the report, whether or not they are included in the analysis. All reasons for exclusion from analysis should be documented; for any subject included in the set of all randomized subjects but not in the per-protocol set, the reasons for exclusion from the latter should also be documented. Similarly, for all subjects included in an analysis set, the measurements of all important variables should be accounted for at all relevant time-points.

The effect of all losses of subjects or data, withdrawals from treatment, and major protocol violations on the main analyses of the primary variable(s) should be considered carefully. Subjects lost to followup, withdrawn from treatment, or with a severe protocol violation should be identified; a descriptive analysis of the subjects should be provided, including the reasons for their loss and the relationship of the loss to treatment and outcome.

Descriptive statistics form an indispensable part of reports. Suitable tables and/or graphical presentations should illustrate clearly the important features of the primary and secondary variables and of key prognostic and demographic variables. The results of the main analyses relating to the objectives of the trial should be the subject of particularly careful descriptive presentation.

Although the primary goal of the analysis of a clinical trial should be to answer the questions posed by its main objectives, new questions based on the observed data may well emerge during the unblinded analysis. Additional and perhaps complex statistical analysis may be the consequence. This additional work should be strictly distinguished in the report from work that was planned in the protocol.

The play of chance may lead to unforeseen imbalances between the treatment groups in terms of baseline measurements not predefined as covariates in the analysis plan but having some prognostic importance nevertheless. This is best dealt with by showing that a subsidiary analysis that accounts for these imbalances reaches essentially the same conclusions as the planned analysis. If this is not the case, the effect of the imbalances on the conclusions should be discussed.

In general, sparing use should be made of unplanned subsidiary analyses. Subsidiary analyses are often carried out when it is thought that the treatment effect may vary according to some other factor or factors. An attempt may then be made to identify subgroups of subjects for whom the effect is particularly beneficial. The potential dangers of over-interpretation of unplanned subgroup analyses are well known (see also section 5.7) and should be carefully avoided. Although similar problems of interpretation arise if a treatment appears to have no benefit, or an adverse effect, in a subgroup of subjects, such possibilities need to be properly assessed and should therefore be reported.

Finally, statistical judgement should be brought to bear on the analysis, interpretation, and presentation of the results of a clinical trial. To this end, the trial statistician should be a member of the team responsible for the study report and should approve the final report.

7.2 Summarizing the Clinical Database

An overall summary and synthesis of the evidence on safety and efficacy from all the reported clinical trials is required for a marketing application. This may be accompanied, when appropriate, by a statistical combination of results.

Within the summary a number of areas of specific statistical interest arise: Describing the demography and clinical features of the population treated during the course of the

clinical trial program; addressing the key questions of efficacy by considering the results of the relevant (usually controlled) trials and highlighting the degree to which they reinforce or contradict each other; summarizing the safety information available from the combined database of all the studies whose results contribute to the marketing application and identifying potential safety issues. During the design of a clinical program, careful attention should be paid to the uniform definition and collection of measurements which will facilitate subsequent interpretation of the series of trials, particularly if they are likely to be combined across trials. A common dictionary for recording the details of medication, medical history, and adverse events should be selected and used. A common definition of the primary and secondary variables is nearly alway aworthwhile and is essential for meta-analysis. The manner of measuring key efficacy variables, the timing of assessments relative to randomization/entry, the handling of protocol violators and deviators, and perhaps the definition of prognostic factors, should all be kept compatible unless there are valid reasons not to do so.

Any statistical procedures used to combine data across trials should be described in detail. Attention should be paid to the possibility of bias associated with the selection of trials, to the homogeneity of their results, and to the proper modeling of the various sources of variation. The sensitivity of conclusions to the assumptions and selections made should be explored.

7.2.1 Efficacy Data

Individual clinical trials should always be large enough to satisfy their objectives. Additional valuable information may also be gained by summarizing a series of clinical trials that address essentially identical key efficacy questions. The main results of such a set of studies should be presented in an identical form to permit comparison, usually in tables or graphs that focus on estimates plus confidence limits. The use of meta-analytic techniques to combine these estimates is often a useful addition because it allows a more precise overall estimate of the size of the treatment effects to be generated and provides a complete and concise summary of the results of the trials. Under exceptional circumstances, a meta-analytic approach may also be the most appropriate way, or the only way, of providing sufficient overall evidence of efficacy via an overall hypothesis test.

7.2.2 Safety Data

In summarizing safety data, it is important to examine the safety database thoroughly for any indications of potential toxicity and to follow up any indications by looking for an associated supportive pattern of observations. The combination of the safety data from all human exposure to the drug provides an important source of information because its larger sample size provides the best chance of detecting the rarer adverse events and, perhaps, of estimating their approximate incidence. However, incidence data from this database are difficult to evaluate without a natural comparator group, and data from comparative studies are especially valuable in overcoming this difficulty. The results from studies that use a common comparator (placebo or specific active comparator) should be combined and presented separately for each comparator providing sufficient data.

All indications of potential toxicity arising from exploration of the data should be reported. The evaluation of the reality of these potential adverse effects should take into account the issue of multiplicity arising from the numerous comparisons made. The evaluation should also make appropriate use of survival analysis methods to exploit the potential relationship of the incidence of adverse events to duration of exposure and/or followup. The risks associated with identified adverse effects should be appropriately quantified to allow a proper assessment of the risk/benefit relationship.

Annex 1 Glossary

All randomized subjects—The analysis set that includes all subjects who were randomized to treatment, with these subjects assigned to the treatment group to which they were randomized. Practical considerations, such as missing data, may lead to some subjects in this set not being included in the corresponding analysis.

Analysis plan—The strategy for analysis predefined in the statistical section of the protocol and/or protocol amendments. The plan may be elaborated in a separate document (internal to the sponsor) to cover technical details and procedures for implementing the statistical analyses. The plan should be reviewed and possibly updated as a result of the blind review of the data.

Bayesian approaches—Approaches to data analysis that provide a posterior probability distribution for some parameter (e.g., treatment effect), derived from the observed data and a prior probability distribution for the parameter. The posterior distribution is then used as the basis for statistical inference.

Bias (statistical and operational)—The systematic tendency of any factors associated with the design, conduct, analysis, and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value. Bias introduced through deviations in conduct is referred to as ''operational'' bias. The other sources of bias listed above are referred to as ''statistical.''

Blind review—The checking and assessment of data during the course of the study, but before the breaking of the blind, for the purpose of finalizing the analysis plan.

Content validity—The extent to which a variable (e.g., a rating scale) measures what it is supposed to measure.

Double dummy—A technique for retaining the blind when administering supplies in a clinical trial, when the two treatments cannot be made identical. Supplies are prepared for Treatment A (active and indistinguishable placebo) and for Treatment B (active and indistinguishable placebo). Subjects then take two sets of treatment; either A (active) and B (placebo), or A (placebo) and B (active).

Dropout—A subject in a clinical trial who for any reason fails to continue in the trial until the last visit required of him/her by the study protocol.

Equivalence trial—A trial with the primary objective of showing that the response to two or more treatments differs by an amount which is clinically unimportant. This is usually demonstrated by showing that the true treatment difference is likely to lie between a lower and an upper equivalence margin of clinically acceptable differences.

Frequentist methods—Statistical methods, such as significance tests and confidence intervals, which can be interpreted in terms of the frequency of certain outcomes occurring in hypothetical repeated realizations of the same experimental situation.

Generalizability, generalization—The extent to which the findings of a clinical trial can be reliably extrapolated from the subjects who participated in the trial to a broader patient population.

Global assessment variable—A single variable, usually a scale of ordered categorical ratings, that integrates objective variables and the investigator's overall impression about the state or change in state of a subject.

Independent data monitoring committee (IDMC) (data and safety monitoring board, monitoring committee, data monitoring committee)—An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Intention-to-treat principle—The principle that asserts that the effect of a treatment policy can be best assessed by evaluating on the basis of the intention to treat a subject (i.e., the planned treatment regimen) rather than the actual treatment given. It has the consequence that subjects allocated to a treatment group should be followed up, assessed, and analyzed as members of that group irrespective of their compliance to the planned course of treatment.

Interaction (qualitative and quantitative)—The situation in which a treatment contrast (e.g., difference between investigational product and control) is dependent on another factor (e.g., center). A quantitative interaction refers to the case where the magnitude of the contrast differs at the different levels of the factor, whereas for a qualitative interaction the direction of the contrast differs for at least one level of the factor.

Inter- and intrarater reliability—The level of consistency of a rater (intra) or a group of raters (inter) in making an assessment of treatment outcome.

Interim analysis—Any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to the formal completion of a trial.

Meta-analysis—The formal evaluation of the quantitative evidence from two or more trials bearing on the same question. This most commonly involves the statistical combination of summary statistics from the various trials, but the term is sometimes used to refer to the combination of the raw data.

Multicenter trial—A trial involving two or more study centers, a common study protocol, and a single analysis plan pooling the data across all centers.

Noninferiority trial—A trial with the primary objective of showing that the response to the investigational product is not clinically inferior to a comparative agent (active or placebo control).

Preferred and included terms—In a hierarchical medical dictionary, for example, WHO-ART, the included term is the lowest level of dictionary term to which the investigator description is coded. The preferred term is the level of grouping of included terms typically used in reporting frequency of occurrence. For example, the investigator text ''Pain in the left arm'' might be coded to the included term ''Joint pain,'' which is reported at the preferred term level as ''Arthralgia.''

Per protocol set (valid cases, efficacy sample, evaluable subjects sample)—The set of data generated by the subset of subjects who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment according to the underlying scientific model. Compliance covers such considerations as exposure to treatment, availability of measurements, and absence of major protocol violations.

Safety and tolerability—The safety of a medical product concerns the medical risk to the subject, usually assessed in a clinical trial by laboratory tests (including clinical chemistry and hematology), vital signs, clinical adverse events (diseases, signs and symptoms), and other special safety tests (e.g., electrocardiograms, ophthalmology). The tolerability of the medical product represents the degree to which overt adverse effects can be tolerated by the subject.

Superiority trial—A trial with the primary objective of showing that the response to the investigational product is superior to a comparative agent (active or placebo control).

Surrogate variable—A variable that provides an indirect measurement of effect in situations where direct measurement of clinical effect is not feasible or practical.

Treatment effect—An effect attributed to a treatment in a clinical trial. In most clinical trials, the treatment effect of interest is a comparison (or contrast) of two or more treatments.

Treatment emergent—An event that emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state.

Dated: April 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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May 9, 1997

Part IV

Department of Housing and Urban Development

24 CFR Parts 960 and 966

Streamlining the Public Housing Admission and Occupancy Regulations; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 960 and 966

[Docket No. FR–4084–P–01]

RIN 2577–AB67

Streamlining the Public Housing Admission and Occupancy Regulations

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule will revise HUD's regulations that govern admission and occupancy issues in the public housing program to do the following: Remove rule text that is repetitive of statutory language and otherwise streamline the rule; respond to relevant recommendations of the Public and Assisted Housing Occupancy Task Force report of April 1994; implement a recent statute regarding screening of applicants for admission and termination of tenancy; add important provisions concerning application processing, previously found only in a superseded Annual Contributions Contract between HUD and Housing Agencies and in HUD Handbooks; and clarify applicability of the part. The overall goal of this rule is to make the regulations clearer and more concise and to implement statutory directives.

DATES: Comments due date: July 8, 1997.

The deadline for comments on the information collection requirements is July 8, 1997, although commenters are advised that a comment is best assured of having its full effect if it is received by the Office of Management and Budget (OMB) within 30 days of publication. See the Public Reporting Burden heading under the Findings and Certifications section of this preamble regarding the information collection burden.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410. Communications should refer to the above docket number and title. Facsimile (FAX) comments are *not* acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

Comments on the information collections contained in the rule, which are described in detail under the heading, FINDINGS AND CERTIFICATIONS, must refer to the docket number and title of the proposed rule and be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Linda Campbell, Director, Marketing, Leasing and Management Division, Office of Public and Assisted Housing Operations, Room 4206, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone number (202) 708–0744, extension 4020. (This telephone number is not toll-free.) For hearing-and speech-impaired persons, this number may be accessed via text telephone by dialing the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Regulatory Reinvention Effort

On March 4, 1995, President Clinton issued a memorandum to all Federal departments and agencies regarding regulatory reinvention. In response to this memorandum, the Department of Housing and Urban Development conducted a page-by-page review of its regulations to determine which can be eliminated, consolidated, or otherwise improved. HUD has determined that the regulations for 24 CFR, Part 960, Admission To, And Occupancy Of, Public Housing, can be improved and streamlined by eliminating unnecessary language. Throughout the part, this rule shortens and simplifies the provisions retained.

The various subparts of part 960 currently contain their own sections on purpose, scope, and/or applicability. The statements of purpose and scope have been eliminated, since they were explanatory only and the information can be provided in HUD documents other than a rule. The applicability provisions have been consolidated into one section in a new subpart A, which deals with general topics. All statements of OMB approval numbers for information collection requirements have also been consolidated in that subpart.

Sections on tenant selection policies and standards for tenant selection criteria (§§ 960.204 and 960.205) have been streamlined and consolidated into one section (new § 960.201) entitled, ''Applicant admission policies.'' Examples have been removed, since they can be provided in HUD guidance documents.

References in the codified rule to reserved subparts and sections have been removed, to eliminate confusion.

A number of the changes made in this proposed rule increase the flexibility of housing agencies (''HAs'') administering the program. For example, § 960.206 now explicitly authorizes HAs to verify information about an applicant's disability to determine appropriate accommodations, to verify information relative to qualification for a preference, and to determine deductions for calculating adjusted income. It clarifies that the HA makes the final determination of whether an applicant's failure to meet the HA's tenant selection criteria is outweighed with respect to these issues. Another example is the explicit authorization for HAs to adopt income limits for continued occupancy, found in § 960.210. This responds to the desire of many HAs to adopt reasonable limits to avoid housing families who can obtain housing on the private market. In addition, language was removed from § 960.208 that required a tenant's approval for direct payment of a utility reimbursement to a utility provider (see discussion below).

II. Statutory Change and Related Change to Bar Admission of Certain Evicted Tenants

The statutory foundation for the public housing program is the United States Housing Act of 1937 (42 U.S.C. 1437a, et seq., ''1937 Act''). On March 28, 1996, that Act was amended by the Housing Opportunity Program Extension Act of 1996 (Pub. L. 104–120, 110 Stat. 834) (''Extender Act''). It makes ineligible for admission to public housing those individuals who have been evicted from housing assisted under the 1937 Act (including Section 8 assistance) for drug-related criminal activity for a three-year period, unless the evicted tenant has successfully completed a rehabilitation program or the circumstances leading to the eviction no longer exist.

The statute also requires HAs to prohibit occupancy in any public housing dwelling unit by any person who the HA determines is illegally using a controlled substance, or whose pattern of illegal use of a controlled substance or pattern of alcohol abuse would interfere with the health, safety, or right to peaceful enjoyment of the premises by other residents of the project. In this connection, the statutory amendment authorizes the housing agency administering the program to determine whether an applicant has

been rehabilitated from drug or alcohol abuse.

The amendment also provides some specific requirements about the administration of this applicant screening authority: (1) It requires law enforcement agencies to provide information to housing agencies concerning criminal convictions for purposes of applicant screening, lease enforcement, and eviction; (2) it requires the housing agency to provide anyone adversely affected by report of a criminal record an opportunity to dispute the accuracy and relevance of that record before any adverse action is taken; and (3) it requires that reports of criminal records be maintained confidentially. The first of these changes is not the subject of this rule but is the subject of current intergovernmental coordination efforts. The second and third changes are being implemented through revisions of the verification procedures contained in the section now designated as § 960.206(e).

A. Ineligibility of Persons Previously Evicted

This rule interprets the statute's ban on admission of a person previously evicted for drug-related criminal activity for three years to be a period of at least three years. Thus, an HA can determine the period of time it believes reasonable for particular types of drug-related activity, as long as that period is at least three years long.

This rule also proposes a related change in § 960.201 to make tenants evicted from housing assisted under the 1937 Act for serious lease violations ineligible for admission to public housing for an appropriate period of time. For example, families evicted for committing crimes against persons or property, and other acts that affect the health, safety or right to peaceful enjoyment of the premises by other residents, would be barred from admission to public housing for a specified period. These proposals will facilitate HUD and HA efforts to crack down on crime and to impose tougher expectations on federally assisted tenants, holding them responsible for their actions.

It is noted that in order to determine the eligibility of an applicant under this proposed rule, an HA needs to know whether the applicant was evicted from housing assisted under the 1937 Act and whether the eviction involved drug-related criminal activity. HUD is specifically requesting public comment on the best means to obtain information on evictions from privately owned assisted projects and ways HAs can share this information with each other.

B. Ineligibility of Persons Involved in Drug or Alcohol Abuse

The Extender Act requires that HAs prohibit occupancy in public housing by any person engaged in illegal use of a controlled substance or any person that the HA has reasonable cause to believe is engaged in a pattern of illegal use of a controlled substance or abuse (or a pattern of abuse) of alcohol that ''may interfere with the health, safety, or right to peaceful enjoyment of the premises by other residents of the project.'' This rule implements that provision by requiring HAs to establish screening criteria to prevent admission of such ineligible persons and by requiring HAs to establish standards for evicting tenants related to illegal drug use and alcohol abuse. (See §§ 960.201(c)(1).) Since the Extender Act makes these same standards the basis for termination of tenancy as well as for denial of admission, this rulemaking revises the provisions of current regulations pertaining to grounds for termination of tenancy, § 966.4(l), to add them.

In addition, consonant with the Department's overall efforts to make public housing safe and following the pattern of Section 8 regulations (§ 982.553), this proposed rule provides that the HA may deny admission or evict a tenant at any time if the HA determines that any family member has engaged in drug-trafficking or violent criminal activity. (Definitions of these terms are added to the rule.)

C. Criminal Background Checks

The rule currently requires, at § 960.206(a), that ''[a]dequate procedures must be developed to obtain and verify information with respect to each applicant.'' It also suggests as sources of information ''parole officers, court records, drug treatment centers, clinics, physicians or police departments where warranted by the particular circumstances.'' That section is being revised to provide, at paragraph (c)(1), that verification procedures include a ''criminal background check of all adult household members to identify any recent history of crimes of physical violence to persons or property and other activities that would adversely affect the health, safety or welfare of others.''

The enactment of the Extender Act makes it clear that Congress wants applicants who are admitted to public housing to be carefully screened for criminal and antisocial behavior, so that public housing developments will be more desirable places to live. HUD concludes that HAs must carefully screen applicants to assure that they are carrying out the new statutory provisions making ineligible for admission persons involved in drug use and alcohol abuse or previously evicted for drug-related activity and requiring that law enforcement agencies make available information about criminal records.

To assure that screening is thorough and is not conducted in a discriminatory way, the proposed rule provides that HAs must do a criminal background check on *all adult household members* of each applicant family. The rule requires HAs to access an individual's criminal history records from a local, State, or Federal government entity with law enforcement responsibility. The type of criminal background check done is left to the discretion of the HA, based on local circumstances.

This approach was discussed at a meeting in the summer of 1996 with representatives of housing agency officials (National Association of Housing and Redevelopment Officials, Council of Large Public Housing Authorities, and Public Housing Authority Directors Association). Although there was not unanimous support for this position among those officials, the Department has determined that benefits will outweigh the costs, as described below, and that the policy should be implemented. Of course, public comments are invited on this subject, as on other elements of this proposed rule.

When considering what type of check to do, an HA may consider factors described in this rule preamble. Local and county records, which may contain records of misdemeanors, as well as felonies, are generally available free or for only a small fee. This type of background check may be appropriate for long-term residents of the locality or county. State records are available, for fees that vary widely, and may be appropriate to check on the background of an applicant that has moved from other localities within a State. In some parts of the country, states have created networks through which HAs can access criminal records from all participating states through one request.

Another possible source is the National Crime Information Center (NCIC), which provides information about felonies and many misdemeanors. At this point, most HAs do not have access to NCIC records, but HUD is working with other Federal agencies to develop procedures so that this option can be pursued where it is deemed appropriate.

A large number of HAs have residency preferences (including New York, Puerto Rico, and Chicago—administering a total of 284,000 units), which, combined with long waiting lists, result in admission primarily of local residents, or those who work in the locality. Background checks on local residents can often be done through local, county, or State systems. In the HAs that have residency preferences, non-local residents rarely reach the top of the waiting list and the stage of screening that involves the criminal background check.

The range of effort an HA undertakes may vary from having the applicant get a document from the local police department or sheriff's office that indicates whether or not the applicant has a criminal record, and the nature of any such record, to having the applicant fingerprinted and checking these prints and other pertinent data with the NCIC. The former method has the advantage that applicants who know they have a criminal history may choose to withdraw their applications, thus screening themselves out of the applicant pool. The cost may range from nothing, to $1 for a name check with local authorities using a diskette for computerized access, to $10 for a name check with NCIC, to $25 for a fingerprint check with NCIC. In no event will the applicant be charged to cover the cost of the criminal background check.

The cost to HAs, in the aggregate, to conduct the required background check, which many are already doing under the existing regulations, is estimated as follows. There are approximately 1.3 million public housing households. Of these, there is turnover in 13% of the units each year, producing a need to do applicant screening to fill 169,000 units per year. Considering that criminal background checks will be done on the adults in applicant households that have already passed other standard screening procedures, it is likely that 1.5 households will be checked for each of the 169,000 admissions. That results in 253,000 households being checked. At an average of 1.2 adults per household, the requirement to check all adult members of an applicant household would require 303,600 individuals to be checked.

We estimate that 95% of these criminal background checks could be done at the local, county, or State level. The cost of this type of check varies widely, from about $1 to more than $15. Using a relatively high estimate of approximately $10 per person, the total annual cost for this category of background check would be $2,884,200. Another 3% of the checks would probably be done through a name check with the NCIC, at a ballpark estimate of $10 per person—for a total cost of $91,080. The last 2% would be checked via the fingerprint check with the NCIC, at an approximate cost of $25 (not including the cost of obtaining the applicant's fingerprints)—for a total cost of $151,800. Altogether, the cost then would be $3,127,080.

The HAs cover the cost of all their screening activities, as well as the cost of other operations, such as evictions, through HUD operating subsidy and rental and other income. If an HA does not properly screen applicants, both tangible and intangible costs will be incurred. The tangible costs to the HA will include the cost of evicting a tenant involved in criminal activity.

Costs associated with an eviction, if the HA uses its own counsel, are estimated to be in the range of $450 to $700 for each eviction, provided there is no appeal. If there is an appeal or a jury trial, the HA is likely to spend, at a minimum, $2,000 per eviction. These estimates do not include the HA staff time devoted to documentation of problems with the tenant family that takes place before the commencement of an eviction action.

The cost of doing adequate screening at the point of admission (at $1–$25 per adult) is an investment in effective management of public housing developments. Lease enforcement—via eviction—is much more costly. Using the high estimate of $25 per adult, the cost per household of universal adult screening is $30, which compares very favorably with an eviction cost of $450 to $2,000.

The intangible costs associated with failing to do adequate criminal background checks would include the effect on neighbors in the development whose peaceful enjoyment of the premises would be impeded by the presence of tenant families involved in criminal activity. These neighbors' dissatisfaction with the development might produce an undesirable image for the development and increased turnover and vacancies in the development. Of course, such turnover would result in costs for cleaning units and additional applicant screening to fill the units, and if units could not be filled because of a negative image of the development, loss in rental income resulting from vacancies. Complaints to the HA staff about tenants who might have been prevented from being admitted if a criminal background check had been completed would require staff to devote time to meet with affected families to attempt to resolve the situation, as well as action necessary to evict the families whose illegal activities could not be terminated by any other means.

The Department concludes that, in fulfillment of the statutory mandate to screen applicants to prevent admission of those who are involved in illegal drug use and drug-related criminal activity or who have been evicted previously for such activity and to terminate the tenancy of persons whose use of illegal drugs or abuses of alcohol interferes with the use of the premises by other residents, applicants must be screened for criminal activity. Considering the costs associated with criminal background checks and the tangible and intangible costs of failure to do adequate criminal background checks, the Department has determined that requiring such checks on all adults in applicant households before admission of a family is justified as a means of satisfying the statutory objective.

III. Annual Contributions Contract and Handbook Provisions

The Department revised the standard contract between it and housing agencies, called the Annual Contributions Contract (''ACC''), in the July 1995 revision streamlining and replacing the November 1969 version. The 1969 standard ACC contained requirements that are no longer found in the new ACC but are still to be kept in force. Therefore, this rule is adding to part 960 some requirements formerly found in the ACC, or in HUD Handbooks, on the subject of applications, waiting lists, and tenant selection and assignment.

A new subpart C requires HAs to obtain a written application from each applicant, and it builds on the framework established in 24 CFR 1.4 for tenant selection and assignment plans and use of waiting lists.

IV. Occupancy Task Force

In 1993, the Secretary established a task force to review all rules, policy statements, handbooks, technical assistance memoranda, and other relevant documents issued by the Department on the standards and obligations governing residency in federally assisted housing, to comply with Section 643 of the Housing and Community Development Act of 1992 (42 U.S.C. 13603).

This task force was comprised of individuals representing the interests of owners, managers, and tenants of federally assisted housing, HAs, owner and tenant advisory organizations, persons with disabilities and disabled families, organizations assisting homeless individuals, and social

service, mental health and other nonprofit servicers and providers who serve federally assisted housing. Members of the task force were directed to review all existing standards, regulations, and guidelines governing occupancy and tenant selection policies in federally assisted housing, as well as lease provisions and other rules of occupancy for federally assisted housing, to determine whether the standards, regulations and guidelines provide sufficient guidance to owners and managers of federally assisted housing to:

(1) Develop procedures for preselection inquiries sufficient to determine the capacity of the applicants to comply with reasonable lease terms and conditions of occupancy;

(2) Use leases that prohibit behavior which endangers the health and safety of other tenants or HA employees or violates the rights of other tenants to peaceful enjoyment of the premises;

(3) Assess the need to provide, and appropriate measures for providing, reasonable accommodations required under the Fair Housing Act and Section 504 of the Rehabilitation Act of 1973 for persons with various types of disabilities; and

(4) Comply with civil rights laws and regulations.

The task force made the necessary review, conducted several public hearings across the country, and received written comments. As mandated, the task force submitted to the Secretary and Congress a final report on April 7, 1994 that set forth the task force's recommendations for occupancy criteria in federally assisted housing, standards for the reasonable performance and behavior of tenants of federally assisted housing, compliance standards consistent with the reasonable accommodation of the requirements of the Fair Housing Act and section 504 of the Rehabilitation Act of 1973, standards for compliance with other civil rights laws, and procedures for the eviction of tenants not complying with such standards consistent with sections 6 and 8 of the 1937 Act.

Some of the recommendations were directed to the Congress, and others would require the appropriation of funds for their implementation. Those recommendations are not covered by this proposed rule.

Most of the remaining recommendations do not require implementation through the rulemaking process but rather through the promulgation of guidance. The Department is committed to minimizing the regulatory burden on the housing agencies. As a result, the only recommendations that are covered in this proposed rule are those related to 24 CFR part 960 that require an explicit, enforceable requirement on the HAs or for which the existing regulation must be modified to be consistent with Task Force recommendations. The Department intends to address and adopt other Task Force recommendations in future revisions of other regulations, such as 24 CFR part 966, covering leases and grievance procedures, and in future training.

The Task Force recommended that HUD provide broader coverage with respect to requiring that HAs provide reasonable accommodations to applicants whose applications would be denied, considering what accommodations could be provided that would permit the applicants to comply with program requirements. The revised § 960.206 addresses this issue.

The Task Force recommended that HUD require all housing providers to ask all applicants at the point of initial contact whether they need another form of communication other than plain language paperwork. Some alternatives recommended were providing sign language interpretation; having material explained orally by staff, either in person or by phone; providing large type materials; offering information on tape; or having some third party representative (a friend, relative or advocate, named by the applicant) accompany the applicant to receive, interpret and explain housing materials and be present at all meetings and discussions. The Department has decided to require that applicants be informed of alternative forms of communication that can be used, upon the request of an applicant. The provision (in § 960.207) is worded in the form of providing information to applicants instead of asking applicants what they need, to respect their privacy.

The Task Force recommended that HUD require housing providers to include in all letters rejecting applicants a notice asking applicants with disabilities who are being rejected to request an interview to determine whether a reasonable accommodation would enable them to comply with essential lease provisions. This recommendation has been accepted and embodied in the same section.

V. Description of Specific Changes

A. General

The entire part has been rewritten, instead of amending some of the existing parts. The new subpart A describes the applicability of the part, clarifying a possible confusion about what leased housing projects are covered—units leased by the HA from a private owner and then subleased to tenants under the Section 23 or the Section 10(c) programs are covered. This subpart also describes the authorization for information collections.

B. Subpart B—Admission, Rent, and Reexamination of Income

When the rule governing Federal preferences was issued, on March 6, 1996, it removed § 960.203 covering nondiscrimination requirements when it added a provision (§ 5.410(i)) imposing the requirements with respect to administration of selection preferences. However, the scope of that provision did not clearly apply to all tenant selection and occupancy determinations made by an HA. Therefore, this rule restores a § 960.203 to apply those nondiscrimination provisions to all such activities. To minimize repetition of lists of statutory references in its rules, the Department cross-references the list already stated in that rule.

While that change restores language previously removed, another change to this subpart eliminates reference to utility reimbursements, in § 960.208. Utility reimbursements are payments to, or on behalf of, tenants who pay their own utility bills in cases where the utility allowance applicable to their unit exceeds their payment for rent, based on their income. Currently, six percent of the total population of public housing residents have a utility allowance that is greater than their payment for rent (''total tenant payment'' under 24 CFR part 5). These households are, therefore, entitled to receive a utility reimbursement. This means that HAs currently send out approximately 75,000 checks monthly to tenants, if tenants have not consented to direct payment to the utility company.

The method of paying utility reimbursements is now covered in both part 960 and the rule defining income that is applicable to the public housing program, now found in 24 CFR part 5 (a broader rule applicable to all programs administered under the 1937 Act). The current provisions require that before an HA can pay a utility reimbursement directly to the utility company, it must obtain the consent of the tenant.

This proposed rule eliminates reference to utility reimbursements from part 960, so that treatment of these reimbursements will be covered in only one part. The final rule based on this proposed rule will include a revision to the income reimbursement provision in part 5 to permit an HA, with the consent

of the utility company—but without obtaining consent of the tenant—to pay the reimbursement directly to the utility company on the tenant's behalf. This change is intended to assure that the funds are used for their intended purpose and to save HAs money by consolidating the number of utility reimbursement checks they must issue from several to one. The Department believes that the change will have no adverse impact on tenants, but specifically invites public comments on this change.

As mentioned above with respect to Task Force recommendations, § 960.207 has been significantly revised. The title reflects that change. It is no longer ''Notification to Applicants'' but is ''Communication With Applicants.''

With respect to reexamination of family income and composition, § 960.209, the rule is being revised to provide that the HA shall prescribe the conditions under which changes in circumstances between annual reexaminations must be reported.

C. Subpart C—Applications, Waiting List, Tenant Selection and Assignment

This subpart prescribes requirements for waiting lists and tenant selection and assignment policies adopted pursuant to 24 CFR 1.4(b)(2)(ii). Section 1.4 requires HAs to use a community-wide waiting list, but permits HAs to seek an exception from this requirement where the exception would be consistent with title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d-1, and the purposes of 24 CFR part 1.

In the waiting list section of this rule, § 960.303, clarification is given that HAs may divide their waiting list into separate categories for general occupancy projects, for mixed population projects, for projects designated for elderly families, and for projects designated for disabled families, provided that all applicants are given an opportunity to be on the waiting list for any category of project for which they are qualified. This provision is intended to permit operation of projects that were previously approved as projects designated for elderly and disabled families in accordance with their designation, while permitting families eligible for that housing to also seek admission to other projects.

The tenant selection and assignment provisions of 24 CFR 1.4 have been augmented in § 960.304 by a provision that explicitly permits an HA to deal with an applicant who refuses offered units a prescribed number of times by removing the applicant from the waiting list entirely. This additional option provides an HA with greater flexibility in administering its program. This new section also specifies that the number of offers to be given an applicant before such action shall not exceed three. Of course, the HA's tenant selection and assignment plan remains subject to HUD review, in accordance with 24 CFR 1.4.

The provisions concerning a preference for elderly families and disabled families in mixed population projects now found in subpart D of part 960 are consolidated into one section (§ 960.307) in this subpart.

D. Subpart D—Exemption From Eligibility Requirements for Police Officers and Other Security Personnel

This subpart permits the admission to public housing of police officers and other security personnel, who are not otherwise eligible under any other admission requirements, under a plan submitted by a housing agency (HA) and approved by the Department, to increase their visible presence to serve as a deterrent to criminal activity in and around public housing.

VI. Findings and Certifications

A. Public Reporting Burden

The information collection requirements contained in this rule, as described in §§ 960.201, 960.206, 960.207, 960.209, 960.301, 960.303, 960.304, and 960.405 are being submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995 (42 U.S.C. 3501–3520).

1. In accordance with 5 CFR 1320.5(a)(1)(iv), the Department is setting forth the following concerning the proposed collections of information:

(a) Title of the information collection proposal: Public Housing Admission and Occupancy Policies.

(b) Summary of the collection of information: The information collected covers the following: (1) Policies on applicant admission, including procedures for selection of applicants, verification of applicant data and criminal history records, communication with applicants, maintenance of waiting lists, and tenant selection and assignment; (2) provision for reexamination of family income; and (3) a plan for housing security officers.

(c) Description of the need for the information and its proposed use: The information collected is needed to monitor compliance with HUD public housing program requirements authorized by statute to assure that sound management practices will be followed in the operation of the projects, consistent with the obligations of the HAs under the United States Housing Act of 1937, 42 U.S.C. 1437, et seq.

(d) Description of the likely respondents, including the estimated number of likely respondents, and proposed frequency of response to the collection of information: The likely respondents are the approximately 3,300 HAs that administer public housing units. The information is collected only once, unless an HA changes its policy.

(e) Estimate of the total reporting and recordkeeping burden that will result from the collection of information: The total number of burden hours for this collection of information is estimated to be 344,800 hours, including the time for reviewing instructions, gathering and maintaining the data. The actual burden to HAs is minimal, since the collections are already a part of the day-to-day operation of the HAs. The only collections actually sent to HUD are those described in § 960.201 (Applicant Admission Policies), in § 960.304 (Tenant Selection and Assignment Plan) and in § 960.405 (Plan Standards and Criteria for Admission of Police Officers). All other collections are developed and maintained at the HA. It is difficult to determine a cost per hour due to the different organizational structure of HAs and the various collections being performed by different individuals. No outside consultation was necessary to ascertain data collection requirements. The information is not reported to the Department on a form.

REPORTING BURDEN

Type of collection	Proposed section of 24 CFR affected	Number of respondents	Frequency of response	Est. ave. response time (hrs.)	Annual burden hrs.
Policies on Applicant Admission	960.201, 960.206, 960.207, 960.209, 960.304	3,300	1	68	224,400
Procedures for Applications & Waiting Lists	960.301, 960.303	3,300	1	36	118,800
Submission of Plan to Exempt Police Officers from Eligibility Requirements.	960.405	800	1	2	1,600
Total Burden					344,800

2. In accordance with 5 CFR 1320.8(b)(3), the Department makes the following statement:

The reason for collecting the information is to permit housing agencies to collect necessary information from program applicants to determine their eligibility for participation in the program, and to permit HUD to monitor housing agencies' activities. HUD uses the information it collects to ensure that the policies and procedures adopted by the housing agencies in administration of the public housing program are consistent with requirements of the authorizing legislation and applicable nondiscrimination laws. The information submitted to HUD is public information and does not lend itself to confidentiality. Information submitted to a housing agency in the verification of applicant data is not public information and is subject to statutory requirements concerning confidentiality (42 U.S.C. 1437d(q)(4)). In accordance with the Paperwork Reduction Act, HUD may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

3. In accordance with 5 CFR 1320.8(d)(1), the Department is soliciting comments from members of the public and affected agencies (see **DATES** and **ADDRESSES** sections above) concerning the proposed collection of information to:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

B. Impact on Small Entities

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this proposed rule, and in so doing certifies that this rule will not have a significant economic impact on a substantial number of small entities. This proposed rule would amend occupancy and tenant selection policies in the Public Housing program. The Department recognizes that uniform application of requirements on entities of differing sizes may place a disproportionate burden on small entities. Therefore, the Department invites small entities to suggest alternatives ways of compliance with the basic provisions of this proposed rule about how they might comply in a way less burdensome to them.

C. Environmental Impact

This proposed rulemaking does not have an environmental impact. This proposed rulemaking simply amends an existing regulation by consolidating and streamlining provisions and does not alter the environmental effect of the regulations being amended. A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332).

D. Federalism Impact

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this proposed rule do not have significant impact on States or their political subdivisions, or the relationship between the Federal Government and State and local governments, or on the distribution of power and responsibilities among the various levels of government. As a result, the proposed rule is not subject to review under the Order. The proposed rule merely streamlines existing regulations and implements certain statutory requirements with respect to admission and occupancy of housing funded by the Federal Government but administered by local entities.

E. Impact on the Family

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that this proposed rule will not have the potential for significant impact on family formation, maintenance, or general well-being, and thus is not subject to review under the Order.

F. Unfunded Mandates Reform Act

The Secretary, in accordance with the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, has reviewed this proposed rule before publication and by approving it certifies that this proposed rule does not impose a Federal mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.

G. Regulatory Review

This proposed rule was reviewed by the Office of Management and Budget under Executive Order 12866, not on the basis of impact in excess of $100 million but on the basis of its importance. Any changes made in this proposed rule as a result of that review are clearly identified in the docket file for this proposed rule, which is available for public inspection in the HUD's Office of the Rules Docket Clerk, Room 10276, 451 Seventh Street, SW., Washington, DC 20410–0500.

Catalog

The Catalog of Federal Domestic Assistance number for the program affected by this proposed rule is 14.850.

List of Subjects

24 CFR Part 960

Aged, Grant programs—housing and community development, Individuals with disabilities, Reporting and recordkeeping requirements, Public housing.

24 CFR Part 966

Grant programs—housing and community development, Public housing.

Accordingly, in title 24 of the Code of Federal Regulations, parts 960 and 966 are proposed to be amended as follows:

1. Part 960 is revised to read as follows:

PART 960—ADMISSION TO, AND OCCUPANCY OF, PUBLIC HOUSING

Subpart A—General

Sec.
960.101 Applicability.
960.105 Approved information collections.

Subpart B—Admission, Rent, and Reexamination

960.201 Applicant admission policies.
960.203 Nondiscrimination requirements.
960.206 Verification procedures.
960.207 Communication with applicants.
960.208 Rent.
960.209 Reexamination of family income and composition.
960.210 Continued occupancy limits.

Subpart C—Applications, Waiting List, Tenant Selection, and Assignment

960.301 Applications.
960.303 Waiting lists.
960.304 Tenant selection and assignment.
960.307 Mixed population projects.

Subpart D—Exemption From Eligibility Requirements for Police Officers and Other Security Personnel

960.401 Exemption from eligibility requirements.
960.402 Definitions.
960.405 Plan standards and criteria.
960.409 Special rent requirements and other terms and conditions.
960.411 Applicability of the annual contributions contract; effect on the Performance Funding System.

Authority: 42 U.S.C. 1437a, 1437c, 1437d, 1437n, and 3535(d).

Subpart A—General

§ 960.101 Applicability.

This part is applicable to all dwelling units assisted under the 1937 Act in projects owned by or leased to HAs and leased or subleased by HAs to tenants, including Section 23 and Section 10(c) leased housing projects directly operated by the HA. This subpart is not applicable to the Low-Rent Housing Homeownership Opportunities Program (Turnkey III); to the Indian Housing Rental, Turnkey III and Mutual Help Homeownership Opportunities Program; or to units assisted under Section 8 of the 1937 Act, 42 U.S.C. 1437f.

§ 960.105 Approved information collections.

The following sections of the part have been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 and assigned the OMB approval number indicated:

Approval No.	Sections
2577– ...	960.201, 960.206, 960.207, 960.301, 960.303, 60.304, and 960.405
2577– ...	960.209

Subpart B—Admission, Rent, and Reexamination of Income

§ 960.201 Applicant admission policies.

(a) *General.* The HA must admit to public housing only families that are qualified for admission, as follows:

(1) They are eligible in terms of income, family composition and citizenship or immigration status;

(2) Their past behavior indicates that they can be reasonably expected to comply with the lease;

(3) No family member has been evicted from housing assisted under the 1937 Act for drug-related criminal activity during a reasonable time period specified by the HA, which is not less than three years from the date of the eviction. Notwithstanding the immediately preceding sentence, the HA may, in its discretion, determine that the family is eligible for admission if the HA determines that the evicted family member who was engaged in drug-related criminal activity has successfully completed a rehabilitation program approved by the HA or that the circumstances leading to the eviction no longer exist (e.g., the evicted family member involved in drugs is no longer in the household because of incarceration); and

(4) No family member has been evicted from housing assisted under the 1937 Act for other serious violations of the lease during a reasonable time period specified by the HA, unless the HA determines that the circumstances leading to the eviction no longer exist.

(b) *Criminal activity by family members.* At any time, the HA may deny admission to an applicant if the HA determines that any family member has engaged in drug-trafficking or violent criminal activity. For purposes of this section, drug-trafficking means the illegal manufacture, sale, or distribution, or the possession with intent to manufacture, sell, or distribute, of a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)). For purposes of this section, violent criminal activity means any illegal criminal activity that has as one of its elements the use, attempted use, or threatened use of physical force against the person or property of another.

(c) *Written policies and procedures.* The HA must adopt and implement written policies for admission of tenants and procedures identifying standards and criteria for tenant selection that comply with the provisions of the 1937 Act, 42 U.S.C. 1437d, and applicable civil rights requirements, including the following elements:

(1) *Policies on illegal drug use and abuse of alcohol.*

(i) The HA must establish standards for denying admission if the HA determines that:

(A) Any Family member is illegally using a controlled substance; or

(B) There is reasonable cause to believe that a Family member's illegal use or pattern of illegal use of a controlled substance or abuse or pattern of abuse of alcohol may interfere with the health, safety, or right to peaceful enjoyment of the premises by other residents.

(ii) In determining whether to deny admission for illegal use or pattern of use of a controlled substance or for abuse or pattern of abuse of alcohol, the HA may consider whether the person:

(A) Is no longer engaging in the illegal use of a controlled substance or in abuse of alcohol (as applicable); or

(B) Has successfully completed a supervised drug or alcohol rehabilitation program (as applicable), has otherwise been rehabilitated successfully, or is participating in a supervised drug or alcohol rehabilitation program (as applicable).

(2) *Requirements for applications and waiting lists.* (See 24 CFR 1.4 and subpart C of this part). A dwelling unit must not be allowed to remain vacant for the purpose of awaiting an application from a family falling within a particular income range or for any other preference;

(3) *Policies for selection of applicants from the waiting list.* Selection policies must include:

(i) *Preferences.* Federal preferences (if any), and any ranking or local preferences, and how they are applied. (See 24 CFR part 5, subpart D, for applicable requirements.)

(ii) *Tenant selection and assignment plan.* The organization of the waiting

list, how applicants are assigned to specific projects and dwelling units, and the precedence of transfers over admissions;

(iii) *General screening criteria.* Applicant screening criteria and information to be considered must be reasonably related to each applicant's individual attributes and behavior, and not imputed to a particular group or category of persons of which an applicant may be a member. These criteria must be related to whether an applicant's conduct would be likely to interfere with other residents by adversely affecting their health, safety or welfare or the physical environment or the financial stability of the project if the applicant were admitted.

(4) *Policies for participant transfer between units, projects, and programs.* These shall include a policy on the transfer to a standard unit of an applicant who was admitted to an accessible unit but does not need its special features when an applicant who does need the unit's special features is being admitted.

(d) *Availability of policies.* These policies must be available in each office where applications are received and be furnished to applicants or tenants upon request, free or at their expense, at the discretion of the HA. A copy must be submitted to HUD upon request.

(e) *Tenant Advisory Boards.* The HA may establish Tenant Advisory Boards for consultation in connection with the tenant selection process.

§ 960.203 Nondiscrimination requirements.

The HA must administer its system of tenant selection and determinations concerning continued assistance in accordance with the nondiscrimination requirements specified with respect to selection preferences in 24 CFR 5.410.

§ 960.206 Verification procedures.

(a) *General.* (1) The HA must develop procedures to obtain and verify information with respect to each applicant's qualification for admission. (See 24 CFR part 5, subpart B.) Information relative to the acceptance or rejection of an applicant and the granting or denial of a preference under 24 CFR part 5 must be documented and placed in the applicant's file. The methods of verification and documentation must be specified in writing.

(2) Relevant information to verify with respect to an applicant's qualification may include, but is not limited to:

(i) An applicant's past performance in meeting financial obligations, especially rent; and

(ii) A record of violent criminal activity, drug-trafficking, destruction of property, disturbance of neighbors, or living or housekeeping habits that may adversely affect the health, safety or welfare of others.

(b) *Disabilities.* (1) With respect to applicants claiming that they have a disability, the HA may verify the claim only to the extent necessary to ensure:

(i) That applicants are qualified for the housing for which they are applying;

(ii) That applicants are qualified for the deductions used in determining adjusted income;

(iii) That applicants are entitled to any preference they may claim; and

(iv) That applicants who have requested a reasonable accommodation have a need for the requested accommodation. For purposes of this part, ''reasonable accommodation'' means special action(s) to overcome barriers to equal access in order to provide access to the HA's programs and activities for a person with a disability.

(2) An applicant who does not want to be considered on the basis of a disability does not have to reveal the existence of a disability. The HA may not inquire about a disability if none is revealed by the applicant.

(3) If an applicant does not satisfy the HA's tenant selection criteria because of a disability, the HA must, if requested by the applicant:

(i) Consider whether any mitigating circumstances related to the disability could be verified to explain and overcome the problematic conduct; and

(ii) Make a reasonable accommodation that will allow the applicant to meet the HA's tenant selection criteria.

(c) *Criminal activity.*—(1) *Background check.* The HA must perform a criminal background check of all adult household members to identify any recent history of crimes of physical violence to persons or property and other activities that would adversely affect the health, safety or welfare of others. The type of criminal background check done is within the discretion of the HA. For purposes of this paragraph (c)(1), a criminal background check is accessing an individual's criminal history records from a local, State, or Federal government entity with law enforcement responsibility or with responsibility for maintaining governmental records relating to criminal acts.

(2) *Standard of evidence.* In determining whether to deny admission to a family based on drug-related criminal activity or violent criminal activity, the HA may act where the preponderance of evidence indicates that a family member has engaged in such activity, regardless of whether the family member has been arrested or convicted.

(d) *Documentation of rehabilitation from drug or alcohol abuse.* The HA may require a family member who has engaged in the illegal use of a controlled substance, or in abuse of alcohol that interfered with the health, safety, and peaceful enjoyment of the premises by other residents, to submit evidence of current participation in, or successful completion of, a supervised drug or alcohol rehabilitation program (as applicable) as a condition to admission.

(e) *Treatment of unfavorable information.*—(1) *General.* If unfavorable information is received about an applicant's ability to meet the tenant selection criteria, consideration must be given to mitigating circumstances such as the time, nature, and extent of the applicant's conduct and to factors that in the judgment of the HA indicate a reasonable probability of favorable future conduct.

(2) *Criminal record.* If the unfavorable information is a criminal record, the HA must safeguard the record in accordance with 42 U.S.C. 1437d(q) (4) and must provide the applicant a copy of the record and an opportunity to dispute the accuracy and relevance of the record.

(f) *Final determination.* After appropriate verification, the HA makes the final determination as to whether a claim of mitigating circumstances or a proposed accommodation is sufficient to overcome a failure to meet the HA's tenant selection criteria.

§ 960.207 Communication with applicants.

(a) *Form of communication.* At the initial point of contact with each applicant, the HA must inform the applicant that forms of communication other than standard written communication, such as oral explanation, sign language, large print, audiotape, or braille, can be made available to the applicant, upon request. If the applicant requests that the HA use an alternative form of communication, the HA must use the agreed upon alternative form, in addition to its written communication, until the applicant requests another form of communication or notifies the HA that an alternative form of communication is no longer necessary.

(b) *Notification of denial.* The HA must promptly notify any applicant determined unqualified for admission to a project of the basis for such

determination, and must provide the applicant upon request, within a reasonable time after the determination is made, with an opportunity to meet with a representative of the HA to review the determination. This meeting may be conducted by any person or persons designated by the HA, including the person who made or reviewed the original determination. The notification must inform the applicant of the HA's responsibility to make reasonable accommodation for applicants with disabilities and the applicant's right to propose a reasonable accommodation to enable the applicant to comply with eligibility criteria.

(c) *Notification of acceptance.* When the HA determines that an applicant is qualified for admission, the applicant must be notified of the approximate date of occupancy insofar as that date can be reasonably determined. Notification of the waiting period of similar applicants who are currently being admitted will meet this requirement.

§ 960.208 Rent.

The amount of rent payable by the tenant to the HA is the Tenant Rent, as defined in part 5 of this title.

§ 960.209 Reexamination of family income and composition.

(a) *Regular reexaminations.* When the HA reexamines the income and composition of tenant families in accordance with 24 CFR part 5, subpart F, it must determine whether the family's unit size is still appropriate. In accordance with that rule, after consultation with the family and upon verification of the information, the HA must make appropriate adjustments in tenant rent. See requirements concerning consent forms for income and eligibility requirements (including citizenship or immigration status) in 24 CFR part 5, subparts B and E.

(b) *Interim redeterminations.* The HA must adopt policies prescribing when and under what conditions tenant changes in circumstances must be reported and prescribing the effective date of rent changes resulting from interim redeterminations. The tenants must comply with provisions in the lease regarding interim reporting of changes. If the HA receives information concerning a change in the tenant income or other circumstances between regularly scheduled reexaminations that would require a redetermination under its policy, the HA must consult with the family and make any adjustments determined to be appropriate. Any change in the family's circumstances that results in adjustment in the Tenant Rent must be verified. See 24 CFR part 5 for other applicable requirements. At any interim redetermination when there is a new family member, the HA must follow the requirements of 24 CFR part 5 concerning obtaining and processing information on the citizenship or eligible immigration status of the new family member.

(c) *Termination.* For provisions requiring termination of tenancy for failure to establish citizenship or eligible immigration status, and for provisions concerning assistance to certain mixed families (families whose members include those with citizenship and eligible immigration status and those without eligible immigration status) in lieu of termination of tenancy, see 24 CFR part 5.

§ 960.210 Continued occupancy limits.

(a) *General.* The HA may adopt reasonable income limits for continued occupancy of its dwelling units. The limits must not be less than the low income limit determined by HUD, in accordance with 24 CFR part 5.

(b) *Action based on ineligibility.* No HA may commence eviction proceedings, or refuse to renew a lease, based on the income of the tenant family unless:

(1) It has identified, for possible rental by the family, a decent, safe, and sanitary unit of suitable size available at a rent not exceeding the tenant rent as defined and calculated in accordance with 24 CFR part 5; or

(2) It is required to do so by local law.

Subpart C—Applications, Waiting List, Tenant Selection and Assignment

§ 960.301 Applications.

(a) The HA must have a written application before placing any applicant on the waiting list. The HA must, if requested, provide assistance to the applicant in completing the application.

(b) The application must provide sufficient information to the HA for it to make a preliminary determination of the applicant's eligibility, type and size of dwelling requirement, and rent.

(c) The HA must record the date and time of receipt of all applications and process them centrally.

(d) Unless the waiting list is closed, the HA must give an applicant an opportunity to submit a written application, even if informal discussion suggests that the applicant is not eligible.

§ 960.303 Waiting lists.

See 24 CFR 1.4 for requirements concerning selection of tenants for all of the public housing projects under an HA's jurisdiction from a community-wide waiting list. The HA may divide its waiting list into separate categories for general occupancy projects, for mixed population projects, for projects designated for elderly families, and for projects designated for disabled families, provided that all applicants are given an opportunity to be on the waiting list for any category of project for which they are qualified.

§ 960.304 Tenant selection and assignment.

(a) Assignment of applicants and units must be conducted in accordance with a Tenant Selection and Assignment Plan that meets the requirements of 24 CFR 1.4(b)(2)(ii) and is approved by HUD.

(b) Unit assignments must be in sequence and must be based on the type of project, size and type of unit required, applicable Federal and local preferences, and date and time of application. See 24 CFR 1.4(b)(2) and 24 CFR part 5, subpart D.

(c) The HA may move to the bottom of the waiting list or remove from the waiting list the name of any applicant who refuses more than the number of offers of suitable units prescribed in the HA's plan. The HA may prohibit any applicant whose name was removed in accordance with such a policy from reapplying for a period of time specified in the plan. The number of offers allowed under the plan must not exceed three.

(d) An applicant who is dropped from the waiting list because a disability interfered with the ability to respond to an HA request can be reinstated as a reasonable accommodation.

§ 960.307 Mixed population projects.

(a) For purposes of this section, a ''mixed population project'' is a public housing project, or portion of a project, that either was reserved for elderly families and disabled families at its inception (and has retained that character), or was approved by HUD for preference in tenant selection to elderly families and disabled families.

(b) Elderly families and disabled families must be given a preference over all other applicants for admission to dwelling units in a mixed population project.

(c) Preference must be given to elderly families and disabled families equally in determining priority for admission to mixed population projects. An HA may not establish a limit on the number of elderly families or disabled families who may be accepted for occupancy in a mixed population project.

(d) In offering available units to elderly families and disabled families in

mixed population projects, units with accessible features must be offered first to persons with disabilities who require the accessibility features of the unit in accordance with the requirements of 24 CFR 8.27 and 24 CFR 100.202(c)(3).

(e) If Federal preferences are in effect, elderly families and disabled families who do not qualify for a Federal preference and who are given preference for admission under paragraph (b) of this section over non-elderly families and non-disabled families that qualify for a Federal preference, are not subject to the statutory limitation on admission of families without a Federal preference over families with such a Federal preference that may initially receive assistance in any one-year period.

Subpart D—Exemption From Eligibility Requirements for Police Officers and Other Security Personnel

§ 960.401 Exemption from eligibility requirements.

HUD may exempt officers from the eligibility requirements for admission to public housing, provided that:

(a) The officers would not be eligible, under any other admission requirements or procedures, for admission to the public housing development without such an exemption; and

(b) The exemption is given under a plan, as described in § 960.402, that has been approved by HUD.

§ 960.402 Definitions.

Officer means a professional police officer or other professional security provider. Police officers and other security personnel are considered professional if they are employed full time, i.e., not less than 35 hours per week, by a governmental unit or a private employer and compensated expressly for providing police or security services. As used in this subpart, ''Officer'' may refer to the Officer as so defined or to the Officer and his or her family taken together, depending on the context.

Plan means the written plan submitted by a housing agency (HA) to the Department, under which, if approved, the Department will exempt Officers from the normal eligibility requirements for residence in public housing and allow Officers, who are otherwise not eligible, to reside in public housing units. An HA may have only one plan in effect at any one time, which will govern exemptions under this subpart for all public housing managed by that HA.

§ 960.405 Plan standards and criteria.

(a) *Minimum requirements.* To be approved, a plan must satisfy the following requirements:

(1) The plan must identify the number of units under management by the HA and the number and location of the units the HA intends to use for officers and the amount of rent to be charged and a basis for determining that it is reasonable;

(2) The plan must identify the specific benefits to the community and to the HA that will result from the presence of the officer in each affected development;

(3) The plan must describe the existing physical and social conditions in and around each affected development sufficient for HUD to make an informed assessment of the level of need for increased security; and

(4) The plan will provide information sufficient for HUD to determine that granting an exemption will:

(i) Increase security for other public housing residents;

(ii) Result in a limited loss of income to the HA; and

(iii) Not result in a significant reduction of units available for residence by qualified families.

(b) *Certifications by HA.* The HA must certify that:

(1) The dwelling units proposed to be allocated to officers are situated so as to place the officers in close physical proximity to other residents;

(2) No resident families will have to be transferred to other dwelling units in order to make available the units proposed to be allocated to officers;

(3) The dwelling units proposed to be allocated to officers will be rented under a lease that enforces the provisions of § 960.409; and

(4) The number of dwelling units proposed to be allocated to officers under the plan does not exceed a reasonable number, as determined on the basis of total number of units under management by the HA, in consultation with HUD.

§ 960.409 Special rent requirements and other terms and conditions.

The HA must lease units to officers under a lease agreement that is consistent with the requirements of this section and with part 966 of this chapter. If there is any inconsistency between the requirements of part 966 and this section, the provisions of this section shall govern.

(a) *Reasonable rent.* The lease must provide for a reasonable rent.

(b) *Continued employment.* The lease must provide that the officer's right of occupancy is dependent on the continuation of the employment that qualified the officer for residency in the development under the plan and provide that the officer will move from the unit within a reasonably prompt time, to be established in the lease, after termination of such employment.

§ 960.411 Applicability of the annual contributions contract; effect on the Performance Funding System.

(a) *Annual contributions contract.* Public housing units occupied by Officers in accordance with a plan submitted and approved under this subpart will be subject to the terms and conditions of the annual contributions contract (ACC) between the HA and HUD. This subpart does not override any of the terms and conditions of the ACC except insofar as they are inconsistent with the provisions of this subpart.

(b) *Performance funding system.* For purposes of the operating subsidy under the Performance Funding System (PFS) described in part 990, subpart A, of this chapter, dwelling units allocated to Officers in accordance with this subpart are excluded from the total unit months available, as defined in § 990.102 of this chapter. Also for purposes of the operating subsidy under the PFS, the full amount of any rent paid by Officers in accordance with this subpart is included in other income, as defined in § 990.102 of this chapter. HAs may receive operating subsidy for one unit per housing development to promote economic self-sufficiency services or anti-drug programs, including housing police officers and security personnel. An HA may request consideration of such units in its calculation of operating subsidy eligibility through the appropriate local HUD Office. (See § 990.108(b) of this chapter.)

PART 966—LEASE AND GRIEVANCE PROCEDURES

2. The authority citation for part 966 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437d note, and 3535(d).

3. In § 966.4, paragraph (l)(2) is revised to read as follows:

§ 966.4 Lease requirements.

* * * * *

(l) * * *

(2) *Grounds for termination.* The PHA shall not terminate or refuse to renew the lease other than for serious or repeated violation of material terms of the lease or for other good cause.

(i) *General.* Failure to make payments due under the lease or to fulfill the tenant obligations set forth in § 966.4(f)

would constitute grounds for termination of tenancy.

(ii) *Crime.* (A) At any time, the PHA may terminate the lease if the PHA determines that any family member has engaged in drug-trafficking or violent criminal activity. For purposes of this section, drug-trafficking means the illegal manufacture, sale, or distribution, or the possession with intent to manufacture, sell, or distribute, of a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)). For purposes of this section, violent criminal activity means any illegal criminal activity that has as one of its elements the use, attempted use, or threatened use of physical force against the person or property of another.

(B) The PHA may terminate the lease if the PHA determines that any family member, a guest, or another person under the tenant's control, is engaged in any criminal activity that threatens the health, safety or right of peaceful enjoyment of the PHA's public housing premises by other residents or any drug-related criminal activity.

(iii) *Illegal drug use and alcohol abuse.* (A) The PHA must establish standards for determining whether to terminate program assistance if the PHA determines that:

(*1*) Any family member is illegally using a controlled substance; or

(*2*) A family member's use of a controlled substance or abuse of alcohol interferes with the health, safety, or right to peaceful enjoyment of the premises by other residents.

(B) In determining whether to deny or terminate program assistance for illegal use or pattern of use of a controlled substance or for abuse or pattern of abuse of alcohol by a family member, the PHA may consider whether the person:

(*1*) Is no longer engaging in the illegal use of a controlled substance or in abuse of alcohol (as applicable); or

(*2*) Has successfully completed a supervised drug or alcohol rehabilitation program (as applicable), has otherwise been rehabilitated successfully, or is participating in a supervised drug or alcohol rehabilitation program (as applicable).

(C) The PHA may require a family member who has engaged in the illegal use of a controlled substance, or in alcohol abuse activity that interfered with the health, safety, and peaceful enjoyment of the premises by other residents, to submit evidence of current participation in, or successful completion of, a supervised drug or alcohol rehabilitation program (as applicable) as a condition to being allowed to reside in the unit.

(D) In determining whether to terminate the lease based on drug-related criminal activity or violent criminal activity, the PHA may act when the preponderance of evidence indicates that the person has engaged in such activity, regardless of whether the person has been arrested or convicted.

* * * * *

Dated: April 9, 1997.

Kevin Emanuel Marchman,

Acting Assistant Secretary for Public and Indian Housing.

[FR Doc. 97–12080 Filed 5–8–97; 8:45 am]

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May 9, 1997

Part V

Department of Housing and Urban Development

24 CFR Part 3500

Amendments to Real Estate Settlement Procedures Act Regulation: Exemption for Employer Payments to Employees Who Make Like-Provider Referrals and Other Amendments; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 3500

[Docket No. FR–4173–P–01]

RIN 2502–AG88

Amendments to Real Estate Settlement Procedures Act Regulation: Exemption for Employer Payments to Employees Who Make Like-Provider Referrals and Other Amendments; Proposed Rule

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

ACTION: Proposed rule.

SUMMARY: In this proposed rule, the Department is seeking comments on a new exemption under Regulation X, its regulation implementing the Real Estate Settlement Procedures Act of 1974 (RESPA). The exemption would allow payments by an employer to its own *bona fide* employees for the referral of settlement service business to an affiliated settlement service provider, provided that the settlement service business that is referred is the same category of settlement service as provided by the employer of the employee making the referral, the employee makes the affiliated business arrangement disclosure as provided in 24 CFR 3500.15, and the employee making the referral does not perform any other category of settlement service in the same transaction.

This rule also proposes to implement two amendments to RESPA in recent legislation. One concerns referrals of settlement service business through telemarketing, in writing, or through electronic media. The other concerns mortgage servicing sales or transfers. The rule also describes additional technical corrections and clarifications the Department intends to make at a later date.

DATES: *Comment due date:* July 8, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

The Department also invites interested persons to submit comments on the proposed information collection requirements in § 3500.15(b) of this proposed rule. Comments should refer to the above docket number and title, and should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for HUD, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David R. Williamson, Director, Office of Consumer and Regulatory Affairs, Room 9146, telephone (202) 708–4560; or, for legal questions, Kenneth A. Markison, Assistant General Counsel for GSE/RESPA, Grant E. Mitchell, Senior Attorney for RESPA, or Richard S. Bennett, Attorney, Office of General Counsel, Room 9262, telephone (202) 708–1550. (The telephone numbers are not toll-free.) For hearing- and speech-impaired persons, these numbers may be accessed via TTY (text telephone) by calling the Federal Information Relay Service at 1–800–877–8339. The address for the above-listed persons is: Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410.

SUPPLEMENTARY INFORMATION:

I. Background

In the final rule published on June 7, 1996 (61 FR 29238) entitled ''Amendments to Regulation X, the Real Estate Settlement Procedures Act: Withdrawal of Employer-Employee and Computer Loan Origination Systems (CLOs) Exemptions,'' the Department withdrew a broad exemption for payments by employers to their own employees for any referral activities (24 CFR 3500.14(g)(1)(vii)). In its place, the rule established three narrower exemptions for employer payments to employees: (1) One for managerial employees (§ 3500.14(g)(1)(viii) of the June 7 rule); (2) One for employees who do not perform settlement services in any transaction (§ 3500.14(g)(1)(ix) of the June 7 rule); and (3) A provision clarifying that ''[a] payment by an employer to its own *bona fide* employee for generating business for that employer'' is permissible (§ 3500.14(g)(1)(vii) of the June 7 rule). The rule was to have become effective on October 7, 1996, 120 days from publication. (Note: The June 7 rule was corrected and revised on August 12, 1996 (61 FR 41944).)

Section 2103 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996, (Title II of the Omnibus Consolidated Appropriations Act, 1997) (Pub. L. 104–208; approved September 30, 1996) (the Act) was signed by the President on September 30, 1996. The Act delayed the effective date of the provisions of the Department's June 7, 1996 final RESPA rule concerning payments to employees by their employers to no earlier than July 31, 1997.

Although not required by the Act, on October 4, 1996 (61 FR 51782), the Department delayed temporarily the effective date of the entire June 7 final rule, as corrected and revised on August 12, 1996. The reason for the delay was to provide the Department with an opportunity to analyze the Act and develop an appropriate time schedule for establishing the effective dates of the various provisions of the June 7 rule, as revised August 12.

On November 4, 1996 (61 FR 56624), the Department published another notice in the **Federal Register** announcing that, consistent with the Act, the Department would shortly publish a revised final rule that would make effective those provisions of the June 7 final rule that are unaffected by the delay provisions of the legislation. On November 15, 1996 (61 FR 58472), the Department published a final rule in the **Federal Register** making effective certain portions of the June 7 final rule and August 12 technical revisions that were not delayed by the Act. The November 15, 1996 final rule put into effect those portions of the June 7 final rule dealing with Computer Loan Origination (CLO) Systems. The November 15 final rule thereby effectuated the withdrawal of the CLO exemption and the elimination of the CLO Fee Disclosure form. It also put into effect the revised Appendix D to part 3500 as published August 12, 1996. Further, it made several technical revisions and corrections to Regulation X.

This proposed rule furthers the plans indicated in the November 4, 1996 notice to move forward as expeditiously as possible, subject to the requirements of the Act, to establish new rules addressing employer payments to employees in lieu of the former broad exemption. It also proposes, in conjunction with putting into effect the revisions in the June 7 rule concerning employer payments to employees, to establish a new exemption. This exemption would allow payments by an employer to its own *bona fide* employees for the referral of settlement service business to an affiliated settlement service provider, under the following conditions: (1) The settlement service business that is referred is the same category of settlement service as provided by the employer of the employee making the referral; (2) The employee makes the affiliated business

arrangement disclosure in accordance with 24 CFR 3500.15; and (3) The employee does not perform any other category of settlement service in the same transaction. The Department anticipates that this new exemption will become effective at the same time as the Department makes the changes that were delayed by the Act (i.e., eliminating the exemption for payments by an employer to its employees for referral activities, currently codified as 24 CFR 3500.14(g)(1)(vii), and substituting the more limited exemptions that the June 7 rule would have codified as 24 CFR 3500.14(g)(1)(vii)-(ix))). The Act does not permit the Department to make those changes before July 31, 1997, or to announce an effective date for those provisions more than 180 days before the effective date.

The Department also anticipates making the following technical clarifications and corrections to those provisions of the June 7 rule, as part of the final rule that will make those provisions effective subject to the requirements of the Act:

(1) A technical clarification indicating that under the managerial exemption (§ 3500.14(g)(1)(viii) of the June 7 rule), a manager not routinely performing settlement services may still receive compensation under the exemption if either: (1) The total value of the services provided by the manager does not exceed 5 percent of the annual income to the office or unit for which the manager is responsible attributable to RESPA-covered transactions, *or* (2) the manager performs settlement services in no more than three RESPA-covered transactions.

(2) A technical clarification indicating that in using the term ''in any transaction'' in the exemption for employees who do not perform settlement services (§ 3500.14(g)(1)(ix) of the June 7 rule), the Department did not intend that an employee who has stopped providing settlement services, an employee who changes jobs and no longer provides settlement services, or a new employee is forever prohibited from receiving compensation for referrals.

(3) A technical correction redesignating ''Controlled Business Arrangements'' as ''Affiliated Business Arrangements'' or ''AfBAs,'' reflecting the change in terminology in section 2103(c) of the Act.

(4) A technical correction relating to the timing of providing the AfBA disclosure, to conform the language of the regulation and Appendix B more closely to the statutory language as revised in section 2103(d) of the Act, to provide consistently that the AfBA disclosure statement must be provided in accordance with § 3500.15(b).

This proposed rule also proposes to implement amendments to RESPA contained in the Act. One amendment concerns referrals through telemarketing and electronic media. The other amendment concerns mortgage servicing sales, assignments, or transfers under section 6 of RESPA.

Finally, the proposed rule proposes some changes in response to section 2101 of the Act. In that section, Congress mandated that the Department and the Federal Reserve Board (the Board) work together to ''simplify and improve'' the disclosures given in a mortgage transaction subject to the Truth in Lending Act (TILA) and RESPA, and to create a unified format to satisfy the requirements of both statutes. On December 31, 1996, the Department and the Board published an Advance Notice of Proposed Rulemaking (ANPR) on Improvement of Disclosures Under RESPA and TILA (61 FR 69055), in order to solicit suggestions from the public regarding possible ways to simplify and improve disclosures required under the statutes. The Department received 82 comments from all sectors of the industry in response to the ANPR. The preamble of this rule describes how the Department proposes to incorporate some of the suggestions and recommendations generated by the ANPR into this proposed rule. The Department anticipates that other suggestions could be incorporated into subsequent rulemaking.

The Department believes, however, that significant simplification may only be possible through legislative changes and will work with the Board in making recommendations towards that end. Under the Act, Congress has required that the Department and the Board recommend any legislation that would be necessary to accomplish the objectives of simplifying and improving the disclosures subject to TILA and RESPA. Both agencies are currently considering several approaches to streamlining the disclosure requirements.

II. Proposed Exemption for Like-Provider Referrals

A. Description of Problem

The Department published a proposed rule on July 21, 1994 (59 FR 37360) to revise Regulation X. During the comment period on the Department's July 21, 1994 proposed rule, some commenters raised concern that the Department's proposed withdrawal of the broad exemption for employer payments to employees for referrals and its replacement with narrower exemptions would unduly restrict compensation of bank employees for making referrals to mortgage banking affiliates. A major trade association for the banking industry, for example, raised concern that while a banker could compensate its employee for the referral of mortgage loan business to a mortgage lending division within the bank, a banker would be prohibited from compensating an employee for the referral of a bank customer to a mortgage banking affiliate of the bank or a mortgage banking subsidiary of the parent holding company.

The trade association urged the Department to reconsider making such a distinction in its final rule, arguing that the distinction lacked justification or merit and, in essence, was solely based on the structure of the bank and the location of the mortgage lending function within the banking institution. The trade association explained that the proposed rule would penalize banks, their affiliates, holding companies, boards of directors, officers, and employees solely because of their corporate structures, which ''are specifically authorized by statute, implemented by state or Federal bank regulatory authorities and constantly monitored and examined for safety and soundness and compliance purposes.'' The trade association argued:

> From the consumer's perspective, the location of this mortgage lending activity within the banking institution's family of companies is irrelevant. The consumer's objective is to obtain a mortgage loan. To the consumer and the bank, this is the *business of banking* whether it takes place within the bank or as part of the banking institution's corporate family.

Since the Department's promulgation of its final rule on June 7, 1996, withdrawing the broader exemption and establishing more limited exemptions, similar concerns have been echoed by others. A mortgage lending subsidiary of a diversified financial services company indicated that for various business and regulatory reasons, it offers its services through more than one corporate entity. It argued that bank branch personnel should be able to receive compensation for referring customers who enter the branch and inquire about a first mortgage loan to the mortgage lending subsidiary. It pointed out that there is no danger of adverse steering since the customer is provided the controlled business disclosure (now referred to as the Affiliated Business Arrangement Disclosure Statement or AfBA Disclosure Statement), which alerts the

customer that he or she is dealing with the mortgage lending subsidiary; from the customer's perspective, the loan is still from the bank.

A major bank made essentially the same arguments. It faulted the June 7 rule for failing to accommodate the practice of referral of loan business by a lender to its affiliate. In a letter to the Department, the bank stated:

> We believe that when a consumer comes to [the bank] to inquire about mortgage financing, whether to purchase a home or refinance an existing mortgage, the consumer has come to us because of our name and reputation. Whether contact is made in person at a branch office, by phone, or over the Internet, the consumer expects to learn about [bank] loan products that meet his or her financing needs, regardless of whether such loans are marketed, originated or serviced by different * * * legal entities. It makes little or no difference to our borrowers which * * * subsidiary originates their loans or whether their original contact was a loan officer employed by a different subsidiary. * * *
>
> Without a change to the final rule, we will be forced into a costly reorganization to create a permissible compensation structure. We would either have to staff each branch with one or more mortgage lending division loan officers, or originate and book mortgage loans in each branch where the initial inquiry was made. In either case, any potential economies would be eliminated without adding value or convenience for our customers.

B. Proposed Solution

Under the June 7 rule, if a bank customer asks a loan officer who provides settlement services in any transaction about a type of loan that the bank does not make, but which the bank's affiliate does make, the bank would have been precluded from compensating the loan officer for making the referral to the appropriate affiliate. However, the June 7 rule would have created an exemption to the prohibition against referral fees for employer payments to employees who do not perform settlement services in any transaction and who refer settlement service business to an affiliate, so long as the controlled business arrangement disclosure is provided. Thus, an employee of a bank could have referred a bank customer to a mortgage banking affiliate of the bank or a mortgage banking subsidiary of the parent holding company and could have received referral-based compensation. The only restrictions would have been that the controlled business arrangement disclosure would have to be provided, and, if the employee was to be compensated for the referral, the employee could not be one who performed settlement services in any residential real estate transaction covered by RESPA. (Part V(B) of this preamble discusses the meaning of ''in any transaction.'')

In light of certain of the expressed concerns, the Department is proposing to exercise its exemption authority under RESPA, to add a new exemption to section 8 of RESPA's prohibition against kickbacks and unearned fees. The Secretary has authority to create exemptions under section 19(a) of RESPA for classes of transactions as may be necessary to achieve the purposes of RESPA (12 U.S.C. 2617(a)). In addition, under section 8(c)(5) of RESPA, the Secretary may create regulatory exemptions for ''such other payments or classes of payments,'' after consulting with various Federal agencies (12 U.S.C. 2607(c)(5)). The exemption to be created under this proposed rule, like the exemptions promulgated June 7, would be issued pursuant to the Secretary's clear authority to create reasonable exemptions to further the purposes of RESPA.

Under the proposed exemption, § 3500.14(g)(1) would be amended by adding an exemption for a payment by an employer to its *bona fide* employee for referring settlement service business to a settlement service provider that has an affiliate relationship with the employer, or in which the employer has a direct or beneficial ownership interest of more than 1 percent, if the following conditions are met:

1. The settlement service business that is referred is the same category of settlement service that the employer of the employee making the referral provides;
2. The employee provides to the person being referred the affiliated business arrangement disclosure in accordance with § 3500.15(b); and
3. The employee making the referral does not perform any other category of settlement service in the same transaction.

The rule would specify that, for purposes of this exemption, each paragraph in the definition of ''settlement service'' provided in 24 CFR 3500.2(b) (excluding paragraphs (b)(15) and (b)(16) of that definition), as it is proposed to be revised, constitutes a separate ''category of settlement service.'' Some ''categories of settlement services'' to which this exemption might commonly apply would include originating mortgage loans, providing services involving hazard insurance, and providing title services.

While the rendering of services by a real estate agent or real estate broker is a settlement service (*see* paragraph (b)(15) of the definition of ''settlement service'' in § 3500.2 as proposed to be revised), referrals from one real estate agent or broker to another are generally exempt pursuant to section 8(c)(3) of RESPA (12 U.S.C. 2607(c)(3)) and 24 CFR 3500.14(g)(1)(v) of the RESPA regulations. Because the section 8(c)(3) exemption already exists, the referral of services by a real estate agent or real estate broker to another real estate agent or real estate broker is not included under the new exemption. In addition, real estate agents are usually independent contractors, and thus would not be considered ''employees'' eligible for this exemption for employer payments to employees.

In addition, paragraph (b)(16) of the definition of ''settlement service'' in § 3500.2 as proposed to be revised includes as a settlement service ''other services for which a settlement service provider requires a borrower or seller to pay.'' This catchall, however, is too open-ended to apply to the new exemption proposed. Commenters are encouraged to provide examples of other settlement services that would qualify under paragraph (b)(16). The Department will consider the examples submitted and possibly add them to the list of categories of settlement services enumerated in the definition so that referrals of such services may qualify for the new exemption proposed.

As with the exemptions contained in the June 7 rule, this additional exemption only pertains to *bona fide* employees. Individuals may not be hired on a part-time basis to make referrals because of their access to consumers as settlement service providers and then be compensated for such referrals. Sham employment arrangements are also prohibited. *See* 61 FR 29243 (column 3). Moreover, the exemption does not affect the prohibition in 24 CFR 3500.14(b) against the entity to which business is referred from compensating the affiliate or the employee of the affiliate making the referral.

It is anticipated that when the Department makes this proposed rule final, it will do so in a rule that will also make effective the changes to the exemptions for employer payments to employees as contained in the June 7 rule, subject to any further technical corrections or clarifications to such exemptions that the Department may announce. The language of the June 7 rule and the technical corrections and clarifications are not republished here, since the Department is not requesting comments on them.

C. Questions for Commenters

The Department is particularly interested in comments on the following issues:

1. What potential disadvantages or dangers, if any, would the exemption for employer payments to employees who make like-provider referrals pose for consumers? As summarized above, it has been argued by members of the settlement service industry that in the types of referrals covered by the proposed rule, there is little danger of adverse steering or adverse consequences to customers. However, the Department would like to hear from those with other views, including those with additional bases in support of such an exemption.

2. The Department seeks comments on whether a potential danger is created for consumers that, through the design of compensation systems, the exemption could cause greater steering of consumers to products that are more profitable for the entity making or receiving the referral, but that are not necessarily in the consumer's best interest. For example, a loan officer of a lender that makes home equity loans might receive a $50 bonus for every home equity loan closed. In contrast, the same loan officer might receive a $100 bonus for referring a customer who inquires about a home equity loan to an affiliate of the lender that will refinance the primary mortgage, or $150 if he or she could originate the refinance of the primary mortgage in the name of the affiliate (and do only a minimum of work regarding origination of the loan). Please comment on whether this exemption would create a danger that consumers will be steered for reasons other than what is in their best interest, and if so, how this danger may be lessened or eliminated. Also comment on whether not creating this exemption would create different dangers for consumers, such as situations in which consumers who would benefit from referrals will not be referred because some employees who would be in a position to make referrals would not be compensated for doing so.

3. What are the advantages and disadvantages of limiting the exemption to those employees who do not perform any other category of settlement service in the same transaction, as proposed? Should the Department narrow the exemption by limiting it to those employees who do not perform any settlement service in the same transaction?

4. The Department recognizes that there could be some overlap among the 16 categories in the proposed rule. What refinements of the categories would ensure that the purposes of the exemption are fulfilled? Does the Department's proposal provide adequate guidance as to what is the ''same category of settlement service?'' How could this point be clarified further? What specific categories of settlement services would fall under paragraph (b)(16) of the definition of ''settlement service'' in § 3500.2 (''provision of any other services for which a settlement service provider requires a borrower or seller to pay''), as it is proposed to be revised?

5. Since the concerns which resulted in this proposed new exemption came mainly from lenders, should the Department narrow the scope of the exemption being proposed to apply only to lenders? What problems would other settlement service providers face if the exemption were limited in this fashion?

6. The exemption, as proposed, would not apply in situations in which a bank that does not originate any mortgage loans refers customers seeking mortgage loans to the bank's mortgage lending subsidiary. In such cases, the referring bank does not originate mortgage loans, and thus does not perform settlement service business in the same category as the business being referred. Should the exemption be expanded to allow compensation for such referrals?

III. Referrals Involving Telemarketing and Electronic Media

This proposed rule would revise § 3500.15(b)(1) of the RESPA regulations to conform to changes to RESPA made in section 2103(d) of the Act. Section 2103(d) of the Act primarily amended section 8(c)(4)(A) of RESPA (12 U.S.C. 2607(c)(4)(A)) to establish special procedures for disclosures of affiliated business arrangements in conjunction with referrals in which the telephone or electronic media are used in marketing. The proposed rule would set forth the new provisions regarding the timing of providing the disclosure, the methods of providing the disclosure, and the evidence needed to substantiate that the disclosure was provided.

The proposed rule would, consistent with the Department's prior rules, require that the Affiliated Business Arrangement Disclosure Statement be provided in writing on a separate piece of paper, and in the format set forth in Appendix D to part 3500. In proposing to revise § 3500.15(b)(1) to be consistent with the Act, the Department is also proposing to clarify the required elements of a proper affiliated business disclosure, as provided in Appendix D, which specifically includes the requirement that the disclosure contain an acknowledgement for the person being referred to sign. It also specifies that the person making the referral must request that the person being referred sign the disclosure promptly and return it to the affiliate making the referral or a designated addressee, and must provide information on where to send the signed disclosure.

Consistent with the Act, the proposed rule provides that, in the case of a face-to-face referral or a referral made in writing or by electronic media, the written disclosure must be provided at or before the time of the referral. In the case of a referral made by telephone, an abbreviated verbal disclosure also must be made during the telephone referral that, in clear and understandable language: (1) Specifies the nature of the relationship (explaining the ownership and financial interest) between the entity making the referral and the entity performing settlement services (or business incident thereto); (2) explains that because of this relationship, this referral may provide a financial or other benefit to the referring party; (3) states that the existence of this relationship does not require that the person being referred use the provider to whom he or she is being referred as a condition of settlement of the loan, or purchase, sale, or refinance of the property, as applicable; and (4) advises that a written disclosure will be provided within 3 business days. Different timing provisions for providing the written disclosure are contained in § 3500.15(b)(2) (iii)–(iv) of this proposed rule. These exceptions, which are simply a continuation of exceptions contained in prior rules regarding provision of such disclosure, involve referrals by a lender and situations involving an attorney or law firm that requires a client to use a particular title insurance agent or company.

Consistent with the Act, in all cases the person being referred must sign the disclosure. The person being referred should sign the disclosure at the time that the disclosure is provided. If the person being referred chooses not to sign the disclosure at the time that the disclosure is provided, the signature of the person being referred must be obtained at or before closing or settlement.

The proposed rule also provides that if a notation was made at the time that the disclosure was provided, in a written, electronic, or similar system of records maintained in the regular course of business, that notation may be used as evidence that the disclosure was provided at the time of the referral. Such a notation is to include a statement that the person being referred

chose not to sign the disclosure at the time that it was provided. The existence of such a notation, however, does not substitute for obtaining a signature at or before closing or settlement. In the case of a face-to-face referral, if the person being referred chooses not to sign the disclosure at the time that the disclosure is provided, such notation is mandatory.

IV. Sales or Transfers of Mortgage Servicing

This proposed rule also proposes to revise the RESPA regulations to reflect an amendment to section 6 of RESPA, set forth in section 2103(a) of the Act. Section 6(a), as amended, requires disclosure to applicants regarding the possibility of the assignment, sale, or transfer of the rights to service the applicant's federally related mortgage loan. Prior to the amendment, section 6 also provided that an applicant for a mortgage loan had to be provided a disclosure of the lender's historical practice in assigning, selling, and transferring servicing of loans, or, as an alternative to providing the historical data, a statement that the lender had previously sold servicing. A signed acknowledgment of receipt of the disclosure statement was also required in the applicant's loan file. The Act eliminates the historical data provisions and the acknowledgment requirement.

This proposed rule would implement the statutory amendment by striking language in § 3500.21 to make it consistent with the statutory amendment. The rule proposes to revise Appendix MS–1 to part 3500, the model Servicing Disclosure Statement format, to conform to the amendment. This proposed rule recognizes that certain entities do not undertake loan servicing and, therefore, transfer servicing before the first payment is due; the disclosure format may so state. The disclosure format in its revised form would be published in the Code of Federal Regulations for the convenience of compliance by affected parties. In response to comments received pursuant to the ANPR urging the Department to consolidate the Mortgage Servicing Disclosure with other RESPA forms, the proposed rule furthers section 2101 of the Act by proposing to clarify that the format language may also be included as part of the Good Faith Estimate.

The Department is interested in comments addressing alternative approaches to implementing the statutory language while protecting consumers. In connection with the report to Congress which the Department is developing pursuant to section 2101 of the Act, which will contain the Department's recommendations for statutory amendments, the Department is also considering whether the disclosure might be combined with other RESPA or Truth In Lending Act (TILA) disclosures, consistent with section 2101 of the Act. In addition, if commenters propose that the Department should continue to require more information in the disclosure than in the format proposed, they should address what the Department's authority to do so would be in light of the statutory amendment in section 2103(a) of the Act.

In a related matter, section 2103(e) establishes a 3-year limitation on the time aggrieved borrowers or classes of borrowers could bring actions under section 6 of RESPA. Inasmuch as this limitation is longer than the statute of limitations for other actions by individuals under RESPA (1 year), a new paragraph (f)(1)(iv) would be added to § 3500.21 of the regulations to highlight this provision.

V. Additional Technical Corrections and Clarifications Contemplated

In addition to the proposed revisions described in the preceding portions of this preamble, the Department intends that when it makes effective the provisions of the June 7 rule amending RESPA regulations concerning employer payments to employees, the Department will make further technical corrections and clarifications to the June 7 rule. While these technical corrections and clarifications are described below for informational purposes, the text is not published here, since the Department is not requesting comments on them.

A. Routine Dealing

The Department has been asked about language in the preamble and in Appendix B, ''Illustrations of the Requirements of RESPA,'' regarding the definition of a managerial employee as an ''employee * * * who does not routinely deal directly with consumers * * *.'' This definition applies to the exemption for employer payments to managerial employees (§ 3500.14(g)(1)(viii) of the June 7 rule). In the preamble to the Department's June 7, 1996 rule (61 FR 29245; bottom of middle column) the Department stated, ''HUD intends this phrase ('does not routinely') to allow a managerial employee who performs and is compensated for occasional settlement services (not more than three transactions a year) to be eligible for the exemption.'' The last sentence of Appendix B, illustration 12 of the June 7 rule also contained a statement referring to this three-transaction guideline.

Following publication of the June 7 rule, the Department has found that setting as a guide a fixed, maximum number of transactions for all managers under the Department's rule would unduly interfere with the functioning of offices. Roles and functions are not rigidly specified and because of departures, absences for illnesses, or other reasons, a manager may be called upon to complete transactions in process or otherwise become involved in troublesome transactions, in addition to any personal transactions the manager might otherwise undertake. Accordingly, the Department agrees that a manager who does not routinely deal with the public may perform greater than three transactions and still remain eligible for the managerial exemption. A more appropriate guideline is that a manager not routinely performing settlement services may still receive compensation under the exemption if either: (1) the total value of the services provided by the manager does not exceed 5 percent of the annual income to the office or unit for which the manager is responsible attributable to RESPA-covered transactions, *or* (2) the manager performs settlement services in no more than three RESPA-covered transactions.

In publishing the final rule, the Department will clarify this point.

B. In Any Transaction

The final rule will put into effect the exemption promulgated in the June 7 rule to the otherwise applicable prohibition against kickbacks and unearned fees. The exemption applies in affiliate relationships and allows payments made to employees who do not perform settlement services ''in any transaction'' and who provide the disclosure statement (24 CFR 3500.14(g)(1)(ix)). The use of the term ''in any transaction'' has created concern for some affiliated settlement service providers regarding the breadth of the restriction.

The Department sought to provide this exemption to those who were not currently involved in the provision of settlement services. Therefore, when the Department puts this exemption into effect in the final rule, it will clarify that it does not intend, by the use of the term ''in any transaction,'' that if an employee performs settlement services one time in his or her life, he or she shall forever lose the ability to receive payments pursuant to this exemption. Rather, in publishing the final rule the Department will clarify that it intends the ''in any transaction'' language to

allow an employee who has performed settlement services in the past to qualify for the exemption in any of the following types of circumstances:

1. *No longer providing settlement services.* This type of circumstance involves an employee who has not performed settlement services for his or her current employer (in the same job position) in any transaction for 1 year or more. *OR*

2. *An employee who changes jobs.* This type of circumstance involves an employee who performed settlement services for his or her employer in the past but, although still employed by the same employer, changes jobs so that he or she no longer holds the former position and does not perform settlement services in the new position. *OR*

3. *A new employee.* This type of circumstance involves an employee who performed settlement services for another employer on a past job, but no longer holds that job or works for that employer, and does not perform settlement services on his or her current job for the new employer.

In publishing the final rule the Department also will clarify that, as explained in the preamble to the June 7 rule (61 FR 29243), under all these circumstances, the employment relationship must be *bona fide* and not a sham designed to facilitate kickbacks among affiliated companies. Otherwise, the exemption will not apply.

C. ''Affiliated Business Arrangement''

The Department will make a technical correction required by an amendment to RESPA in section 2103(c) of the Act. That legislation redesignated ''Controlled Business Arrangements'' as ''Affiliated Business Arrangements'' or ''AfBAs.'' The final rule will incorporate into the RESPA rules the term ''affiliated business arrangement'' instead of the term ''controlled business arrangement'' used in the June 7 rule, completing the process of changing the terminology begun in the November 15, 1996 rule (61 FR 58472).

D. Timing of Affiliated Business Arrangement Disclosure

The Department will make a technical correction relating to the timing of providing the AfBA disclosure. The June 7 rule used inconsistent language to describe when the disclosure was to be provided. (*See* 24 CFR 3500.14(g)(1)(ix)(A)(2) (''before the referral''); 24 CFR 3500.15(b)(1) (''prior to the referral,'' ''no later than the time of each referral,''); Appendix B, illustration 11 (''at or before the time that the referral is made''); Appendix B, illustration 12 (''at the time of the referral'').) The Department will conform the language of the regulation and Appendix B more closely to the statutory language as revised in section 2103(d) of the Act, to provide consistently that the AfBA disclosure statement must be provided in accordance with § 3500.15(b).

Section 3500.15(b) sets forth the applicable time frames for providing the disclosure. This provision requires, in the case of a face-to-face referral or a referral made in writing or by electronic media, providing a written disclosure at or before the time of the referral, except in cases of a referral by a lender or situations involving an attorney or law firm that requires a client to use a particular title insurance agent. In the case of a telephone referral, a written disclosure must be provided within 3 business days after the referral by telephone and an abbreviated verbal disclosure must be made during the telephone referral. The change that will be included in the final rule will eliminate the use of inconsistent terminology and will conform the description of the timing for providing the disclosure to be consistent with section 8(c)(4) of RESPA, as amended by section 2103(d) of the Act.

Findings and Certifications

Executive Order 12866

The Office of Management and Budget (OMB) reviewed this proposed rule under Executive Order 12866, *Regulatory Planning and Review*, issued by the President on September 30, 1993. OMB determined that this rule is a ''significant regulatory action,'' as defined in section 3(f) of the Order (although not economically significant, as provided in section 3(f)(1) of the Order). Any changes made in this rule subsequent to its submission to OMB are identified in the docket file, which is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC.

Paperwork Reduction Act

The information collection requirements contained in § 3500.15(b) prior to this proposed rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), and assigned OMB control number 2502–0516. In securing that approval, the Department had estimated that the annual reporting and recordkeeping hour burden would be 240,000 hours (2.4 million annual responses at 6 minutes per response). The provisions of § 3500.15(b) of this proposed rule regarding the Affiliated Business Arrangement Disclosure would simply clarify the timing and the methods of providing the disclosure, and the evidence needed to substantiate that the disclosure was provided, in circumstances in which the referral is made over the telephone or through electronic media. The Department does not anticipate that the provisions of § 3500.15(b) of this proposed rule will increase the number of annual burden hours described above. The Department has, however, submitted the information collection requirements in § 3500.15(b) of this proposed rule to OMB for review under the Paperwork Reduction Act and the procedures set forth in 5 CFR part 1320. As required by the Paperwork Reduction Act, interested persons are invited to submit comments according to the instructions in the **DATES** and **ADDRESSES** sections in the preamble of this proposed rule. The Department specifically requests comments on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;

(2) The accuracy of the Department's estimate of the burden of the proposed collection of information;

(3) How to enhance the quality, utility, and clarity of the information to be collected; and

(4) How to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

The information collection requirements in § 3500.21 of this proposed rule also have been approved by OMB, and assigned OMB control number 2502–0458. The rule does not propose to make changes to the information collection requirements set forth in § 3500.21. The rule proposes to make changes to the Servicing Disclosure Statement format described in this section, but this format is a model format and is not required to be used. The OMB approval number for this section is also in the process of being renewed in accordance with the procedures set forth in OMB's regulations implementing the Paperwork Reduction Act of 1995 and codified at 5 CFR part 1320.

Environmental Impact

In accordance with 24 CFR 50.19(c)(1) of the Department's regulations, published in a final rule on September 27, 1996 (61 FR 50914), this proposed rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate property acquisition, disposition, lease, rehabilitation, alteration, demolition, or new construction, or set out or provide for standards for construction or construction materials, manufactured housing, or occupancy. Therefore, this proposed rule is categorically excluded from the requirements of the National Environmental Policy Act.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed rule before publication and by approving it certifies that this rule would not have a significant economic impact on a substantial number of small entities, other than those impacts specifically required to be applied universally by the RESPA statute. In this proposed rule, the Department strives to provide flexible requirements in order to reduce any burden on small entities.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that the policies contained in this proposed rule would not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. As a result, the proposed rule is not subject to review under the Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4; approved March 22, 1995) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and the private sector. This rule does not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects in 24 CFR Part 3500

Condominiums, Consumer protection, Housing, Mortgages, Mortgage servicing, Reporting and recordkeeping requirements.

Accordingly, for the reasons set out in the preamble, part 3500 of Title 24 of the Code of Federal Regulations is proposed to be amended as follows:

PART 3500—REAL ESTATE SETTLEMENT PROCEDURES ACT

1. The authority citation for 24 CFR part 3500 continues to read as follows:

Authority: 12 U.S.C. 2601 *et seq.*; 42 U.S.C. 3535(d).

2. In § 3500.2, paragraph (b) is amended by revising the definition of ''*Settlement service*'' to read as follows:

§ 3500.2 Definitions.

* * * * *

(b) * * *

Settlement service means any service provided in connection with a prospective or actual settlement, including any one or more of the following:

(1) Origination of a federally related mortgage loan (including, but not limited to, the taking of loan applications, loan processing, and the underwriting and funding of such loans), or rendering of services by a mortgage broker (including counseling, taking of applications, obtaining verifications and appraisals, and other loan processing and origination services, and communicating with the borrower and lender);

(2) Provision of title services, including title searches, title examinations, abstract preparation, insurability determinations, and the issuance of title commitments and title insurance policies;

(3) Rendering of services by an attorney;

(4) Preparation of documents, including notarization, delivery, and recordation;

(5) Rendering of credit reports;

(6) Rendering of appraisals;

(7) Rendering of inspections, including inspections required by applicable law or any inspections required by the sales contract or mortgage documents prior to transfer of title;

(8) Conducting of settlement by a settlement agent and any related services;

(9) Provision of services involving mortgage insurance;

(10) Provision of services involving hazard or other casualty insurance;

(11) Provision of services involving flood insurance;

(12) Provision of services involving homeowner's warranties;

(13) Provision of services involving mortgage life, disability, or similar insurance designed to pay a mortgage loan upon disability or death of a borrower, but only if such insurance is required by the lender as a condition of the loan;

(14) Provision of services involving real property taxes or any other assessments or charges on the real property;

(15) Rendering of services by a real estate agent or real estate broker; and

(16) Provision of any other services for which a settlement service provider requires a borrower or seller to pay.

* * * * *

3. Section 3500.14 is amended by adding and reserving new paragraphs (g)(1)(viii) and (g)(1)(ix), and by adding a new paragraph (g)(1)(x), to read as follows:

§ 3500.14 Prohibition against kickbacks and unearned fees.

* * * * *

(g) * * *

(1) * * *

(viii) [Reserved]

(ix) [Reserved]

(x)(A) A payment by an employer to its *bona fide* employee for the referral of settlement service business to a settlement service provider that has an affiliate relationship with the employer or in which the employer has a direct or beneficial ownership interest of more than 1 percent, if the following conditions are met:

(*1*) The settlement service business that is referred is the same category of settlement service that the employer of the employee making the referral provides;

(*2*) The employee provides to the person being referred the affiliated business arrangement disclosure in accordance with § 3500.15; and

(*3*) The employee making the referral does not perform any other category of settlement service (including a service described by paragraph (b)(15) or (b)(16) of the definition of ''*Settlement service*'' in § 3500.2(b)) in the same transaction.

(B) For purposes of this paragraph (g)(1)(x), each service described in the definition of ''*Settlement service*'' in § 3500.2 (b)(1) through (b)(15) constitutes a different category of settlement service that may qualify for this exemption.

* * * * *

4. Section 3500.15 is amended by revising paragraph (b)(1); by redesignating paragraphs (b)(2) and (b)(3) as paragraphs (b)(5) and (b)(6), respectively; and by adding new paragraphs (b)(2) through (b)(4); to read as follows:

§ 3500.15 Affiliated business arrangements.

* * * * *

(b) * * *

(1) The person making a referral provides to each person being referred a written disclosure on a separate piece of paper, in the format of the Affiliated Business Arrangement Disclosure Statement set forth in Appendix D to this part. The person making the referral must request that the person being referred sign the disclosure promptly and return it to the affiliate making the referral or a designated addressee, and must provide information on where to send the signed disclosure. The disclosure shall:

(i) Specify the nature of the relationship (explaining the ownership and financial interest) between the person performing settlement services (or business incident thereto) and the person making the referral;

(ii) Describe the estimated charge or range of charges (using the same terminology, as far as practical, as Section L of the HUD–1 or HUD–1A settlement statement) generally made by the provider of settlement services; and

(iii) Include an acknowledgement for the person being referred to sign.

(2) The person making the referral shall provide the disclosure in accordance with the following timetable:

(i) In the case of a face-to-face referral or a referral made in writing or by electronic media, at or before the time of the referral, except as provided in paragraph (b)(2)(iii) or (b)(2)(iv) of this section;

(ii) In the case of a referral made by telephone, within 3 business days after the referral by telephone, except as provided in paragraph (b)(2)(iii) or (b)(2)(iv) of this section. In the case of a referral made by telephone, an abbreviated verbal disclosure also must be made during the telephone referral that, in clear and understandable language:

(A) Specifies the nature of the relationship (explaining the ownership and financial interest) between the entity making the referral and the entity performing settlement services (or business incident thereto);

(B) Explains that because of this relationship, this referral may provide a financial or other benefit to the referring party;

(C) States that the existence of this relationship does not mean that the person being referred must use the provider to whom he or she is being referred as a condition of settlement of the loan, or purchase, sale, or refinance of the property, as applicable; and

(D) Advises that a written disclosure will be provided within 3 business days.

(iii) In the case of a referral by a lender (including a referral by a lender to an affiliated lender) the disclosure may be provided at the time that the good faith estimate required under section 5(c) of RESPA (12 U.S.C. 2604) is provided.

(iv) In the case of an attorney or law firm that requires a client to use a particular title insurance agent, the attorney or law firm shall provide the written disclosure no later than the time the attorney or law firm is engaged by the client.

(3)(i) *Signature.* In all cases, the person being referred must sign the disclosure. The person being referred should sign the disclosure at the time that the disclosure is provided. If the person being referred chooses not to sign the disclosure at the time that the disclosure is provided, the signature of the person being referred must be obtained at or before closing or settlement.

(ii) *Other evidence of compliance.* The existence of a notation having been made, at the time that the disclosure was provided, in a written, electronic, or similar system of records maintained in the regular course of business, which includes a notation of the fact that the person being referred chose not to sign the disclosure at the time that it was provided, may be used as evidence that the disclosure was provided at the time of the referral, but does not substitute for obtaining a signature in accordance with paragraph (b)(3)(i) of this section. In the case of a face-to-face referral, if the person being referred chooses not to sign the disclosure at the time that the disclosure is provided, such notation is mandatory.

(4) Failure to comply with the disclosure requirements of this section may be overcome if the person making a referral can prove by a preponderance of the evidence that procedures reasonably adopted to result in compliance with these conditions have been maintained and that any failure to comply with these conditions was unintentional and the result of a *bona fide* error. An error of legal judgment with respect to a person's obligations under RESPA is not a *bona fide* error. Administrative and judicial interpretations of section 130(c) of the Truth in Lending Act (15 U.S.C. 1640(c)) shall not be binding interpretations of the preceding sentence or section 8(d)(3) of RESPA (12 U.S.C. 2607(d)(3)).

* * * * *

5. Section 3500.21 is amended by revising paragraphs (b) and (c); and by adding a new paragraph (f)(1)(iv); to read as follows:

§ 3500.21 Mortgage servicing transfers.

* * * * *

(b) *Servicing Disclosure Statement; Requirements.* (1) At the time an application for a mortgage servicing loan is submitted, or within 3 business days after submission of the application, the lender, mortgage broker who anticipates using table funding, or dealer who anticipates a first lien dealer loan shall provide to each person who applies for such a loan a Servicing Disclosure Statement. A format for the Servicing Disclosure Statement appears as Appendix MS–1 to this part. The specific language of the Servicing Disclosure Statement is not required to be used, and the statement may be included in the Good Faith Estimate required under § 3500.7(a), so long as the title ''SERVICING DISCLOSURE STATEMENT'' is used. The information set forth in ''Instructions to Preparer'' on the Servicing Disclosure Statement need not be included with the information given to applicants, and material in square brackets is optional or alternative language. The model format may be annotated with additional information that clarifies or enhances the model language. The lender, table funding mortgage broker, or dealer should use the language that best describes the particular circumstances.

(2) The Servicing Disclosure Statement must indicate whether the servicing of the loan may be assigned, sold, or transferred to any other person at any time while the loan is outstanding. If the lender, table funding mortgage broker, or dealer in a first lien dealer loan does not engage in the servicing of any mortgage loans, the disclosure may consist of a statement that such entity intends to assign, sell, or transfer servicing of the loan before the first loan payment is due.

(c) *Servicing Disclosure Statement; Delivery.* The lender, table funding mortgage broker, or dealer that anticipates a first lien dealer loan shall deliver Servicing Disclosure Statements to each applicant for a mortgage servicing loan at the time of application, or by placing it in the mail with prepaid first-class postage within 3 business days from receipt of the application. In the event the borrower is denied credit within the 3-business day period, no servicing disclosure statement is required to be delivered. If co-applicants indicate the same address on their application, one copy delivered to that address is sufficient. If different addresses are shown by co-applicants on the application, a copy must be delivered to each of the co-applicants.

* * * * *

(f) * * *

(1) * * *

(iv) *Limitation on time of action.* Any action pursuant to this section must be brought within 3 years from the date of the occurrence of the violation.

* * * * *

6. Appendix B to part 3500 is amended by adding a new illustration 15 at the end of the appendix, to read as follows:

Appendix B to Part 3500—Illustrations of Requirements of RESPA

* * * * *

15. *Facts:* A, a bank, is affiliated with, B, a mortgage banking company. A customer walks into the bank, A, and asks F, A's loan officer, about getting a mortgage loan to purchase a house. While A makes home equity loans, A does not make first mortgage loans. Thus, F refers the customer to B, the mortgage banking affiliate, takes an application, and provides the customer with the affiliated business arrangement disclosure statement. F receives a payment from his employer, A, for making the referral. F does not perform any other category of settlement service in this transaction.

Comments: Under § 3500.14(g)(1)(x), employers may pay their own *bona fide* employees for the referral of settlement service business to a settlement service provider that has an affiliate relationship with the employer or in which the employer has a direct or beneficial ownership interest of more than 1 percent, if the following conditions are met:

(1) The settlement service business that is referred is the same category of settlement service that the employer of the employee making the referral provides;

(2) The employee provides to the person being referred the affiliated business arrangement disclosure in accordance with § 3500.15; and

(3) The employee making the referral does not perform any other category of settlement service in the same transaction.

Employees who perform settlement services in other transactions may still qualify for the exemption.

In this case, the settlement service business that is referred is originating a mortgage loan, and the business entity for which the employee works also provides this service. Thus, the same category of settlement service is being referred as is performed by the employer of the employee making the referral. (Categories of settlement services that may qualify for this exemption are listed in the definition of ''*Settlement services*'' in § 3500.2 (b)(1) through (b)(15).) Also, the employee provides the affiliated business disclosure in accordance with § 3500.15. While this particular employee takes an application, he does not perform any other category of settlement service in this transaction.

Thus, in the circumstances described, the employee may receive the referral fee for making the referral without violating RESPA.

7. Appendix MS–1 to part 3500 is revised to read as follows:

BILLING CODE 4210–27–P

APPENDIX MS-1 TO PART 3500

[Sample language; use business stationery or similar heading]

[Date]

SERVICING DISCLOSURE STATEMENT

NOTICE TO FIRST LIEN MORTGAGE LOAN APPLICANTS: THE RIGHT TO COLLECT YOUR MORTGAGE LOAN PAYMENTS MAY BE TRANSFERRED.

You are applying for a mortgage loan covered by the Real Estate Settlement Procedures Act (RESPA) (12 U.S.C. Sec. 2601 et seq.). RESPA gives you certain rights under Federal law. This statement tells you what the chances are that the servicing for this loan may be transferred to a different loan servicer. "Servicing" refers to collecting your principal, interest and escrow account payments, if any. You will be given advance notice before a transfer occurs.

Servicing Transfer Information

[We may assign, sell or transfer the servicing of your loan while the loans is outstanding.]

[or]

[We do not service mortgage loans. We intend to assign, sell or transfer the servicing of your mortgage loan before the first payment is due.]

[INSTRUCTIONS TO PREPARER: Insert the date and select the appropriate language under "Servicing Transfer Information." The model format may be annotated with further information that clarifies or enhances the model language.]

Dated: February 13, 1997.

Nicolas P. Retsinas,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 97–12081 Filed 5–8–97; 8:45 am]

BILLING CODE 4210–27–C

federal register

Friday
May 9, 1997

Part VI

Postal Service

39 CFR Part 111

Experimental Nonletter-Size Business Reply Mail Categories and Fees; Implementation Standards; Changes in Domestic Classifications and Fees; Final Rule and Notice

POSTAL SERVICE

39 CFR Part 111

Experimental Nonletter-Size Business Reply Mail Categories and Fees; Implementation Standards

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This final rule sets forth the Domestic Mail Manual (DMM) standards adopted by the Postal Service to implement the Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees, Docket No. MC97–1.

Over a 2-year period, the Postal Service plans to study the effect of these experimental business reply mail (BRM) categories and fees as related to a controlled number of recipients of nonletter-size BRM. The nonletter-size BRM pieces in the experiment are expected to contain nonhazardous products that are typically received by firms such as medical diagnostic and pharmaceutical companies, medical supply houses, film processing companies, market research companies, and greeting card companies.

EFFECTIVE DATE: June 8, 1997.

FOR FURTHER INFORMATION CONTACT: Neil Berger, (202) 268–2859, or Michael T. Tidwell, (202) 268–2998.

SUPPLEMENTARY INFORMATION:

The Postal Service will review applications and select as many as 20 mailers to participate in the experiment. It is hoped that the BRM received by the participants will represent a diverse range of products returned by BRM. The limitation on the number of participants reflects a balance between the need to conduct an experiment that can be managed effectively with the need to collect sufficient data to ensure meaningful results.

Selection of experiment participants depends on various criteria such as mail volume, product type and packaging, geographic location, ability to implement and maintain quality control procedures for accounting and documentation, and availability of postal resources. A prospective participant should be able to participate for at least 1 year and, if selected, begin within a short period of time. Only two methods of counting the returned nonletter-size BRM pieces will be tested as part of this experiment: reverse manifesting and weight averaging.

As part of this 2-year study, participants will be charged lower per piece BRM fees for qualifying pieces as follows:

- For participants using the weight averaging method, the per piece fee is 3 cents plus the appropriate First-Class Mail (or Priority Mail) postage.
- For participants using the reverse manifesting method, the per piece fee is 2 cents plus the appropriate First-Class Mail (or Priority Mail) postage.

Participants must pay an annual business reply mail permit fee and an annual business reply mail advance deposit accounting fee, which are currently $85 and $205, respectively. A one-time set-up/qualification fee of $1,000 will be charged to participants using the reverse manifesting method. A one-time set-up/qualification fee of $3,000 will be charged to participants using the weight averaging method. In addition, there will be a monthly audit and maintenance fee of $1,000 for participants using the reverse manifesting method and a monthly fee of $3,000 for participants using the weight averaging method.

Background

On December 13, 1996, pursuant to its authority under 39 U.S.C. 3621, *et seq.*, the Postal Service filed with the Postal Rate Commission (PRC) a Request for a Recommended Decision on experimental classifications and fees for specific types of nonletter-size business reply mail. The PRC designated the filing as Docket No. MC97–1 and published a notice of the filing, with a description of the Postal Service's proposals, on December 24, 1996, in the **Federal Register** (61 FR 67860–67862).

The Postal Service's Request to the PRC proposed that the Postal Service be permitted to establish new classifications and fees for nonletter-size business reply mail (BRM) on an experimental basis. The Postal Service proposed that these experimental BRM categories be put into effect for 2 years to provide sufficient time to determine the costs associated with the categories and the feasibility of implementing the experimental BRM categories on a permanent basis.

Manual BRM Verification Method

The manual counting, weighing, rating, and billing for incoming nonletter-size BRM at delivery post offices is a labor-intensive and time-consuming task usually performed by postage due unit employees. These postal employees must weigh and rate each piece and calculate the appropriate postage and fees.

This manual process frequently takes place during a short period between the arrival of the BRM at the postage due unit and the arrival of the BRM recipient at the post office to pick up the mail. Depending on mail volume, the necessary accounting sometimes delays the release and delivery of the mail. Such delays can adversely affect the recipient's ability to meet customer fulfillments expeditiously.

Alternative Verification Methods

Some BRM recipients of large volumes of incoming nonmachinable BRM and local postal officials have developed alternative accounting methods that allow the recipients to take custody of their incoming mail sooner than mail manually weighed and rated on a piece-by-piece basis by the Postal Service.

In some situations, these methods also make it less expensive for the Postal Service to determine the postage and fees. Two alternative accounting procedures, known as reverse manifesting and weight averaging, have been used for these purposes.

As a rule, these alternative methods reduce postal workhours, provide more expeditious accounting, allow for earlier delivery of BRM pieces, and increase recipient satisfaction with BRM service. The experience of the Postal Service with these two methods has been limited.

Review of these two methods has shown that the Postal Service should not permanently extend them to other BRM recipients until suitable and uniform standards are developed and the associated Postal Service costs are more fully documented.

Experimental Use of Alternative Methods

On an experimental basis, the Postal Service proposed using these two alternative accounting procedures for processing large volumes of incoming nonletter-size BRM that, in contrast to letter-size BRM handled through the Business Reply Mail Accounting System (BRMAS), cannot be distributed on automated mail processing equipment.

In consideration of these cost-saving accounting methods, the Postal Service proposed an experimental 2-cent per piece fee, in addition to the appropriate postage, for nonletter-size pieces using the reverse manifesting method and an experimental 3-cent per piece fee, in addition to the appropriate postage, for nonletter-size pieces using the weight averaging method.

The Postal Service expects that establishing either method for a BRM permit account requires periodic

sampling, auditing, and monitoring of the permit holder's operations. As a consequence, this added administrative overhead will generate extraordinary postal costs beyond the current $85 annual BRM permit fee and $205 annual BRM advance deposit accounting fee.

To recover these extraordinary costs, the Postal Service has adopted the following additional experimental fees:

- A one-time set-up/qualification fee of either $1,000 for the reverse manifesting method or $3,000 for the weight averaging method.
- A $1,000 monthly maintenance fee for accounts using the reverse manifesting method and $3,000 for accounts using the weight averaging method.

Data Collection and Analysis

This experiment should give the Postal Service an opportunity to develop sampling, accounting, auditing, and monitoring procedures that meet acceptable standards of revenue protection. At the same time, the experiment should help the Postal Service determine the type of requirements that mailers must meet for their nonletter-size BRM to be accounted for using these alternative methods.

The experiment will permit the Postal Service to evaluate more precisely the costs of the reverse manifesting and weight averaging methods. This evaluation can be achieved with the collection of data that represents a cross-section of recipients of nonletter-size BRM. These data will help the Postal Service assess the market for and potential financial impact of any permanent classification change.

The Postal Service plans to select no more than 20 applicants to participate in the experiment, with as many as 10 selected applicants using reverse manifesting, and up to 10 applicants using weight averaging. The experiment has been authorized for a 2-year duration. The objectives of the experiment are as follows:

- To collect sufficient data for analyzing operational procedures, associated costs, and market research.
- To gauge and compare the costs and benefits of the two alternative methods: reverse manifesting and weight averaging.

Selection Process for Participants

A mailer who wants to participate in the nonletter-size BRM experiment must submit a written request to: Manager, Classification and Product Development, Postal Service Headquarters, 475 L'Enfant Plaza SW, Room 6630, Washington, DC 20260–2453. The request must include sufficient data to assist in making an initial determination.

Consideration is given to product type, geographic location, variability in the weight and daily volume of BRM, current accounting and quality control procedures, and availability of postal resources. In selecting participants, the manager of Classification and Product Development also uses the following criteria:

- The applicant must receive at one site a yearly average of several hundred thousand nonletter-size BRM pieces eligible for the current $0.10 per piece fee.
- The applicant must be able to participate in the experiment for at least 1 year.
- The applicant must be prepared to begin operation at a mutually agreed-upon time after selection.

If the manager of Classification and Product Development determines that the applicant is suitable for participation, the applicant is instructed to follow the appropriate application procedures for authorization as described in Domestic Mail Manual G092 and published in this final rule. If the manager of Classification and Product Development determines that the applicant is not suitable, that manager sends the applicant a written notice explaining the reasons for the determination and, if appropriate, requests additional information for further review.

Decisions of the manager of Classification and Product Development may be appealed to the BRM Experiment Review Board, Postal Service Headquarters, 475 L'Enfant Plaza SW, Room 6630, Washington DC 20260–2453. Appeals must include sufficient information to assist the Review Board in reconsideration of initial determinations. Decisions of the Review Board are final.

Implementation

Pursuant to 39 U.S.C. 3624, the PRC on April 2, 1997, issued to the Governors of the Postal Service its Recommended Decision on the Postal Service's Request. The PRC recommendation followed the mail classification structure and fees requested by the Postal Service.

After reviewing the PRC's Recommended Decision and its consequences for the Postal Service and postal customers, the Governors, pursuant to 39 U.S.C. 3625, acted on the PRC's recommendations on May 6, 1997. Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees, Docket No. MC97–1.

The Governors determined to approve the PRC's recommendations, and the Board of Governors set an implementation date of June 8, 1997, for those fee and classification changes to take effect. A notice announcing the Governors' Decision and the final Domestic Mail Classification Schedule and Rate Schedule changes is published elsewhere in this issue of the **Federal Register**.

This final rule contains the DMM standards adopted by the Postal Service to implement the Governors' decision. The final rule reflects the criteria presented by the Postal Service in its pleadings before the PRC.

As described above, the Postal Service is limiting these experimental rate categories to those pieces of nonletter-size business reply mail that are outside the parameters of current automation-compatible letter-size business reply mail. As a consequence, the final rule excludes letter-size pieces prepared for a discount under the Business Reply Mail Accounting System (BRMAS).

Because of the limited scope of this experiment, the Postal Service finds no need to solicit comment on the standards for nonletter-size BRM or to delay implementation of this experiment, pending their evaluation.

List of Subjects in 39 CFR Part 111

Postal Service.

For the reasons discussed above, the Postal Service hereby adopts the following amendments to the Domestic Mail Manual, which is incorporated by reference in the Code of Federal Regulations (see 39 CFR part 111).

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

2. Add new G092 to the Domestic Mail Manual as follows:

G General Information:

* * * * *

G090 Experimental Classifications and Rates

* * * * *

G092 Nonletter-Size Business Reply Mail

1.0 BASIC ELIGIBILITY

1.1 Description

The standards in G092 apply to pieces claimed by an authorized mailer at the experimental fees for nonletter-size business reply mail (BRM). To participate in the experiment, a mailer must have the ability to establish and maintain quality control procedures that can document the receipt of large volumes of nonletter-size BRM. Draft Publication 405, **Guide to Business Reply Mail,** contains the principal operating procedures for the experiment, including application forms, mailpiece design, and reverse manifesting and weight averaging calculations.

1.2 Applicability

BRM pieces eligible under G092 must:

a. Be mailed as First-Class Mail or Priority Mail and meet the specific standards in 2.0 or 3.0.

b. Meet the applicable physical standards for nonletter-size mail in C050 (i.e., flat-size mail, machinable parcels, irregular parcels, or outside parcels) and C100 for First-Class Mail, except any BRM piece accounted for under the weight averaging method in 3.0 may not exceed 5 pounds.

c. Meet the basic standards for BRM in S922 other than those specific to letter-size pieces or pieces processed under the Business Reply Mail Accounting System (BRMAS).

d. Meet the addressing standards in A010 and bear a delivery address with the correct ZIP+4 code and BRM ZIP+4 barcode assigned by the USPS.

e. Be marked as specified in the service agreement under 2.0 or 3.0 and comply with any current or future USPS marking standard.

f. Meet the documentation and postage payment standards in 2.0 or 3.0 and the service agreement.

g. Be received at the post office that serves the permit holder.

1.3 Fees

Each BRM piece eligible under G092 is charged the corresponding single-piece rate for First-Class Mail or Priority Mail plus the appropriate fee as shown in 5.2. To begin receiving pieces under this fee schedule, the participating mailer must also pay fees for these accounts and services:

a. Annual BRM permit.

b. Annual BRM advance deposit account, with an opening balance determined by expected volume for 2 days.

c. Post office box service under D910 or caller service under D920, if applicable.

d. One-time set-up/qualification fee.

e. Applicable monthly maintenance fee.

1.4 Participation in Test

A business reply mail recipient who wants to participate in the experiment and receive an account for nonletter-size BRM under G092 must submit a written request for consideration to the manager of Classification and Product Development, USPS Headquarters (see G043 for address). The request must include sufficient data to assist the manager in making an initial determination. The manager may request additional data and an on-site visit to the applicant's plant. If the manager determines that the applicant is suitable for participation, the applicant follows the application procedures in either 2.0 or 3.0, as appropriate. Consideration is given to product type, geographic location of the mailer's site of operation, variability in the weight and daily volume of BRM, current accounting and quality control procedures, and availability of postal resources. In selecting participants, the manager also uses the following additional criteria:

a. The applicant must receive or expect to receive at one site a yearly average of several hundred thousand nonletter-size BRM pieces eligible for the current $0.10 per piece fee under S922.

b. The applicant must be able to participate in the experiment for at least 1 year.

c. The applicant must be prepared to begin operation at a mutually agreed-upon time after selection.

2.0 REVERSE MANIFESTING

2.1 Basic Requirements

Reverse manifesting is a method of assessing postage due and per piece fees for BRM by using a computerized database for calculating the weight and postage for each BRM piece received and to output a tabulation from the system for verification by the USPS. The weight is determined by weighing each piece or by using predetermined weights based on the data entered during processing (coded weight based on piece type). To participate in reverse manifesting for nonletter-size BRM, a mailer must meet these standards:

a. Receive or expect to receive nonletter-size BRM on a consistent basis.

b. Have or obtain a BRM permit and a BRM advance deposit account. The mailer must maintain sufficient funds in the advance deposit account to cover at least 2 days' postage and fees.

c. Have or be able to develop an approved computerized manifest system.

d. Provide documentation showing current internal quality control procedures for tracking and processing BRM or the ability to establish such procedures.

2.2 Application

A business reply mail recipient applying for participation in the reverse manifesting portion of the experiment must complete a standard application provided by the USPS. The applicant submits this application to the manager of Classification and Product Development. The applicant includes the following documentation:

a. Detailed specifications about the computerized manifest system, with all records identified and labeled.

b. Detailed explanation of the supporting records, including samples of each manifest type, samples of each BRM piece and label, and postage due statements.

c. Detailed description of internal quality control procedures.

2.3 Authorization

The manager of Classification and Product Development reviews the application and proceeds as follows:

a. If the applicant meets the conditions required for the reverse manifesting method and the application is otherwise consistent with the purposes and goals of the experiment, the manager approves the application and prepares a service agreement with the applicant. The agreement details the operating procedures for the reverse manifesting system and the responsibilities of the applicant and the USPS. For the purposes of the experiment, the Postal Service may require additional documentation and periodic review and inspection of each experiment participant's BRM processing and accounting operations. No agreement may remain in effect beyond the 2-year duration established for the experiment. The experimental classifications and fees take effect on June 8, 1997; they will be in effect no later than June 7, 1999.

b. If the applicant does not appear to meet the conditions required for the reverse manifesting method or it is determined that approval of an application would not be consistent with the purposes and goals of the experiment, the manager of Classification and Product Development denies the application and sends

written notice to the applicant, with the reasons for denial. The applicant has 30 days after receipt of the notice to file a written appeal to the BRM Experiment Review Board, USPS Headquarters. Decisions of the Review Board are final.

2.4 Renewal

A reverse manifesting service agreement may be renewed before its expiration date after a review by the manager of Classification and Product Development. The preparation of a new agreement or an addendum to the current agreement depends on the type of modifications made to the system. Authorization may not extend beyond the ending date of the experimental classification.

3.0 WEIGHT AVERAGING

3.1 Basic Requirements

Weight averaging is a method of assessing postage due and per piece fees for BRM without counting and weighing each piece. The USPS develops an average piece weight factor and an average piece count factor through verification procedures. These two factors (the weight average factors) are applied to the bulk weight of future BRM volumes to assess postage due and per piece fees. To participate in weight averaging for nonletter-size BRM, a mailer must meet these standards:

a. Receive or expect to receive nonletter-size BRM on a consistent basis, within a statistically acceptable weight range.

b. Have or obtain a BRM permit and a BRM advance deposit account. The mailer must maintain sufficient funds in the advance deposit account to cover at least 2 days' postage and fees.

c. Provide documentation showing current internal quality control procedures for tracking and processing BRM or the ability to establish such procedures.

3.2 Application

A business reply mail recipient applying for participation in the weight averaging portion of the experiment must complete a standard application provided by the USPS. The applicant submits this application to the manager of Classification and Product Development. The applicant includes with the application documentation that contains sample BRM pieces and labels representative of the weight range and types of pieces to be weight-averaged.

3.3 Authorization

The manager of Classification and Product Development reviews the application and proceeds as follows:

a. If the applicant meets the conditions required for the weight averaging method and the application is otherwise consistent with the purposes and goals of the experiment, the manager approves the application and prepares a service agreement with the applicant. The agreement details the operating procedures for weight averaging and the responsibilities of the applicant and the USPS. For the purposes of the experiment, the Postal Service may require additional documentation and periodic review and inspection of each experiment participant's BRM processing and accounting operations. No agreement may remain in effect beyond the 2-year duration established for the experiment. The experimental classifications and fees take effect on June 8, 1997; they will be in effect no later than June 7, 1999.

b. If the application does not appear to meet the conditions required for the weight averaging method, the manager of Classification and Product Development denies the application and sends written notice to the applicant, with the reasons for denial. The applicant has 30 days after receipt of the notice to file a written appeal to the BRM Experiment Review Board, USPS Headquarters. Decisions of the Review Board are final.

3.4 Renewal

A weight averaging service agreement may be renewed before its expiration date after a review by the manager of Classification and Product Development. The preparation of a new agreement or an addendum to the current agreement depends on the type of modifications made. Authorization may not extend beyond the ending date of the experimental classification.

4.0 REVOCATION

4.1 Reasons

The manager of Classification and Product Development may revoke a BRM participant's authorization for the experiment if that participant:

a. Provides incorrect data on the manifest or other required documentation and appears unable or unwilling to correct the problems.

b. Neglects to perform the required quality control procedures.

c. No longer meets the criteria in this standard and the service agreement.

4.2 Notice

After a revocation notice is issued, the participant and the USPS determine corrective actions and an implementation schedule, at the conclusion of which the USPS reexamines the participant's system. Failure to correct identified problems is sufficient grounds to revoke the participant's authorization.

4.3 Appeal

Revocation proceeds if the participant is unable or unwilling to correct the discrepancies found. The participant may file a written appeal of revocation within 15 days from the date of receipt of the notice, with evidence explaining why the authorization should not be revoked. The appeal must be filed with the BRM Experiment Review Board, which issues the final agency decision. The participant may continue to accept BRM under the authorization, pending a decision on appeal. The revocation decision takes effect 7 days after receipt by the participant.

5.0 RATES AND FEES

5.1 Rate Application

Each BRM piece received under G092 is charged the applicable per piece fee in 5.2 and the appropriate single-piece First-Class Mail rate or Priority Mail rate. In addition to the fees in 5.3 and 5.4, the required BRM permit fee and BRM advance deposit account fee must be paid every 12-month period.

5.2 Per Piece Fee

Per piece, in addition to single-piece rate First-Class Mail or Priority Mail postage:

a. Nonletter-size experimental (reverse manifesting): $0.02.

b. Nonletter-size experimental (weight averaging): $0.03.

5.3 Monthly Maintenance Fee

Per month:

a. Nonletter-size experimental (reverse manifesting): $1,000.00.

b. Nonletter-size experimental (weight averaging): $3,000.00.

5.4 Set-Up/Qualification Fee

Per initial application:

a. Nonletter-size experimental (reverse manifesting): $1,000.00.

b. Nonletter-size experimental (weight averaging): $3,000.00.

A transmittal letter making these changes in the pages of the Domestic Mail Manual will be published and will be transmitted to subscribers automatically. As provided by 39 CFR 111.3, notice of issuance will be published in the **Federal Register**.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 97–12206 Filed 5–7–97; 9:42 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Experimental Nonletter-Size Reply Mail Categories and Fees; Changes in Domestic Classifications and Fees

AGENCY: Postal Service.

ACTION: Notice of implementation of changes to the Domestic Mail Classification Schedule and accompanying fee changes.

SUMMARY: This notice sets forth the changes to the Domestic Mail Classification Schedule and the accompanying fee changes to be implemented as a result of the May 5, 1997, Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees.

EFFECTIVE DATE: June 8, 1997.

FOR FURTHER INFORMATION CONTACT: Michael Tidwell, (202) 268–2998.

SUPPLEMENTARY INFORMATION: On December 13, 1996, pursuant to its authority under 39 U.S.C. 3621, *et seq.*, the Postal Service filed with the Postal Rate Commission (PRC) a request for a recommended decision on experimental classifications and fees for nonletter-size Business Reply Mail. The PRC designated the filing as Docket No. MC97–1. The PRC published a notice of the filing, with a description of the Postal Service's proposals, on December 24, 1996, in the **Federal Register** (61 FR 67860–67862).

On April 2, 1997, pursuant to its authority under 39 U.S.C. 3624, the PRC issued to the Governors of the Postal Service its Recommended Decision on the Postal Service's Request. The PRC recommended the experimental nonletter-size Business Reply Mail classifications and fees requested by the Postal Service.

Pursuant to 39 U.S.C. 3625, the Governors of the United States Postal Service acted on the PRC's recommendations on May 5, 1997. Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees, Docket No. MC97–1. The Governors determined to approve the PRC's recommendations, and the Board of Governors set an implementation date of June 8, 1997, for the classifications and fee changes to take effect. A copy of the attachments to that Decision, setting forth the classification and fee changes approved by the Governors, is set forth below.

Also on May 5, 1997, the Board of Governors of the Postal Service, pursuant to their authority under 39 U.S.C. 3625(f), determined to make the classification and fee changes approved by the Governors effective at 12:01 a.m. on June 8, 1997 (Resolution No. 97–8).

In accordance with the Decision of the Governors and Resolution No. 97–8, the Postal Service hereby gives notice that the classification and fee changes set forth below will become effective at 12:01 a.m. on June 8, 1997. Implementing regulations also become effective at that time, as noted elsewhere in this issue.

Stanley F. Mires,

Chief Counsel, Legislative.

Attachment A to the Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees, (May 5, 1997)

CHANGES IN THE DOMESTIC MAIL CLASSIFICATION SCHEDULE

The following material represents changes to the Domestic Mail Classification Schedule (DMCS) approved by the Governors of the United States Postal Service in response to the Commission's Recommended Decision in Docket No. MC97–1. Changes are identified by underlining additions to the DMCS.

Domestic Mail Classification Schedule SS–2 Business Reply Mail

2.01 Definitions

2.010 Business reply mail is a service whereby business reply cards, envelopes, cartons and labels may be distributed by or for a business reply distributor for use by mailers for sending First-Class Mail without prepayment of postage to an address chosen by the distributor. A distributor is the holder of a business reply license.

2.011 A business reply mail piece is nonletter-size for purposes of Classification Schedule SS–2 if it meets addressing and other preparation requirements, but does not meet the machinability requirements prescribed by the Postal Service for mechanized or automated letter sortation.

This provision expires June 7, 1999.

2.02 Description of Service

2.020 The distributor guarantees payment on delivery of postage and fees for all returned business reply mail. Any distributor of business reply cards, envelopes, cartons and labels under any one license for return to several addresses guarantees to pay postage and fees on any returns refused by any such addressee.

2.03 Requirements of the Mailer

2.030 Business reply cards, envelopes, cartons and labels must be preaddressed and bear business reply markings.

2.031 Handwriting, typewriting or handstamping are not acceptable methods of preaddressing or marking business reply cards, envelopes, cartons, or labels.

2.04 Fees

2.040 The fees for business reply mail are set forth in Rate Schedule SS–2.

2.041 To qualify as an active business reply mail advance deposit trust account, the account must be used solely for business reply mail and contain sufficient postage and fees due for returned business reply mail.

2.042 An accounting fee as set forth in Rate Schedule SS–2 must be paid each year for each advance deposit business reply account at each facility where the mail is to be returned.

2.043 Experimental Reverse Manifest Fees

2.0431 A set-up/qualification fee as set forth in Rate Schedule SS–2 must be paid by each business reply mail advance deposit trust account holder at each destination postal facility at which it applies to receive nonletter-size business reply mail for which the postage and fees will be accounted for through a reverse manifest method approved by the Postal Service for ascertaining and verifying postage.

A distributor must pay this fee for each business reply mail advance deposit trust account for which participation in the nonletter-size business reply mail experiment is requested.

This provision expires June 7, 1999.

2.0432 A nonletter-size reverse manifest monthly fee as set forth in Rate Schedule SS–2 must be paid each month during which the distributor's reverse manifest account is active.

This fee applies to the (no more than) 10 advance deposit account holders which are selected by the Postal Service to participate in the reverse manifest nonletter-size business reply mail experiment and which utilize reverse manifest accounting methods approved by the Postal Service for ascertaining and verifying postage and fees.

This provision expires June 7, 1999.

2.044 Experimental Weight Averaging Fees

2.0441 A set-up/qualification fee as set forth in Rate Schedule SS–2 must be paid by each business reply mail

advance deposit trust account holder at each destination postal facility at which it applies to receive nonletter-size business reply mail for which the postage and fees will be accounted for through a weight averaging method approved by the Postal Service for ascertaining and verifying postage.

A distributor must pay this fee for each business reply mail advance deposit trust account for which participation in the nonletter-size business reply mail experiment is requested.

This provision expires June 7, 1999.

2.0442 A nonletter-size weight averaging monthly fee as set forth in Rate Schedule SS–2 must be paid each month during which the distributor's weight averaging account is active.

This fee applies to the (no more than) 10 advance deposit account holders which are selected by the Postal Service to participate in the weight averaging nonletter-size business reply mail experiment.

This provision expires June 7, 1999.

2.05 Authorizations and Licenses

2.050 In order to distribute business reply cards, envelopes, cartons or labels, the distributor must obtain a license or licenses from the Postal Service and pay the appropriate fee as set forth in Rate Schedule SS–2.

2.0501 Except as provided in section 2.0502, the license to distribute business reply cards, envelopes, cartons, or labels must be obtained at each office from which the mail is offered for delivery.

2.0502 If the business reply mail is to be distributed from a central office to be returned to branches or dealers in other cities, one license obtained from the post office where the central office is located may be used to cover all business reply mail.

2.051 The license to mail business reply mail may be canceled for failure to pay business reply postage and fees when due, and for distributing business reply cards or envelopes which do not conform to prescribed form, style or size.

2.052 Authorization to pay experimental nonletter-size business reply mail fees as set forth in Rate Schedule SS–2 may be canceled for failure of a business reply mail advance deposit trust account holder to meet the standards prescribed by the Postal Service for the applicable reverse manifest or weight averaging accounting method.

This provision expires June 7, 1999.

Attachment B to the Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees (May 5, 1997)

CHANGES TO RATE SCHEDULE SS–2

The following material represents changes in Rate Schedule SS–2 approved by the Governors of the United States Postal Service in response to the Commission's Recommended Decision in Docket No. MC97–1. Changes are identified by underlining additions to Rate Schedule SS–2.

RATE SCHEDULE SS–2

	Fee [1]
Active business reply advanced deposit account:	
Per piece:	
Prebarcoded	$.02
Nonletter-size, using reverse manifest (experimental)	.02
Nonletter-size, using weight averaging (experimental)	.03
Other	.10
Payment of postage due charges if active business reply mail advance deposit account not used:	.44
Annual License and Accounting Fees:	
Accounting Fee for Advance Deposit Account	205
Permit fee (with or without Advance Deposit Account)	85
Monthly Fees for customers using a reverse manifest or weight averaging for nonletter-size business reply:	
Nonletter-size, using reverse manifest (experimental)	1,000
Nonletter-size, using weight averaging (experimental)	3,000
Set-up/Qualification Fee for customers using a reverse manifest or weight averaging for nonletter-size business reply:	
Nonletter-size, using reverse manifest (experimental)	1,000
Nonletter-size, using weight averaging (experimental)	3,000

[1] Experimental per piece, monthly and set-up/qualification fees are applicable only to participants selected by the Postal Service for nonletter-size business reply mail experiment. The experimental fees expire on June 7, 1999.

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federal register

Friday
May 9, 1997

Part VII

Department of Education

National Institute on Disability and Rehabilitation Research; Notice of Funding Priorities for FY 1997–1998; Office of Special Education and Rehabilitative Services, Notice Inviting Applications for New Awards Under Certain Programs for Fiscal Year 1997

DEPARTMENT OF EDUCATION

National Institute on Disability and Rehabilitation Research; Notice of Final Funding Priorities for Fiscal Years 1997–1998 for Research and Demonstration Projects, Rehabilitation Research and Training Centers, and a Knowledge Dissemination and Utilization Project

AGENCY: Department of Education.

SUMMARY: The Secretary announces final funding priorities for the Research and Demonstration Project (R&D) Program, the Rehabilitation Research and Training Center (RRTC) Program, and the Knowledge Dissemination and Utilization (D&U) Program under the National Institute on Disability and Rehabilitation Research (NIDRR) for fiscal years 1997–1998. The Secretary takes this action to focus research attention on areas of national need to improve rehabilitation services and outcomes for individuals with disabilities, and to assist in the solutions to problems encountered by individuals with disabilities in their daily activities.

EFFECTIVE DATE: These priorities take effect on June 9, 1997.

FOR FURTHER INFORMATION CONTACT: David Esquith. Telephone: (202) 205–8801. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–2742. Internet: David__—Esquith@ed.gov.

SUPPLEMENTARY INFORMATION: This notice contains final priorities to establish R&D projects for model systems for burn injury and traumatic brain injury, RRTCs for research related to aging with a spinal cord injury and severe problem behaviors, and a D&U project to improve the utilization of existing and emerging rehabilitation technology in the State vocational rehabilitation program.

These final priorities support the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

Note: This notice of final priorities does *not* solicit applications. A notice inviting applications under these competitions is published in a separate notice in this issue of the **Federal Register**.

Analysis of Comments and Changes

On March 4, 1997, the Secretary published a notice of proposed priorities in the **Federal Register** (62 FR 9886–9892). The Department of Education received ninety-four letters commenting on the notice of proposed priorities by the deadline date. Seventy-eight additional comments were received after the deadline date and were not considered in this response. Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under statutory authority—are not addressed.

Research and Demonstration Projects Program

Priority 1: Burn Injury Rehabilitation Model System

Comment: The Burn Injury Rehabilitation Model System projects should provide care from the point of injury to the completion of care.

Discussion: The projects are intended to provide care from the point of injury to the completion of care. The priority is not as clear as it could be on this point.

Changes: The initial purpose statement of the priority has been revised to require a project to provide care from the point of injury through community integration and long-term follow-up.

Comment: The 1992 Burn Model system's final priority excluded children. The new projects should provide care to children and adults.

Discussion: The 1992 final priority discussion of the exclusion of children from the Burn Model system's program stated, ''The burn injury model system will be developed initially to serve and collect data on adults since NIDRR's experience with the model systems for spinal cord injury and traumatic brain injury projects indicates that these systems can be successful with adults. The model systems can be adapted for children later.'' (57 FR 57284). The commenter is correct, and the Burn Model System program should be able to include children without jeopardizing the database or service delivery progress that has been made to date.

Including children will require the Burn Model System projects to address new and unique issues, such as the effect of the burn injury on physical, cognitive, and social development. It will also demand that the projects coordinate with children's service providers, including special educators. The annual funding of the Burn Model System projects has been increased in order to provide adequate support for the additional tasks that will result from this change.

Changes: The background statement and the priority have been revised to require the projects to include children in the model system and the projects' research and demonstration activities. The fourth purpose statement has been revised to include special education interventions and education outcomes.

Comment: The model system projects should be required to use electronic communication.

Discussion: The use of electronic communication is so common that it is unnecessary to require it.

Changes: None.

Comment: What guidelines have been established for defining the cost of care data from the data which are more commonly available, i.e., charges of care?

Discussion: There are no guidelines for defining cost of care. Applicants have the discretion to propose how they will define cost, and the peer review process will evaluate the merits of the definition. An applicant could propose to define cost as charges of care.

Changes: None.

Comment: A comment in response to the TBI Model System proposed priority questioned the use of the term ''multidisciplinary'' to describe the model system. The commenter opined that the manner in which care is rendered in most, if not all, the model systems is in an ''interdisciplinary'' or ''transdisciplinary'' fashion. ''Interdisciplinary'' or ''transdisciplinary'' should be used instead of ''multidisciplinary.''

Discussion: This comment, although not addressed to the proposed Burn Injury Rehabilitation Model System priority, applies equally to it. The term ''multidisciplinary'' was used to convey that the projects should involve all necessary and appropriate disciplines in the delivery of care. Since there are no universally accepted definitions of any of these terms, use of any one term could lead to a misunderstanding.

Changes: The term ''multidisciplinary'' has been deleted from the Burn Injury Rehabilitation Model System priority, and the priority requires the projects to involve all necessary and appropriate disciplines in the delivery of care.

Priority 2: Traumatic Brain Injury Model Systems

Comment: The priority limits inclusion in the model systems database to patients who are admitted to a participating trauma unit and then transferred to a participating acute rehabilitation hospital for inpatient services. This limitation excludes patients who, after participating in a trauma unit, receive services at alternative post-acute treatment sites such as a skilled nursing facility, a subacute rehabilitation facility, or at home. Increasingly, managed care

organizations and rehabilitation providers are utilizing these excluded treatment sites. These exclusions should be eliminated from the priority in order to allow the projects to study the impact of these alternative treatment pathways.

Discussion: This recommendation raises fundamental questions about the purpose and future directions of the TBI Model Systems program. As indicated in the background statement, ''NIDRR's multi-center model systems program is designed to study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute neuro-trauma management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services.'' Including other pathways of post-acute treatment such as skilled nursing facilities, subacute rehabilitation facilities, and home care would significantly change the nature of the model system that has been in place for since 1987. This change would require projects to engage in data collection activities from a wider range of treatment sites, and possibly a wider range of severity of brain injury. The nature and quality of services provided at these alternative treatment sites, as well as the population served, may vary significantly, and this variation would need to be addressed in the compilation of the national database.

Post-acute treatment of TBI is going through a period of transition, and it is necessary for the TBI Model system program to be equally dynamic in order to maintain the program's relevance. In order to facilitate a smooth transition, the priority is being changed to provide applicants with the option of expanding their scope of activities to include alternative post-acute treatment sites while maintaining the requirement that all projects include the current pathway of inpatient rehabilitation treatment. This change is made with the acknowledgment that complications may occur. For example, if some projects expand to include alternative post-acute treatment sites, while others maintain the current treatment pathway, the uniformity of the database will be affected. These complications should be outweighed by the new information that will be generated about the post-acute alternative treatment sites. In addition, if at some future date, the inclusion of alternative post-acute treatment sites becomes a requirement rather than an option, the experience of the next round of projects that include those sites in their systems will serve as a useful source of information about the transition.

Changes: The background statement and the priority have been revised to provide projects with the option of including alternative post-acute treatment sites in their system while maintaining the requirement that all projects include post-acute inpatient rehabilitation sites. In addition, the final priority includes an invitational priority in order to encourage applicants to pursue this option.

Comment: The phrase ''specific treatment interventions'' should be added to the fourth purpose of the priority.

Discussion: The fourth purpose of the priority requires a project to determine the relationship between cost of care and functional outcomes. In order to make this determination, the project should link the cost of care to a specific intervention. The commenter's recommendation clarifies this point.

Changes: The fourth purpose statement has been revised to require a project to determine the relationship between cost of care, specific treatment interventions, and functional outcomes.

Comment: The projects should examine the issues of aging with TBI.

Discussion: Applicants have the discretion to propose areas of investigation as long as those areas are within the purpose of the priority. However, examining issues of aging with TBI is outside of the scope of activities that an applicant could propose to fulfill the purpose of a project in the TBI Model Systems program. There is insufficient evidence to support establishing an absolute priority on this topic under other NIDRR research programs.

Changes: None.

Comment: The projects should examine the impact of pre-injury psychosocial factors on rehabilitation outcomes.

Discussion: Applicants have the discretion to propose areas of investigation as long as those areas are within the purpose of the priority. Thus, in response to the revised third purpose statement, an applicant could propose to delineate the role of premorbid factors in outcome in TBI. The peer review process will evaluate the merits of the proposal.

Changes: None.

Comment: The priority refers to a ''multidisciplinary'' model system of care. The manner in which care is rendered in most, if not all, the model systems is in an ''interdisciplinary'' or ''transdisciplinary'' fashion. ''Interdisciplinary'' or ''transdisciplinary'' should be used instead of ''multidisciplinary.''

Discussion: The term ''multidisciplinary'' was used to convey that the projects should involve all necessary and appropriate disciplines in the delivery of care. Since there are no universally accepted definitions of any of these terms, use of any one term could lead to a misunderstanding.

Changes: The term ''multidisciplinary'' has been deleted, and the priority requires the projects to involve all necessary and appropriate disciplines in the delivery of care.

Comment: In order to provide the priority with a consumer perspective, ''subjective well-being'' should be added to the third purpose statement.

Discussion: The third purpose statement requires the project to develop key predictors of rehabilitation outcomes at hospital discharge and at long-term follow-up. Including subjective well-being in the priority will promote the inclusion of consumers' perspectives among the rehabilitation outcomes.

Changes: The third purpose statement has been revised to require a project to address subjective well-being when it develops key predictors of rehabilitation outcomes.

Comment: The efficacy of interventions should not be weighed against the cost of interventions alone. Purposes statements four and five should be revised to refer to ''costs to society.''

Discussion: Determining ''costs to society'' is an imprecise endeavor. While ''cost of interventions'' admittedly constitutes a more limited perspective, it is a measure that can be used consistently across projects with a much higher degree of confidence.

Changes: None.

Comment: The projects should investigate potential systematic biases in longitudinal studies of persons with TBI.

Discussion: Applicants have the discretion to propose areas of investigation as long as those areas are within the purpose of the priority. However, investigating potential systematic biases in longitudinal studies of persons with TBI is outside of the scope of activities that an applicant could propose to fulfill the purpose of a project in the TBI Model Systems program. There is insufficient evidence to support establishing an absolute priority on this topic under other NIDRR research programs.

Changes: None.

Comment: The TBI Model Systems program should promote variation in care, along with systematic data collection, so that the impact of variations can be studied. To the extent

that all funded model systems are encouraged to develop similar systems of care, the opportunity to understand the impact of differences in care is lost. Specifically, the study of the impact of differences in the design and organization of rehabilitation interventions can be advanced by changing the enrollment constraints of model system patients, including those who are in a vegetative state, encouraging program innovations, developing innovative financing approaches to TBI rehabilitation, and supporting rigorous research on the treatment of both motor and cognitive impairments, including training regimens, pharmacologic treatments, and the use of orthotic and prosthetic devices.

Discussion: The TBI Model System program is intended to demonstrate the effectiveness of a prescribed system of care implemented in a similar fashion by a number of projects. Some degree of variation occurs across projects, and this variation will increase markedly if grantees exercise the option of including alternative post-acute treatments pathways in their model system of care. The commenter is correct that to the extent all funded model systems are encouraged to develop similar systems of care, the opportunity to understand the impact of differences in care is lost. However, there are substantial benefits in regard to the quality of the knowledge that can be generated by demonstrating and evaluating a prescribed system across projects. In light of the resources available to the program, those benefits outweigh benefits that would result from a model system that would systematically promote variation in care.

Changes: None.

Comment: The projects should study the impact of managed care on healthcare delivery to persons with TBI.

Discussion: Applicants have the discretion to propose areas of investigation so long as those areas are within the purpose of the priority. Thus, in response to the revised fourth purpose statement, an applicant could propose to study the impact of managed care on healthcare delivery to persons with TBI. The peer review process will evaluate the merits of the proposal. It should be noted that NIDRR has recently awarded an RRTC in fiscal year 1997 to study issues in Managed Health Care for individuals with disabilities.

Changes: None.

Comment: The impact of computers and technology should be emphasized in the priority.

Discussion: Emerging technology is having a significant impact on the rehabilitation outcomes of persons with TBI. In order to keep pace with these developments, all of the TBI Model Systems projects should identify and evaluate the effectiveness of interventions that use emerging technology.

Changes: The second purpose of the priority has been revised to require a project to examine the role of emerging technology in improving vocational outcomes and community integration.

Comment: Rather than determine the relationships between cost of care and functional outcomes, the fourth purpose of the priority should require a project to understand factors that determine costs, i.e., ''Quantify factors that affect the cost and benefits of care, such as functional outcomes.''

Discussion: In response to the fourth purpose of the priority, an applicant could propose to quantify factors that affect the cost and benefits of care. Determining the relationships between cost of care, specific treatment interventions, and functional outcomes, and understanding factors that determine costs are not necessarily exclusive activities.

Changes: None.

Comment: Control groups or stable baselines are needed to study the outcomes and value of TBI rehabilitation. Databases that allow comparisons of similar patients who may experience different treatment strategies are invaluable in research designed to infer the effectiveness of rehabilitative interventions. All projects should be required to participate in controlled research.

Discussion: Applicants have the discretion to propose the research design that a project will use, and the peer review process will evaluate the merits of the design. Thus, an applicant could propose to use controlled research, and the peer review process will evaluate the merits of the research design. However, requiring all projects to carry out controlled research could exclude equally effective research methodologies.

Changes: None.

Comment: The priority does not attend sufficiently to issues related to acute care of TBI. Attention should be focused on the prevention of secondary conditions through early rehabilitation interventions in the acute care setting. Incorporation of this component permits the investigation of novel pharmacologic strategies and early cognitive interventions to enhance long-term functional and vocational outcomes.

Discussion: In response to the revised second purpose statement, an applicant could propose to emphasize the prevention of secondary conditions through early rehabilitation interventions in the acute care setting, and the peer review process will evaluate the merits of the emphasis. However, there is insufficient evidence to warrant requiring all applicants to emphasize the prevention of secondary conditions through early rehabilitation interventions in the acute care setting.

Changes: None.

Comment: Projects should study the effectiveness of behavioral management strategies and the role of family dynamics in TBI patients.

Discussion: An applicant could propose to study the effectiveness of behavioral management strategies or the role of family dynamics under the second and third purpose statements, respectively. The peer review process will evaluate the merits of the proposals. However, there is insufficient evidence to warrant requiring all applicants to study the effectiveness of behavioral management strategies or the role of family dynamics.

Changes: None.

Rehabilitation Research and Training Centers (RRTCs)

Priority 4: Aging With Spinal Cord Injury

Comment: The background statement acknowledges an array of health maintenance problems including, but not limited to cardiovascular problems, urinary tract infections, pressure sores, hypertension, fractures, blood in the urine or bowel problems, and diabetes. However, the priority does not include a commensurate purpose statement requiring the RRTC to address these problems. The employment problems experienced by persons aging with SCI are usually problems of maintaining employment, and not gaining employment. Their difficulties maintaining employment are most often a function of a health maintenance problem. The priority places too much emphasis on employment-related issues and fails to address critical health issues.

Discussion: This concern was expressed by thirty-seven of the thirty-eight comments that the Department received on this proposed priority by the deadline date. The commenters are persuasive that the priority places too much emphasis on employment-related issues and fails to address critical health issues.

Changes: The priority has been revised to include a new purpose statement addressing health maintenance problems and to de-

emphasize employment-related issues. In addition, in recognition of the additional work that will be required to address health maintenance problems, the number of purpose statements has been reduced and the dissemination and training requirements have been consolidated and modified.

Comment: Forty-four percent of the people who get a SCI are members of a minority group. The RRTC should place special emphasis on people aging with a SCI from minority backgrounds.

Discussion: The commenter is correct. There are an increasing number of persons from minority backgrounds who are experiencing SCI, and their unique and varying needs merit special attention from the RRTC.

Changes: The background statement and priority have been revised to evidence the unique needs of persons aging with SCI from minority backgrounds and require the RRTC to address those needs.

Comment: Proper research designs need to be used to identify the potential causes of late life changes. Complex cross-sequential designs are needed to test these questions. Otherwise the results, even from longitudinal designs (which do not control from the effect of era), are flawed.

Discussion: An applicant could propose to use complex cross-sequential designs, and the peer review process will evaluate the merits of the design. However, requiring all projects to use complex cross-sequential designs could exclude equally effective research designs.

Changes: None.

Comment: The part of the second purpose of the priority that requires the RRTC to evaluate rehabilitation techniques that will assist individuals aging with SCI to cope with changes should be revised to develop better assessment and treatment methods for depression as people attempt to cope.

Discussion: In response to the second purpose statement, an applicants could propose to develop better assessment and treatment methods for depression as people attempt to cope, and the peer review process will evaluate the merits of the proposal. However, there is insufficient evidence to warrant requiring all applicants to develop better assessment and treatment methods for depression as people attempt to cope.

Changes: None.

Comment: The RRTC should address the significant ethnic differences that exist among caregivers as well as the great diversity in who serves as caregiver (spouse, parent, sibling, friend, paid attendant).

Discussion: An applicant could propose to address the significant ethnic differences that exist among caregivers as well as the diversity in who serves as caregiver under the third purpose of the priority. There is insufficient evidence to warrant requiring all applicants to propose to study these two topics.

Changes: None.

Comment: The data from the 1992 SCI Model Systems Annual Report that is included in the background statement is partially contradicted by the 1996 SCI Model Systems Annual Report. The background statement indicates that employment rate peaks at about 40 percent for persons with paraplegia and at 28 percent for persons with quadriplegia, and sharply declines about 18 years after the post-injury. However, the 1996 Report shows employment peaking at 39 percent at fifteen years after injury and at 38.4 percent at 20 years after injury.

Discussion: The 1992 and the 1996 report findings are different, but not contradictory. However, since the 1996 findings are more recent, they should be included in the background statement in place of the 1992 data.

Changes: The background statement uses the information from the 1996 SCI Model Systems Annual Report instead of the 1992 Report data.

Research and Demonstration Projects

Authority for the R&D program of NIDRR is contained in section 204(a) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760–762). Under this program the Secretary makes awards to public agencies and private agencies and organizations, including institutions of higher education, Indian tribes, and tribal organizations. This program is designed to assist in the development of solutions to the problems encountered by individuals with disabilities in their daily activities, especially problems related to employment (see 34 CFR 351.1). Under the regulations for this program (see 34 CFR 351.32), the Secretary may establish research priorities by reserving funds to support the research activities listed in 34 CFR 351.10.

Priorities

Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet one of the following priorities. The Secretary will fund under this program only applications that meet one of these absolute priorities:

Priority 1: Burn Injury Rehabilitation Model System

Background

Each year more than 2.0 million persons (about one percent of the population of the United States) receive a burn injury. Of these, 6,500 to 12,000 do not survive; 500,000 require medical care and result in temporary disability with respect to home, school, or work activities; and 70,000 to 100,000 are severe enough to be admitted to a hospital (Rice, D.P. and MacKenzie, E.J., ''Cost of Injury in the United States: A Report to Congress,'' Atlanta, GA: Centers for Disease Control, 1989).

In 1994, NIDRR provided funding to establish Burn Injury Rehabilitation Model Systems of Care. These R&D projects focused primarily on developing and demonstrating a comprehensive, multidisciplinary model system of rehabilitative services for individuals with severe burns, and evaluating the efficacy of that system through the collection and analysis of uniform data on system benefits, costs, and outcomes. NIDRR's multi-center model systems program is designed to study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute care management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services.

Burn rehabilitation requires interventions as soon as possible after admission to hospitals and has treatment implications for several years following hospital discharge. Burn trauma often causes injuries and impairments in addition to the burn, and many individuals with burn injuries have secondary complications related to the burn condition. These may include open wounds, contractures, neuropathies, cosmetic abnormalities, deconditioning, bony deformities, hypersensitivity to heat and cold, amputation, psychosocial distress, chronic pain, and scarring. The complicated nature of burn injuries, the difficulty of treatment, and the risk of infection with possible loss of function requires interventions quickly and frequently to attempt to maintain a functional lifestyle and return to living independently. Minimization of physical deterioration and prevention of further impairment and functional limitation is critical and research is needed to find the appropriate procedures for clinical applications. Research is needed to develop and refine methods to determine the effectiveness of interventions to prevent, manage, and reduce medical

complications that contribute to short and long-term disability in burn patients.

Children who are severely burned may present unique challenges to health care providers, educators, and family members due to the physical, cognitive and emotional development stages that they experience. For example, returning to school and neighborhood may pose a serious threat to the development of a child's self-esteem if disfigurement is evident. In order to minimize the impact of a severe burn on a child's development, an efficient, well-coordinated system of care must be in place that involves medical, rehabilitation, and educational service providers, including special educators.

Improved measures are needed of an individual's functional ability as a result of burn rehabilitation interventions. Functional assessment brings objectivity to rehabilitation by establishing appropriate, uniform descriptors of rehabilitation care and changes in individual capacity to perform activities of daily living or other measurable elements of an individual's major life activities (Granger, C. and Brownscheidle, C., ''Outcome Measurement in Medical Rehabilitation,'' *International Journal of Technology Assessment in Health Care,* 11:2, 1995). Increasingly, health and rehabilitation services require effectiveness and impact measures to evaluate their services as a part of procedures for cost-reimbursement and billing for services. With greater emphasis on individual choice in services delivery, consumers and advocates are likewise advocates for functional assessment measures as encoders of service effectiveness. Few existing functional assessment measures, however, address the specialized and complex combination of psychosocial and medical challenges encountered by an individual who has experienced severe burn injury (Rucker, K., et al., ''Analysis of Functional Assessment Instruments for Disability Rehabilitation Programs,'' SEW Contract No. 600–95–2194, Virginia Commonwealth University, 1996).

Burn injuries can produce emotional problems, such as post-traumatic stress disorders, anxiety, and depression. These problems may result from a variety of causes (e.g., reaction to cosmetic alterations, changes in functional abilities, changes in work status, restrictions on recreational activities) (Cromes, G.F. and Helm, P.A., ''Burn Injuries,'' in *Medical Aspects of Disability,* pgs. 92–104, 1993). The aesthetic disability of disfigurement is frequently more severe than the physical disability and may result in profound social consequences for those afflicted (Hurren, J.S., ''Rehabilitation of the Burned Patient: James Laing Memorial Essay for 1993,'' *Burns,* Vol. 21, No. 2, 1995). The more severe the burn, the greater the likelihood of long-term psychosocial adjustment issues related to both physical and psychosocial problems, that affect quality of life. Although psychosocial adjustment is a critical factor in the long-term recovery of burn injury patients, there continues to be limited emphasis on research in the area of psychosocial rehabilitation and its relationship to quality of life. Family and friends play an important role and provide major support in the psychological recovery of burn patients. Research in this area needs to address the role of the family and personal advocacy systems in providing support during the burn injury rehabilitation process.

Difficulty with long-term follow-up of all patients after hospital discharge has always been a problem, but it is even more difficult when the individual lives far from the specialized rehabilitation unit. Problems are also encountered with those individuals living in rural areas, where access to burn injury rehabilitation, including mental health services, may be quite limited due to lack of proximity to specialized practitioners, limited access to technological advances, and hospital closures.

Return-to-work and educational pursuits are important measures of rehabilitation success. Work is an important source of satisfaction, self-respect, and dignity, as well as an arena for socialization for individuals who have experienced burn injury (Salisbury, R., ''Burn Rehabilitation: Our Unanswered Challenge,'' 1992 Presidential Address to the American Burn Association, April, 1992). However, the efficacy of vocational rehabilitation interventions for this population has not been documented adequately. The physical, psychosocial, and emotional factors that lead to successful employment have not been clearly identified. Research is needed to examine relationships between vocational interventions and supports, employment, functional capacity, and degree of burn injury, including secondary complications.

Priority 1

The Secretary will establish Burn Injury Rehabilitation Model Systems R&D projects for the purpose of demonstrating a comprehensive, model system of rehabilitative services, involving all necessary and appropriate disciplines, for children and adults with severe burns from point of injury to community integration and long-term follow-up. An R&D project must:

(1) Identify and evaluate techniques to prevent secondary complications;

(2) Develop and evaluate outreach programs to improve follow-up services for rural populations;

(3) Develop and evaluate measures of functional outcome for burn rehabilitation; and

(4) Identify and evaluate interventions, including vocational rehabilitation and special education interventions, to improve psychosocial adjustment, quality of life, community integration, and education and employment-related outcomes.

In carrying out these purposes, the R&D project must:

- Participate in clinical and systems analysis studies of the burn injury rehabilitation model system by collecting and contributing data on patient characteristics, diagnoses, causes of injury, interventions, outcomes, and costs to a uniform, standardized national data base as prescribed by the Secretary; and
- Consider collaborative projects with other model systems.

Priority 2: Traumatic Brain Injury Model Systems

Background

An estimated 1.9 million Americans experience traumatic brain injury (TBI) each year (Collins, J.F., ''Types of Injuries by Selected Characteristics: US 1985–87,'' National Center for Health Statistics, Vital Health Stat 10 (175), 1990). Incidence is highest among youth and younger adults. Young males have the highest incidence rates of any group (''Disability Statistics Abstract,'' No. 14, Disability Statistics Rehabilitation Research & Training Center, University of California, San Francisco, November, 1995). Each year approximately 70,000 to 90,000 TBI survivors enter a life of continuing, debilitating loss of function; an estimated 5,000 survivors experience seizure disorders; and 2,000 enter into a persistent vegetative state. The number of people surviving head injuries has increased significantly over the last 25 years as a result of faster and better emergency treatment, more rapid and safer transport to specialized treatment facilities, and advances in medical treatment (National Foundation for Brain Research, Washington, DC, 1994).

In 1987, NIDRR provided funding to establish TBI Model Systems of Care. These R&D projects focused primarily

on developing and demonstrating a comprehensive, multidisciplinary model system of rehabilitative services for individuals with TBI, and evaluating the efficacy of that system through the collection and analysis of uniform data on system benefits, costs, and outcomes. NIDRR's multi-center model systems program is designed to study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute neuro-trauma management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services. Projects are being given an option at this time of including, in addition to comprehensive inpatient rehabilitation, alternative pathways of post-acute treatment such as skilled nursing facilities, subacute rehabilitation facilities, and home care.

The TBI Model Systems serve a substantial number of patients, allowing the projects to conduct clinical research and program evaluation, which maximize the potential for project replication. In addition, the TBI Model Systems have the advantage of a complex data collection and retrieval program with the capability to analyze the different system components and provide information on project cost effectiveness and benefits. Information is collected throughout the rehabilitation process, permitting long-term follow-up on the course of injury, outcomes, and changes in employment status, community integration, substance abuse and family needs. The TBI Model Systems projects serve as regional and national models for program development and as information centers for consumers, families, and professionals.

The TBI Model Systems National Database reports that the average length of stay in acute care has decreased approximately 50 percent, from 30 days in 1989 to 15 days in 1996; and the average length of stay in inpatient rehabilitation has decreased 38 percent, from 52 days in 1989 to 32 days in 1996. With the changing patterns of service delivery, there continues to be a need to establish and evaluate new rehabilitation interventions and strategies. Specialized measurement tools have been developed by the TBI Model Systems to assess progress and describe clinical and functional outcomes. Refinement of these measurement tools is necessary to demonstrate the effectiveness of rehabilitation interventions in inpatient and outpatient settings. After the individual is discharged from an inpatient setting, there is an ongoing need for outpatient and community reintegration services in order to continue therapeutic interventions and the educational and referral process. As the average length of stay in inpatient settings decreases, there is a greater need to evaluate outpatient and community reintegration programs.

Findings from a multi-center investigation of employment and community integration following TBI highlight the need for post-acute rehabilitation programs with particular emphasis on vocational rehabilitation (Sander, A., et al., *Journal of Head Trauma Rehabilitation,* Vol. 11, No. 5, pgs. 70–84, 1996). Kreutzer states that employment and productivity, relating to others in the community, and independently caring for oneself at home are important quality-of-life components (''TBI: Models and Systems of Care,'' Conference Syllabus, Medical College of Virginia, April, 1996). As functional recovery progresses during the first year or more after the injury, the focus of rehabilitation shifts from medical intervention and physical restoration to psychosocial and vocational adaptation. The ultimate goal of psychosocial and vocational rehabilitation is community reintegration and employment. It is important to emphasize that services aimed at community reintegration must consider not only attributes and limitations of the injured individuals, but also the social, educational, and vocational systems in which the individual will function. In addition, rates of competitive employment decrease substantially from pre-injury levels. Head injury frequently results in unemployment, and there are significant relationships between risk factors (e.g., substance abuse) and this changed employment status. However, there is no reliable information regarding the magnitude of risk associated with different factors, or with different levels of these factors (Dikmen, S., et al., ''Employment following Traumatic Head Injuries,'' *Archives of Neurology,* Vol. 51, February, 1994).

A major disability like TBI has a profoundly disorganizing impact on the lives of individuals with TBI and their families. Questions involving community, family, and vocational restoration, as well as generic concerns about future happiness and fulfillment, are common (Banja, J., & Johnston, M., ''Ethical Perspectives and Social Policy,'' *Archives of Physical Medicine Rehabilitation,* Vol. 75, SC–19, December, 1994). Even individuals who have integrated well into society experience adverse psychosocial effects. Employment instability, isolation from friends, and increased need for support are a few of the problems encountered by individuals with TBI. Families often function as the primary support system for individuals with TBI after they are discharged. There is a clear need for research to develop family treatment strategies and explore their effect on outcomes for individuals with TBI.

The health care costs associated with TBI are staggering. The direct medical costs of TBI treatment have been estimated at more than $4 billion annually (Max, W., et al., ''Head Injuries: Costs and Consequences,'' *Journal of Head Trauma Rehabilitation,* Vol. 6, pgs. 76–91, 1991). In view of current scrutiny of all health care spending, which may result in pressures to constrict or deny rehabilitation care to individuals with traumatic brain injury, it is important to gather information on the efficacy and cost-effectiveness of various treatment interventions and service delivery models. Credible outcome monitoring systems are needed to establish guidelines by which fair compromises can be reached (Johnston, M. & Hall, K., ''Outcomes Evaluation in TBI Rehabilitation, Part I: Overview and System Principles,'' *Archives of Physical Medicine and Rehabilitation,* Vol. 75, December, 1994). A greater emphasis on outcomes measurements and management will foster the gathering of information on efficacy and cost-effectiveness.

Violence-induced TBI is increasingly common, and has significant implications for rehabilitation and community reintegration. According to the 1991 National Health Interview Survey data, violence was responsible for nine percent of all non-fatal TBIs. In addition, violence was a cause of injury in 30 percent of the 684 external injury cases in the TBI Model Systems database (a higher frequency due, in part, to the urban setting of one of the TBI Model Systems). The frequency of violence as a cause of TBI, in part, can be attributed to the fact that the individuals most likely to sustain TBI (i.e., males under age 18) are also those most likely to be involved in crimes and violence. The increase in violence as a cause of brain injury may have consequences with regard to rehabilitation costs, treatment interventions and long-term outcomes. For example, individuals with violence-related injuries show more difficulties with community integration skills one year following injury, which evidences itself in areas of social integration and productivity. Further research is needed to examine whether individuals who sustain a TBI as a result of violence

require specialized rehabilitation interventions.

Priority 2

The Secretary will establish Model Systems TBI R&D projects for the purpose of demonstrating a comprehensive, model system of care for individuals with TBI, involving all necessary and appropriate disciplines. An R&D project must:

(1) Investigate the efficacy of alternative methods of service delivery interventions after inpatient rehabilitation discharge and after other post-acute treatment pathways when applicable;

(2) Identify and evaluate interventions, including those utilizing emerging technology, that can improve vocational outcomes and community integration;

(3) Develop key predictors of rehabilitation outcome, including subjective well-being, at hospital discharge and at long-term follow-up;

(4) Determine the relationship between cost of care, specific treatment interventions, and functional outcomes; and

(5) Examine the implications of violence as a cause of TBI on treatment interventions, rehabilitation costs, and long-term outcomes.

In carrying out these purposes, the R&D Systems project must:

- Participate in clinical and systems analysis studies of the traumatic brain injury model system by collecting and contributing data on patient characteristics, diagnoses, causes of injury, interventions, outcomes, and costs to a uniform, standardized national data base as prescribed by the Secretary;
- Consider collaborative projects with other model systems; and
- Coordinate research efforts with other NIDRR grantees that address TBI-related issues.

Invitational Priority: The Secretary is particularly interested in applications that address the following invitational priority within this absolute priority. However, under 34 CFR 75.105(c)(1) an application that meets an invitational priority does not receive competitive or absolute preference over other applications. The invitational priority is for projects that include, in addition to comprehensive inpatient rehabilitation, alternative pathways of post-acute treatment such as skilled nursing facilities, subacute rehabilitation facilities, and home care.

Rehabilitation Research and Training Centers (RRTCs)

Authority for the RRTC program of NIDRR is contained in section 204(b)(2) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760–762). Under this program the Secretary makes awards to public and private organizations, including institutions of higher education and Indian tribes or tribal organizations for coordinated research and training activities. These entities must be of sufficient size, scope, and quality to effectively carry out the activities of the Center in an efficient manner consistent with appropriate State and Federal laws. They must demonstrate the ability to carry out the training activities either directly or through another entity that can provide such training.

The Secretary may make awards for up to 60 months through grants or cooperative agreements. The purpose of the awards is for planning and conducting research, training, demonstrations, and related activities leading to the development of methods, procedures, and devices that will benefit individuals with disabilities, especially those with the most severe disabilities.

Under the regulations for this program (see 34 CFR 352.32) the Secretary may establish research priorities by reserving funds to support particular research activities.

Description of the Rehabilitation Research and Training Center Program

RRTCs are operated in collaboration with institutions of higher education or providers of rehabilitation services or other appropriate services. RRTCs serve as centers of national excellence and national or regional resources for providers and individuals with disabilities and the parents, family members, guardians, advocates or authorized representatives of the individuals.

RRTCs conduct coordinated and advanced programs of research in rehabilitation targeted toward the production of new knowledge to improve rehabilitation methodology and service delivery systems, to alleviate or stabilize disabling conditions, and to promote maximum social and economic independence of individuals with disabilities.

RRTCs provide training, including graduate, pre-service, and in-service training, to assist individuals to more effectively provide rehabilitation services. They also provide training including graduate, pre-service, and in-service training, for rehabilitation research personnel and other rehabilitation personnel.

RRTCs serve as informational and technical assistance resources to providers, individuals with disabilities, and the parents, family members, guardians, advocates, or authorized representatives of these individuals through conferences, workshops, public education programs, in-service training programs and similar activities.

NIDRR encourages all Centers to involve individuals with disabilities and minorities as recipients in research training, as well as clinical training.

Applicants have considerable latitude in proposing the specific research and related projects they will undertake to achieve the designated outcomes; however, the regulatory selection criteria for the program (34 CFR 352.31) state that the Secretary reviews the extent to which applicants justify their choice of research projects in terms of the relevance to the priority and to the needs of individuals with disabilities. The Secretary also reviews the extent to which applicants present a scientific methodology that includes reasonable hypotheses, methods of data collection and analysis, and a means to evaluate the extent to which project objectives have been achieved.

The Department is particularly interested in ensuring that the expenditure of public funds is justified by the execution of intended activities and the advancement of knowledge and, thus, has built this accountability into the selection criteria. Not later than three years after the establishment of any RRTC, NIDRR will conduct one or more reviews of the activities and achievements of the Center. In accordance with the provisions of 34 CFR 75.253(a), continued funding depends at all times on satisfactory performance and accomplishment.

General

The following requirements apply to these RRTCs pursuant to the priorities unless noted otherwise:

Each RRTC must conduct an integrated program of research to develop solutions to problems confronted by individuals with disabilities.

Each RRTC must conduct a coordinated and advanced program of training in rehabilitation research, including training in research methodology and applied research experience, that will contribute to the number of qualified researchers working in the area of rehabilitation research.

Each RRTC must disseminate and encourage the use of new rehabilitation knowledge. They must publish all

materials for dissemination or training in alternate formats to make them accessible to individuals with a range of disabling conditions.

Each RRTC must involve individuals with disabilities and, if appropriate, their family members, as well as rehabilitation service providers, in planning and implementing the research and training programs, in interpreting and disseminating the research findings, and in evaluating the Center.

Priorities

Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet one of the following priorities. The Secretary will fund under these competitions only applications that meet one of these absolute priorities:

Priority 3: Effective Interventions for Children and Youth With Disabilities Who Exhibit Severe Problem Behaviors

Background

In recent years researchers have focused on the application of non-aversive approaches to reduce and eliminate severe problem behaviors (SPBs) exhibited by children and youth with disabilities. This has been the case because of ethical concerns about aversive interventions expressed by disability professionals, parents, and advocates, as well as research findings which indicate that aversive interventions are largely ineffective in eliminating or reducing SPBs over an extended period of time. Because of their disruptive nature, SPBs such as physical aggression, self-injury, violence, and property destruction are among the primary obstacles to full inclusion of children and youth with disabilities in age-appropriate community-based activities and regular education settings. School and community-based program personnel need effective methods to reduce and eliminate SPBs in order to provide these children and youth with disabilities with opportunities to learn, play, and work with their non-disabled peers.

Previous research in this area has improved our understanding of the early indicators of SPBs. For example, children with disabilities who display minor self-injurious behavior during the preschool years are strong candidates to exhibit more SPBs within two years (Hall, S., ''Early Intervention of Self-injurious Behavior in Young Children with Intellectual Disabilities: Naturalistic Observation,'' Presented at the Annual Meeting of the American Association of Mental Retardation, San Francisco, June, 1995). Further research is needed on how severe problem behavior patterns develop and whether early intervention efforts can reduce, and perhaps prevent, SPBs.

Preliminary research has also indicated that problem behaviors can be reduced by understanding the antecedents to and function of the behavior. Accordingly, children and youth with disabilities who exhibit SPBs may be able to learn to self-manage their problem behaviors.

While there are encouraging indications that non-aversive approaches can be effective in reducing and eliminating SPBs, there is a need to develop effective interventions that can be maintained over extended periods of time. Treatments of self-injurious behaviors are particularly problematic in regard to long-term effectiveness. Research has shown that children who exhibit self-injurious behaviors, even after intensive non-aversive treatment programs, may revert to self-injury at high rates within a few months of intervention (Durand, V.M., et al., ''The Course of Self-injurious Behavior Among People with Autism,'' Paper presented at the Annual Meeting of the Berkshire Association for Behavior Analysis and Therapy, Amherst, MA. 1995).

Information from functional assessments can be used to develop educational plans and address inappropriate behavior. Functional assessment is the general label assigned to describe a set of processes (e.g., interviews, rating, rating scales, direct observations, and systematic experimental analyses of specific situations) for defining the events in an environment that reliably predict and maintain behaviors. More research needs to be done in order to expand the application of functional assessments with children and youth with disabilities who exhibit severe problem behaviors.

Under normal circumstances, children and youth with disabilities who exhibit SPBs in school and the community are also exhibiting these behaviors at home. In order for non-aversive approaches to be implemented consistently across environments, parents and other caregivers must not only consent to the approach, but also be capable of implementing the approach effectively in the home environment. The non-aversive strategies that are developed must be compatible with the home environment, and take into account providing parents and guardians with the skills they need to implement the program effectively.

Priority 3

The Secretary will establish an RRTC for the purpose of providing school and community-based program personnel with effective methods to reduce and eliminate SPBs in children and youth with disabilities. The RRTC shall:

(1) Develop and evaluate non-aversive interventions that reduce and eliminate severe behavior problems exhibited by children and youth with disabilities;

(2) Investigate the etiology of SPBs for the purpose of developing prevention and early intervention strategies;

(3) Investigate the durability and maintenance of effective non-aversive interventions;

(4) Investigate the effectiveness of self-management strategies;

(5) Develop and evaluate functional assessments to address SPBs in educational and community-based settings;

(6) Develop materials and provide training to educators, community-based program personnel, parents, and caregivers who address SPBs; and

(7) Develop and disseminate informational materials and provide technical assistance to local and State educational agencies to address SPBs.

In carrying out the purposes of the priority, the RRTC shall disseminate materials and coordinate training activities with related projects supported by the Office of Special Education Programs, including the Regional Resource Centers and Parent Information Centers.

Priority 4: Aging With Spinal Cord Injury

Background

While the mortality rate of persons who experience a spinal cord injury (SCI) and related conditions has improved markedly, life expectancy estimates are still well below normal (DeVivo, M. and Stover, S., ''Long-term Survival and Causes of Death,'' in *Spinal Cord Injury: Clinical Outcomes from the Model Systems,* Aspen Publications, Gaithersburg, Maryland, 1995). Estimates of spinal cord injury prevalence in America range from 180,000 to 250,000 with between 7,000 and 10,000 new spinal cord injuries each year (National Spinal Cord Injury Statistical Center, The University of Alabama at Birmingham, 1995). One of four individuals who previously sustained a spinal cord injury is now at least 20 years post-onset. The average age of a SCI survivor is now about 48 years and about 20 percent of SCI survivors are over age 60.

Many SCI survivors develop new medical, functional, and psychological

problems that threaten their independence. In addition, many experience job loss, barriers to accessing proper health maintenance and caregiver/personal assistance services, loss of financial assistance, and economic hardship. Persons aging with SCI are susceptible to multiple health maintenance problems including, but not limited to, cardiovascular problems, urinary tract infections, pressure sores, hypertension, fractures, blood in the urine or bowel problems, and diabetes (Whiteneck, G.(Ed.), *Aging with a Spinal Cord Injury,* 1992). The leading medical cause of death and further disability that affects people with SCI is now premature cardiovascular disease of the atherosclerotic kind. Whiteneck, using data from England, found that cardiovascular disease is now tied with genito-urinary problems as the leading cause of death in people aging with SCI.

Individuals aging with a SCI also experience complications as a result of osteoporosis and lower extremity fractures (Garland, D.E., ''Bone Mineral Density about the Knee in SCI Patients with Pathological Fractures,'' *Contemporary Orthopaedics,* 1992 and Garland, D.E., ''Osteoporosis Following SCI,'' *Journal of Orthopaedic Research,* 1992). Garland discovered a high prevalence of carpal tunnel syndrome, which increased with the length of time after injury. In addition, Sie found an increased prevalence of general upper extremity pain and shoulder pain with time since injury in both paraplegic and tetraplegia individuals (Sie, I., ''Upper Extremity Pain in the Post-Rehabilitation SCI Injured Patient,'' *Archives of Physical Medicine and Rehabilitation,* 1992). Shoulder pain occurs in about 50 percent of people with paraplegia secondary to prolonged wheelchair use. Pain, fatigue and weakness are also commonly reported but accommodations for them are poorly understood.

The 1996 SCI Model Systems Annual report shows employment peaking at 39 percent at fifteen years after injury and at 38.4 percent at 20 years after injury. Interventions are needed to maintain the employment status of people aging with SCI and prevent job loss due to premature aging effects. In addition, further research is needed to determine the changes in functional ability to perform activities of daily living (ADL) and work.

As people age and their functioning changes, the need for assistance from others (i.e., family, friends, and paid caregivers) increases. Strategies to best assist the caregiver, in turn, to help the person who is aging with SCI need to be developed. Moreover, there is no ''typical'' caregiver; some are spouses, some are parents, and some are children. Fifty percent of people with SCI receive help exclusively from their families, and an additional 19 percent receive substantial help from their families. Living with family is the most frequently reported living situation, occurring in over 90 percent of cases (Nosek, M.A., ''Personal Assistance: Key to Maintaining Ability of Persons with Physical Disabilities,'' *Applied Rehabilitation Counselor,* Vol. 21, 1990).

Declining or unstable support systems for people aging with SCI are also a major concern. Since parents of aging SCI individuals are often elderly, they are also at risk of poor health or death. Spousal support providers may experience ''burn-out'' and stress, or develop health problems. There are few alternatives to the informal support system. As individuals with SCI age, access to proper health care, especially with the growing trend toward managed care, is becoming a bigger problem. There is need for research on maintaining independence in the community for people aging with SCI through both the informal and formal systems of care.

Psychological well-being for individuals aging with SCI is also of major concern. Depression is a very important issue requiring additional study because of its bearing on quality of life, its importance for overall health, and its relationship to suicide (Schulz, R., ''Long Term Adjustment to Physical Disability: The Role of Social Support Service of Control and Self Blame,'' *Journal of Personality and Social Psychology,* 5, pgs. 1162–1172, 1985). The research indicates that over 40 percent of people who have sustained functional changes as a consequence of aging with SCI show high levels of distress and depression. Pilot data on treatment are available from the NIDRR-funded centers, but a full treatment procedure for stress and depression needs to be developed.

A significant trend over time has been observed in the racial distribution of persons in the SCI Model Systems database. Among persons injured between 1973 and 1978, 77.5 percent of persons in the database were Caucasian, 13.6 percent were African-American, and 6 percent were Hispanic. Among those injured since 1990, 55.2 percent were Caucasian, 29 percent were African-American, and 12.8 percent were Hispanic (''Spinal Cord Injury, Facts and Figures at a Glance,'' National Spinal Cord Injury Statistical Center, University of Alabama at Birmingham, July, 1996). This increase in incidence of SCI among persons from minority backgrounds is accompanied by research at the current RRTC on Aging with SCI indicating that people from minority backgrounds experience different long-term consequences from SCI.

Priority 4

The Secretary will establish an RRTC for the purpose of conducting research on rehabilitation techniques that assist individuals aging with SCI to maintain employment and independence in the community. The RRTC shall:

(1) Identify, develop, and evaluate interventions to address health maintenance issues, and prevent and treat secondary conditions for individuals aging with SCI;

(2) Identify, develop, and evaluate rehabilitation techniques that will assist individuals aging with SCI to maintain employment and to cope with changes in functional abilities and ADL;

(3) Investigate how formal and informal systems of care could be improved to address the impact of problems associated with long-term care givers and personal service assistants;

(4) Develop a better understanding of the natural course of SCI as persons age and develop regimens to minimize or take account of the impacts of aging with SCI; and

(5) Develop materials and a program of information dissemination and training for individuals aging with SCI, their families, service providers and educators that will assist them to understand the natural course of SCI as persons age.

In carrying out the purposes of the priority, the RRTC shall:

- Emphasize the needs of persons from minority backgrounds; and
- Coordinate with all other relevant SCI research and demonstration activities, including those sponsored by the National Center on Medical Rehabilitation Research, the Rehabilitation Services Administration, Paralyzed Veterans of America, National Spinal Cord Injury Association and NIDRR-funded SCI projects.

Knowledge Dissemination and Utilization Projects

Authority for the D&U program of NIDRR is contained in sections 202 and 204(a) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760–762). Under this program the Secretary makes awards to public and private organizations, including institutions of higher education and Indian tribes or tribal organizations. Under the regulations for this program (see 34 CFR 355.32), the Secretary may establish

research priorities by reserving funds to support particular research activities.

Priority

Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet the following priority. The Secretary will fund under this competition only applications that meet this absolute priority:

Priority 5: Improving the Utilization of Existing and Emerging Rehabilitation Technology in the State Vocational Rehabilitation Program

Background

One of the more persistent issues in the rehabilitation of individuals with disabilities has been maximizing the use of existing and emerging rehabilitation technology in the service settings of the State Vocational Rehabilitation (VR) programs. As defined in Section 7(13) of the Rehabilitation Act, as amended (Act), rehabilitation technology means ''the systematic application of technologies, engineering methodologies, or scientific principles to meet the needs of and address the barriers confronted by individuals with disabilities in areas which include education, rehabilitation, employment, transportation, independent living and recreation'' and includes ''rehabilitation engineering, assistive technology devices, and assistive technology services.'' Under Section 101(a)(5)(C) of the Act, designated VR agencies must describe in their State plan how the State will provide a broad range of rehabilitation technology services at each stage of the rehabilitation process. As appropriate, rehabilitation technology services are provided to individuals with disabilities served by State VR programs under an Individualized Written Rehabilitation Program.

Rehabilitation technology, and information about rehabilitation technology, is generated by a variety of sources including, but not limited to, NIDRR-funded Rehabilitation Engineering and Research Centers, the Assistive Technology program funded under the Technology-Related Assistance for Individuals with Disabilities Act of 1988, ABLEDATA, the Department of Veteran's Affairs Research and Development projects, and manufacturers in the private sector. While many of these sources may undertake dissemination activities, too often rehabilitation counselors and related vocational rehabilitation service providers are unaware of existing or emerging rehabilitation technologies, resulting in a number of problems for clients of the State vocational rehabilitation system.

The provision of inappropriate rehabilitation technology can result in nonuse. The nonuse of a device may lead to decreases in functional abilities, freedom, and independence. On a service delivery level, device abandonment represents ineffective use of limited funds by Federal, State, and local government agencies, insurers, and other provider organizations (Phillips, B. and Hongxin, Z., ''Predictors of Assistive Technology Abandonment,'' *Assistive Technology*, Vol. 5, No. 1, pg. 36, 1993).

If vocational rehabilitation personnel are unfamiliar with an emerging technology, their clients are disadvantaged by not having access to recent developments in the field. These developments may be more effective and economical than existing rehabilitation technology. Because of the costs that can be involved, the decision to utilize a particular rehabilitation technology, even if the technology is outdated, can be difficult to reverse or modify.

Information barriers related to rehabilitation technology also apply to secondary students with disabilities who increasingly complete their education with the help of assistive devices (Everson, J., ''Using Person-centered Planning Concepts to Enhance School-to-Adult Life Transition Planning,'' *Journal of Vocational Rehabilitation*, Vol. 6, 1996). In order to ensure their continued access to technical accommodation as part of their transition to employment and independent living, special education and vocational rehabilitation personnel involved in their transition must have proper training and access to current information.

Assigning inappropriate or outdated rehabilitation technology to consumers can be avoided if vocational rehabilitation personnel are provided with comprehensive and current information on existing and emerging rehabilitation technology. Rehabilitation counselors and related vocational rehabilitation service providers gain access to information about rehabilitation technology from various sources including, but not limited to, their pre-service and in-service training, memberships in professional organizations, conferences, and more recently through the information superhighway. Because the field of rehabilitation technology is developing rapidly, and because it is a technically diverse and complex field, it has been a challenge for rehabilitation personnel development programs to keep pace with rehabilitation technology. There is a growing need for dissemination of information about rehabilitation technology, including the development of pre-service and in-service resources, in order to promote improved rehabilitation professional training on rehabilitation technology.

Priority 5

The Secretary will establish a knowledge dissemination and utilization project for the purpose of improving the ability of rehabilitation professionals to more effectively use rehabilitation technology in providing services to individuals through the State VR Services program. The D&U project must:

(1) Evaluate the pre-service and in-service rehabilitation professional training materials that address rehabilitation technology and identify strengths and deficiencies in those materials;

(2) Based on this evaluation, develop training materials that will improve the ability of rehabilitation counselors and related professionals to utilize existing and emerging rehabilitation technology;

(3) Disseminate these materials to pre-service and in-service rehabilitation professional training programs;

(4) As needed, provide technical assistance to these pre-service and in-service training programs to maximize the use of the materials; and

(5) Using a variety of strategies, disseminate information about existing and emerging rehabilitation technology to rehabilitation counselors, special educators involved with the transition of secondary students, and related rehabilitation professionals.

In carrying out the purposes of the priority, the D&U project must:

- Coordinate with the Assistive Technology projects to avoid duplication of effort;
- Develop information about existing and emerging rehabilitation technology from a wide variety of sources; and
- On a regular basis, update the information and materials that are developed.

APPLICABLE PROGRAM REGULATIONS: 34 CFR Parts 350, 351, and 352. Program Authority: 29 U.S.C. 760–762.

(Catalog of Federal Domestic Assistance Numbers: 84.133A, Research and Demonstration Projects, 84.133B, Rehabilitation Research and Training Center Program, 84.133D, Knowledge Dissemination and Utilization Program)

Dated: May 6, 1997.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

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DEPARTMENT OF EDUCATION

[CFDA Nos.: 84.133A, 84.133B, and 84.133D]

Office of Special Education and Rehabilitative Services, National Institute on Disability and Rehabilitation Research; Notice Inviting Applications for New Awards Under Certain Programs for Fiscal Year 1997

NOTE TO APPLICANTS: This notice is a complete application package. Together with the statute authorizing the programs and applicable regulations governing the programs, including the Education Department General Administrative Regulations (EDGAR), this notice contains information, application forms, and instructions needed to apply for a grant under these competitions.

These programs support the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

The estimated funding levels in this notice do not bind the Department of Education to make awards in any of these categories, or to any specific number of awards or funding levels, unless otherwise specified in statute.

Applicable Regulations:

The Education Department General Administrative Regulations (EDGAR), 34 CFR Parts 74, 75, 77, 80, 81, 82, 85, and 86; and the following program regulations:

(a) *Research and Demonstration Projects (R&D)*—34 CFR Parts 350 and 351;

(b) *Knowledge Dissemination and Utilization Program (D&U)*—34 CFR Parts 350 and 355; and

(c) *Rehabilitation Research and Training Centers (RRTCs)*—34 CFR Parts 350 and 352.

Program Title: Research and Demonstration Projects

CFDA Number: 84.133A

Purpose of Program: The Research and Demonstration Projects program is designed to support discrete research, demonstration, training, and related projects to develop methods, procedures, and technology that maximize the full inclusion and integration into society, independent living, employment, family support, and economic and social self-sufficiency of individuals with disabilities, especially those with the most severe disabilities. In addition, the R&D program supports discrete research, demonstration, and training projects that specifically address the implementation of Titles I, III, VI, VII, and VIII of the Rehabilitation Act, with emphasis on projects to improve the effectiveness of these programs and to meet the needs described in State Plans submitted to the Rehabilitation Services Administration by State vocational rehabilitation agencies.

Eligible Applicants

Parties eligible to apply for grants under this program are public and private nonprofit and for-profit agencies and organizations, including institutions of higher education and Indian tribes and tribal organizations.

Program Authority: 29 U.S.C. 761a and 762.

Program Title: Knowledge Dissemination and Utilization Program

CFDA Number: 84.133D

Purpose of Program: The Knowledge Dissemination and Utilization is designed to support activities that will ensure that rehabilitation knowledge generated from projects and centers funded by NIDRR and from other sources is fully utilized to improve the lives of individuals with disabilities and their families.

Eligible Applicants: Parties eligible to apply for grants under this program are public and private nonprofit and for-profit agencies and organizations, including institutions of higher education and Indian tribes and tribal organizations.

Program Authority: 29 U.S.C. 761a and 762.

APPLICATION NOTICE FOR FISCAL YEAR 1997—RESEARCH AND DEMONSTRATION PROJECTS, CFDA NO. 84.133A, KNOWLEDGE DISSEMINATION AND UTILIZATION PROGRAM, CFDA NO. 84.133D

Funding priority	Deadline for transmittal of applications	Estimated number of awards	Maximum award amount (per year in dollars)*	Project period (months)
Burn Injury Rehabilitation Model System 84.133A	6/23/97	4	295,000	60
Traumatic Brain Injury Model Systems 84.133A	6/23/97	5	345,000	Up to 60**
Improving the Utilization of Rehabilitation Technology in Rehabilitation 84.133D	6/23/97	1	500,000	60

Applications Available: May 9, 1997.

* Note 1: The Secretary will reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount (See 34 CFR 75.104(b)).

** Note 2: Applicants should submit proposals covering a 60 month project period. The Secretary will assess, during the third year of the project period, whether the model as described in the TBI Model Systems Priority is the most appropriate approach and whether revisions are needed in the model. Based on this determination the Secretary will determine whether there is a continuing need to provide funding beyond 36 months.

Research and Demonstration Projects and Knowledge Dissemination and Utilization Program Selection Criteria

The Secretary uses the following selection criteria to evaluate applications under the R&D and D&U programs.

(a) *Potential Impact of Outcomes: Importance of Program* (Weight 3.0).

The Secretary reviews each application to determine to what degree—

(1) The proposed activity relates to the announced priority;

(2) The research is likely to produce new and useful information (research activities only);

(3) The need and target population are adequately defined;

(4) The outcomes are likely to benefit the defined target population;

(5) The training needs are clearly defined (training activities only);

(6) The training methods and developed subject matter are likely to meet the defined need (training activities only); and

(7) The need for information exists (utilization activities only).

(b) *Potential Impact of Outcomes: Dissemination/Utilization* (Weight 3.0). The Secretary reviews each application to determine to what degree—

(1) The research results are likely to become available to others working in the field (research activities only);

(2) The means to disseminate and promote utilization by others are defined;

(3) The training methods and content are to be packaged for dissemination and use by others (training activities only);

(4) The utilization approach is likely to address the defined need (utilization activities only); and

(5) There is likely to be widespread dissemination of the results, in a usable and effective manner, to all appropriate target populations, including individuals with disabilities and their family members.

(c) *Probability of Achieving Proposed Outcomes; Program/ Project Design* (Weight 5.0). The Secretary reviews each application to determine to what degree—

(1) The objectives of the project(s) are clearly stated;

(2) The hypothesis is sound and based on evidence (research activities only);

(3) The project design/methodology is likely to achieve the objectives;

(4) The measurement methodology and analysis is sound (research and development/demonstration activities only);

(5) The conceptual model (if used) is sound (development/ demonstration activities only);

(6) The sample populations are correct and significant (research and development/demonstration activities only);

(7) The human subjects are sufficiently protected (research and development/demonstration activities only);

(8) The device(s) or model system is to be developed in an appropriate environment;

(9) The training content is comprehensive and at an appropriate level (training activities only);

(10) The training methods are likely to be effective (training activities only);

(11) The new materials (if developed) are likely to be of high quality and uniqueness (training activities only);

(12) The target populations are linked to the project (utilization activities only);

(13) The format of the dissemination medium is the best to achieve the desired result (utilization activities only); and

(14) The materials to be used in the project and the materials to be disseminated are likely to be in formats that are accessible to the appropriate populations.

(d) *Probability of Achieving Proposed Outcomes: Key Personnel* (Weight 4.0). The Secretary reviews each application to determine to what degree—

(1) The principal investigator and other key staff have adequate training and/or experience and demonstrate appropriate potential to conduct the proposed research, demonstration, training, development, or dissemination activity;

(2) The principal investigator and other key staff are familiar with pertinent literature and/or methods;

(3) All required disciplines are effectively covered;

(4) Commitments of staff time are adequate for the project; and

(5) The applicant is likely, as part of its non-discriminatory employment practices, to encourage applications for employment from persons who are members of groups that traditionally have been underrepresented, such as—

(i) Members of racial or ethnic minority groups;

(ii) Women;

(iii) Handicapped persons; and

(iv) The elderly.

(e) *Probability of Achieving Proposed Outcomes: Evaluation Plan* (Weight 1.0). The Secretary reviews each application to determine to what degree—

(1) There is a mechanism to evaluate plans, progress and results;

(2) The evaluation methods and objectives are likely to produce data that are quantifiable; and

(3) The evaluation results, where relevant, are likely to be assessed in a service setting.

(f) *Program/Project Management: Plan of Operation* (Weight 2.0). The Secretary reviews each application to determine to what degree—

(1) There is an effective plan of operation that insures proper and efficient administration of the project(s);

(2) The applicant's planned use of its resources and personnel is likely to achieve each objective;

(3) Collaboration between institutions, if proposed, is likely to be effective; and

(4) There is a clear description of how the applicant will include eligible project participants who have been traditionally underrepresented, such as—

(i) Members of racial or ethnic minority groups;

(ii) Women;

(iii) Handicapped persons; and

(iv) The elderly.

(g) *Program/Project Management: Adequacy of Resources* (Weight 1.0). The Secretary reviews each application to determine to what degree—

(1) The facilities planned for use are adequate;

(2) The equipment and supplies planned for use are adequate; and

(3) The commitment of the applicant to provide administrative support and adequate facilities is evident.

(h) *Program/Project Management: (Budget and Cost Effectiveness* (Weight 1.0). The Secretary reviews each application to determine to what degree—

(1) The budget for the project(s) is adequate to support the activities;

(2) The costs are reasonable in relation to the objectives of the projects(s); and

(3) The budget for subcontracts (if required) is detailed and appropriate.

Program Title: Rehabilitation Research and Training Centers

CFDA Number: 84.133B

Purpose of Program: RRTCs conduct coordinated and advanced programs of research on disability and rehabilitation that will produce new knowledge that will improve rehabilitation methods and service delivery systems, alleviate or stabilize disabling conditions, and promote maximum social and economic independence for individuals with disabilities. RRTCs provide training to service providers at the pre-service, in-service training, undergraduate, and graduate levels, to improve the quality and effectiveness of rehabilitation services. They also provide advanced research training to individuals with disabilities and those from minority backgrounds, engaged in research on disability and rehabilitation. RRTCs serve as national and regional technical assistance resources, and provide training for service providers, individuals with disabilities and families and representatives, and rehabilitation researchers.

APPLICATION NOTICE FOR FISCAL YEAR 1997 REHABILITATION RESEARCH AND TRAINING CENTERS CFDA NO. 84.133B

Funding priority	Deadline for transmittal of applications	Estimated number of awards	Maximum award amount (per year in dollars)*	Project period (months)
Effective Interventions for Children and Youth Who Exhibit Severe Problem Behaviors	6/23/97	1	600,000	60
Aging with Spinal Cord Injury	6/23/97	1	650,000	60

Applications Available: May 9, 1997.

*Note: The Secretary will reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount (See 34 CFR 75.104(b)).

Selection Criteria

The Secretary uses the following selection criteria to evaluate applications under this program.

(a) *Relevance and importance of the research program* (20 points). The Secretary reviews each application to determine to what degree—

(1) The proposed activities are responsive to a priority established by the Secretary and address a significant need of a disabled target population and rehabilitation service providers;

(2) The overall research program of the Center includes appropriate interdisciplinary and collaborative research activities, is likely to lead to new and useful knowledge in the priority area, and is likely to become a nationally recognized source of scientific knowledge; and

(3) The applicant demonstrates that all component activities of the Center are related to the overall objective of the Center, and will build upon and complement each other to enhance the likelihood of solving significant rehabilitation problems.

(b) *Quality of the research design* (35 points). The Secretary reviews each application to determine to what degree—

(1) The applicant proposes a comprehensive research program for the entire project period, including at least three interrelated research projects;

(2) The research design and methodology of each proposed activity are meritorious in that—

(i) The literature review is appropriate and indicates familiarity with current research in the field;

(ii) The research hypotheses are important and scientifically relevant;

(iii) The sample populations are appropriate and significant;

(iv) The data collection and measurement techniques are appropriate and likely to be effective;

(v) The data analysis methods are appropriate; and

(vi) The applicant assures that human subjects, animals, and the environment are adequately protected; and

(3) The application discusses the anticipated research results and demonstrates how those results would satisfy the original hypotheses and could be used for planning future research, including generation of new hypotheses where applicable.

(c) *Quality of the training and dissemination program* (25 points). The Secretary reviews each application to determine the degree to which—

(1) The proposed plan for training and dissemination provides evidence that research results will be effectively disseminated and utilized based on the identification of appropriate and accessible target groups; the proposed training materials and methods are appropriate; the proposed activities are relevant to the regional and national needs of the rehabilitation field; and the training materials and dissemination packages will be developed in alternate media that are usable by people with various types of disabilities.

(2) The proposed plan for training and dissemination provides for—

(i) Advanced training in rehabilitation research;

(ii) Training rehabilitation service personnel and other appropriate individuals to improve practitioner skills based on new knowledge derived from research;

(iii) Training packages that make research results available to service providers, researchers, educators, individuals with disabilities, parents, and others;

(iv) Technical assistance or consultation that is responsive to the concerns of service providers and consumers;

(v) Dissemination of research findings through publication in professional journals, textbooks, and consumer and other publications, and through other appropriate media such as audiovisual materials and telecommunications.

(vi) Widespread dissemination of findings and other appropriate materials to providers of rehabilitation and other relevant services to individuals with disabilities, family members of individuals with disabilities, and other authorized representatives, advocates, and organizations that provide information and support to individuals with disabilities and their families; and

(vii) Dissemination of research findings and other materials in appropriate formats and accessible media for use by individuals with various disabilities.

(d) *Quality of the organization and management* (20 points). The Secretary reviews each application to determine the degree to which—

(1) The staffing plan for the Center provides evidence that the project director, research director, training director, principal investigators, and other personnel have appropriate training and experience in disciplines required to conduct the proposed activities; the commitment of staff time is adequate to conduct all proposed activities; and the Center, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or handicapping conditions;

(2) The budgets for the Center and for each component project are reasonable, adequate, and cost-effective for the proposed activities;

(3) The facilities, equipment, and other resources are adequate and are appropriately accessible to persons with disabilities;

(4) The plan of operations is adequate to accomplish the Center's objectives and to ensure proper and efficient management of the Center;

(5) The proposed relationships with Federal, State, and local rehabilitation service providers and consumer organizations are likely to ensure that the Center program is relevant and applicable to the needs of consumers and service providers;

(6) The past performance and accomplishments of the applicant indicate an ability to complete successfully the proposed scope of work;

(7) The application demonstrates appropriate commitment and support by

the host institution and opportunities for interdisciplinary activities and collaboration with other institutions and organizations; and

(8) The plan for evaluation of the Center provides for an annual assessment of the outcomes of the research, the impact of the training and dissemination activities on the target populations, and the extent to which the overall objectives have been accomplished.

Eligible Applicants

Institutions of higher education and public or private agencies and organizations collaborating with institutions of higher education, including Indian tribes and tribal organizations, are eligible to apply for awards under this program.

Program Authority: 29 U.S.C. 762.

Instructions for Application Narrative

The Secretary strongly recommends that applicants include a one-page abstract in their application. The Secretary strongly recommends that the narrative for Research and Demonstration Projects applications and Knowledge Dissemination and Utilization Program applications be limited to no more than 50 double-spaced, typed pages (on one side only), not including appendices. The Secretary strongly recommends that the narrative for Rehabilitation Research and Training Center applications be limited to no more than 100 double-spaced, typed pages (on one side only), not including appendices. These recommended page limits apply only to the narrative and not to the abstract, application forms, assurances, certifications and attachments to those forms, assurances, and certifications.

Instructions for Transmittal of Applications

(a) If an applicant wants to apply for a grant, the applicant shall—

(1) Mail the original and two copies of the application on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # [Applicant must insert number and letter]), Washington, DC. 20202–4725, or

(2) Hand deliver the original and two copies of the application by 4:30 p.m. [Washington, DC time] on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # [Applicant must insert number and letter]), Room #3633, Regional Office Building #3, 7th and D Streets, SW., Washington, DC.

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Notes: (1) The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

(2) An applicant wishing to know that its application has been received by the Department must include with the application a stamped self-addressed postcard containing the CFDA number and title of this program.

(3) The applicant *must* indicate on the envelope and—if not provided by the Department—in Item 10 of the Application for Federal Assistance (Standard Form 424) the CFDA number—and letter, if any—of the competition under which the application is being submitted.

Application Forms and Instructions

The appendix to this application is divided into four parts. These parts are organized in the same manner that the submitted application should be organized. These parts are as follows:

PART I: Application for Federal Assistance (Standard Form 424 (Rev. 4–88)) and instructions.

PART II: Budget Form—Non-Construction Programs (Standard Form 524A) and instructions.

PART III: Application Narrative.

Additional Materials

Estimated Public Reporting Burden.

Assurances—Non-Construction Programs (Standard Form 424B).

Certification Regarding Lobbying, Debarment, Suspension, and Other Responsibility Matters: and Drug-Free Work-Place Requirements (ED Form 80–0013).

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED Form 80–0014) and instructions.

Note: ED Form GCS–014 is intended for the use of primary participants and should not be transmitted to the Department.

Disclosure of Lobbying Activities (Standard Form LLL (if applicable) and instructions; and Disclosure Lobbying Activities Continuation Sheet (Standard Form LLL–A).

An applicant may submit information on a photostatic copy of the application and budget forms, the assurances, and the certifications. However, the application form, the assurances, and the certifications must each have an *original signature*. No grant may be awarded unless a completed application form has been received.

FOR APPLICATIONS CONTACT: The Grants and Contracts Service Team, Department of Education, 600 Independence Avenue S.W., Switzer Building, 3317, Washington, D.C. 20202, or call (202) 205–8207. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–9860. The preferred method for requesting information is to FAX your request to (202) 205–8717.

Information about the Department's funding opportunities, including copies of application notices for discretionary grant competitions, can be viewed on the Department's electronic bulletin board (ED Board), telephone (202) 260–9950; on the Internet Gopher Server (at gopher://gcs.ed.gov); or on the World Wide Web (at http://gcs.ed.gov). However, the official application notice for a discretionary grant competition is the notice published in the **Federal Register**.

Program Authority: 29 U.S.C. 760–762.

Dated: May 6, 1997.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

Appendix

Application Forms and Instructions

Applicants are advised to reproduce and complete the application forms in this Section. Applicants are required to submit an original and two copies of each application as provided in this Section.

Frequent Questions

1. CAN I GET AN EXTENSION OF THE DUE DATE?

No! On rare occasions the Department of Education may extend a closing date for all applicants. If that occurs, a notice of the revised due date is published in the **Federal Register**. However, there are no extensions or exceptions to the due date made for individual applicants.

2. WHAT SHOULD BE INCLUDED IN THE APPLICATION?

The application should include a project narrative, vitae of key personnel, and a budget, as well as the Assurances forms included in this package. Vitae of staff or consultants should include the individual's title and role in the proposed project, and other information that is specifically pertinent to this proposed project. The budgets for both the first year and all subsequent project years should be included.

If collaboration with another organization is involved in the proposed activity, the application should include assurances of participation by the other parties, including written agreements or assurances of cooperation. It is *not* useful to include general letters of support or endorsement in the application.

If the applicant proposes to use unique tests or other measurement instruments that are not widely known in the field, it would be helpful to include the instrument in the application.

Many applications contain voluminous appendices that are not helpful and in many cases cannot even be mailed to the reviewers. It is generally not helpful to include such things as brochures, general capability statements of collaborating organizations, maps, copies of publications, or descriptions of other projects completed by the applicant.

3. WHAT FORMAT SHOULD BE USED FOR THE APPLICATION?

NIDRR generally advises applicants that they may organize the application to follow the selection criteria that will be used. The specific review criteria vary according to the specific program, and are contained in this Consolidated Application Package.

4. MAY I SUBMIT APPLICATIONS TO MORE THAN ONE NIDRR PROGRAM COMPETITION OR MORE THAN ONE APPLICATION TO A PROGRAM?

Yes, you may submit applications to any program for which they are responsive to the program requirements. You may submit the same application to as many competitions as you believe appropriate. You may also submit more than one application in any given competition.

5. WHAT IS THE ALLOWABLE INDIRECT COST RATE?

The limits on indirect costs vary according to the program and the type of application.

An applicant for a project in the R&D or D&U grant programs is limited to the organization's approved indirect cost rate. If the organization does not have an approved indirect cost rate, the application should include an estimated actual rate.

An applicant for a project in the RRTC program is limited to an indirect cost rate of 15 percent.

6. CAN PROFITMAKING BUSINESSES APPLY FOR GRANTS?

Yes. However, for-profit organizations will not be able to collect a fee or profit on the grant, and in some programs will be required to share in the costs of the project.

7. CAN INDIVIDUALS APPLY FOR GRANTS?

No. Only organizations are eligible to apply for *grants* under NIDRR programs. However, individuals are the only entities eligible to apply for fellowships.

8. CAN NIDRR STAFF ADVISE ME WHETHER MY PROJECT IS OF INTEREST TO NIDRR OR LIKELY TO BE FUNDED?

No. NIDRR staff can advise you of the requirements of the program in which you propose to submit your application. However, staff cannot advise you of whether your subject area or proposed approach is likely to receive approval.

9. HOW DO I ASSURE THAT MY APPLICATION WILL BE REFERRED TO THE MOST APPROPRIATE PANEL FOR REVIEW?

Applicants should be sure that their applications are referred to the correct competition by clearly including the competition title and CFDA number, including alphabetical code, on the Standard Form 424, and including a project title that describes the project.

10. HOW SOON AFTER SUBMITTING MY APPLICATION CAN I FIND OUT IF IT WILL BE FUNDED?

The time from closing date to grant award date varies from program to program. Generally speaking, NIDRR endeavors to have awards made within five to six months of the closing date.

Unsuccessful applicants generally will be notified within that time frame as well. For the purpose of estimating a project start date, the applicant should estimate approximately six months from the closing date, but no later than the following September 30.

11. CAN I CALL NIDRR TO FIND OUT IF MY APPLICATION IS BEING FUNDED?

No. When NIDRR is able to release information on the status of grant applications, it will notify applicants by letter. The results of the peer review cannot be released except through this formal notification.

12. IF MY APPLICATION IS SUCCESSFUL, CAN I ASSUME I WILL GET THE REQUESTED BUDGET AMOUNT IN SUBSEQUENT YEARS?

No. Funding in subsequent years is subject to availability of funds and project performance.

13. WILL ALL APPROVED APPLICATIONS BE FUNDED?

No. It often happens that the peer review panels approve for funding more applications than NIDRR can fund within available resources. Applicants who are approved but not funded are encouraged to consider submitting similar applications in future competitions.

BILLING CODE 4000–01–P

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

1. TYPE OF SUBMISSION: *Application* ☐ Construction ☐ Non-Construction; *Preapplication* ☐ Construction ☐ Non-Construction	2. DATE SUBMITTED	Applicant Identifier
	3. DATE RECEIVED BY STATE	State Application Identifier
	4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address *(give city, county, state, and zip code)*:	Name and telephone number of the person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER (EIN):

☐☐ – ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify): _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other *(specify)*:

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐ . ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(cities, counties, states, etc.)*:

13. PROPOSED PROJECT: Start Date	Ending Date	14. CONGRESSIONAL DISTRICTS OF: a. Applicant	b. Project

15. ESTIMATED FUNDING:	
a. Federal	$ .00
b. Applicant	$ .00
c. State	$ .00
d. Local	$ .00
e. Other	$ .00
f. Program Income	$ .00
g. TOTAL	$ .00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE_____

b NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item: Entry:

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. if more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

Item: Entry:

12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

U.S. DEPARTMENT OF EDUCATION

BUDGET INFORMATION

NON-CONSTRUCTION PROGRAMS

OMB Control No. 1875-0102

Expiration Date: 9/30/98

Name of Institution/Organization

Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

SECTION A - BUDGET SUMMARY
U.S. DEPARTMENT OF EDUCATION FUNDS

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	**Total (f)**
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

ED FORM NO. 524

Name of Institution/Organization	Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

SECTION B - BUDGET SUMMARY
NON-FEDERAL FUNDS

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	Total (f)
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

SECTION C - OTHER BUDGET INFORMATION (see instructions)

ED FORM NO. 524

Public reporting burden for this collection of information is estimated to vary from 13 to 22 hours per response, with an average of 17.5 hours, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, Information Management and Compliance Division, Washington, D.C. 20202-4651; and the Office of Management and Budget, Paperwork Reduction Project 1875-0102, Washington, D.C. 20503.

INSTRUCTIONS FOR ED FORM NO. 524

General Instructions

This form is used to apply to individual U.S. Department of Education discretionary grant programs. Unless directed otherwise, provide the same budget information for each year of the multi-year funding request. Pay attention to applicable program specific instructions, if attached.

Section A - Budget Summary
U.S. Department of Education Funds

All applicants must complete Section A and provide a breakdown by the applicable budget categories shown in lines 1-11.

Lines 1-11, columns (a)-(e): For each project year for which funding is requested, show the total amount requested for each applicable budget category.

Lines 1-11, column (f): Show the multi-year total for each budget category. If funding is requested for only one project year, leave this column blank.

Line 12, columns (a)-(e): Show the total budget request for each project year for which funding is requested.

Line 12, column (f): Show the total amount requested for all project years. If funding is requested for only one year, leave this space blank.

Section B - Budget Summary
Non-Federal Funds

If you are required to provide or volunteer to provide matching funds or other non-Federal resources to the project, these should be shown for each applicable budget category on lines 1-11 of Section B.

Lines 1-11, columns (a)-(e): For each project year for which matching funds or other contributions are provided, show the total contribution for each applicable budget category.

Lines 1-11, column (f): Show the multi-year total for each budget category. If non-Federal contributions are provided for only one year, leave this column blank.

Line 12, columns (a)-(e): Show the total matching or other contribution for each project year.

Line 12, column (f): Show the total amount to be contributed for all years of the multi-year project. If non-Federal contributions are provided for only one year, leave this space blank.

Section C - Other Budget Information
Pay attention to applicable program specific instructions, if attached.

1. Provide an itemized budget breakdown, by project year, for each budget category listed in Sections A and B.

2. If applicable to this program, enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period. In addition, enter the estimated amount of the base to which the rate is applied, and the total indirect expense.

3. If applicable to this program, provide the rate and base on which fringe benefits are calculated.

4. Provide other explanations or comments you deem necessary.

BILLING CODE 4000–01–C

Public reporting burden for these collections of information is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of these collections of information, including suggestions for reducing this burden, to: the U.S. Department of Education, Information Management and Compliance Division, Washington, D.C. 20202–4651; and to the Office of Management and Budget, Paperwork Reduction Project 1820–0027, Washington, D.C. 20503.

Research and Demonstration Projects (CFDA No. 84.133A) 34 CFR Parts 350 and 351.

Rehabilitation Research and Training Center (CFDA No. 84.133B) 34 CFR Parts 350 and 352.

Knowledge Dissemination and Utilization Program (CFDA No. 84.133D) 34 CFR Parts 350 and 355.

Assurances—Non-Construction Programs

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728–4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88–352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681–1683, and 1685–1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101–6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92–255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91–616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290dd–3 and 290ee–3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91–646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501–1508 and 7324–7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a–7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327–333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93–234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) Institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91–190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93–523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93–205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a–1 et seq.).

14. Will comply with P.L. 93–348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89–544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

_____

Signature of Authorized Certifying Official

_____

Title

_____

Applicant Organization

_____

Date submitted

Certifications Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and Drug-Free Workplace Requirements

Applicants should refer to the regulations cited below to determine the certification to which they are required to attest. Applicants should also review the instructions for certification included in the regulations before completing this form. Signature of this form provides for compliance with certification requirements under 34 CFR Part 82, ''New Restrictions on Lobbying,'' and 34

CFR Part 85, ''Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants).'' The certifications shall be treated as a material representation of fact upon which reliance will be placed when the Department of Education determines to award the covered transaction, grant, or cooperative agreement.

1. Lobbying

As required by Section 1352, Title 31 of the U.S. Code, and implemented at 34 CFR Part 82, for persons entering into a grant or cooperative agreement over $100,000, as defined at 34 CFR Part 82, Sections 82.105 and 82.110, the applicant certifies that:

(a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement;

(b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form—LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions;

(c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all suberscripients shall certify and disclose accordingly.

2. Debarment, Suspension, and Other Responsibility Matters

As required by Executive Order 12549, Debarment and Suspension, and implemented at 34 CFR Part 85, for prospective participants in primary covered transactions, as defined at 34 CFR Part 85, Sections 85.105 and 85.110—

A. The applicant certifies that it and its principles:

(a) Are not presently debarred, suspended, proposed for debarment, declared intelligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this application been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicated for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application had one or more public transactions (Federal, State, or local) terminated for cause or default; and

B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.

3. Drug-Free Workplace (Grantees Other Than Individuals)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610—

A. The applicant certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an on-going drug-free awareness program to inform employees about—

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employees assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency, in writing, within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, SW., (Room 3124, GSA Regional Office Building No. 3), Washington, DC 20202–4571. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted—

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

_____

_____

_____

Check ☐ if there are workplaces on file that are not identified here.

Drug-Free Workplace (Grantees who are Individuals)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined in at 34 CFR Part 85, Sections 85.605 and 85.610—

A. As a condition of the grant, I certify that I will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant; and

B. If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, I will report the conviction, in writing, within 10 calendar days of the conviction, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, SW., (Room 3124, GSA Regional Office Building No. 3), Washington, DC 20202–4571. Notice shall include the identification number(s) of each affected grant.

As the duly authorized representative of the applicant, I hereby certify that the applicant will comply with the above certifications.

_____

Name of Applicant

_____

PR/Award Number and/or Project Name

_____

Printed Name and Title of Authorized Representative

_____

Signature

_____

Date

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions

This certification is required by the Department of Education regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, for all lower tier transactions meeting the

threshold and tier requirements stated at Section 85.110.

Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

4. The terms ''covered transaction,'' ''debarred,'' ''suspended,'' ''ineligible,'' ''lower tier covered transaction,'' ''participant,'' ''person,'' ''primary covered transaction,'' ''principal,'' ''proposal,'' and ''voluntarily excluded,'' as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled ''Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions,'' without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

Certification

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

_____

Name of Applicant

_____

PR/Award Number and/or Project Name

_____

Printed Name and Title of Authorized Representative

_____

Signature

_____

Date

BILLING CODE 4000–01–P

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:
☐ a. contract
b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

2. Status of Federal Action:
☐ a. bid/offer/application
b. initial award
c. post-award

3. Report Type:
☐ a. initial filing
b. material change

For Material Change Only:
year _____ quarter ____
date of last report _____

4. Name and Address of Reporting Entity:
☐ Prime ☐ Subawardee
Tier _____, *if known:*

Congressional District, *if known:*

5. If Reporting Entity in No.4 is Subawardee, Enter Name and Address of Prime:

Congressional District, *if known:*

6. Federal Department/Agency:

7. Federal Program Name/Description:

CFDA Number, *if applicable*: _____

8. Federal Action Number, *if known:*

9. Award Amount, *if known:*

$

10. a. Name and Address of Lobbying ~~Entity~~ Registrant
(if individual, last name, first name, MI):

b. Individuals Performing Services *(including address if different from No. 10a)*
(last name, first name, MI):

~~11. Amount of Payment *(check all that apply):*~~

~~$ _____ ☐ actual ☐ planned~~

~~12. Form of Payment *(check all that apply):*~~

~~☐ a. cash~~
~~☐ b. in-kind; specify: nature _____~~
~~value _____~~

~~13. Type of Payment *(Check all that apply):*~~

~~☐ a. retainer~~
~~☐ b. one-time fee~~
~~☐ c. commission~~
~~☐ d. contingent fee~~
~~☐ e. deferred~~
~~☐ f. other; specify: _____~~

~~14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11:~~

~~*(attach Continuation Sheet(s) SF-LLL-A, if necessary)*~~

~~15. Continuation Sheet(s) SF-LLL attached: ☐ Yes ☐ No~~

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____

Print Name: _____

Title: _____

Telephone No.: _____ Date: _____

Federal Use Only

Authorized for Local Reproduction
Standard Form - LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. ~~Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate.~~ Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and conract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee" then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number, grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state, and zip code of the ~~lobbying entity~~ registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a). Enter Last Name, First Name, and Middle Initial (MI).

~~11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this a material change report, enter the cumulative amount of payment made or planned to be made.~~

~~12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of in-kind payment.~~

~~13. Check the appropriate box(es). Check all boxes that apply. If other specify nature.~~

~~14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.~~

~~15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.~~

16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

[FR Doc. 97–12258 Filed 5–8–97; 8:45 am]
BILLING CODE 4000–01–C

federal register

Friday
May 9, 1997

Part VIII

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Parts 12, 14, 15, 19, 33, 52, and 53

Federal Acquisition Regulation; Reform of Affirmative Action in Federal Procurement; Proposed Rule

Proposed Collection; Comment Request Entitled Summary Subcontract Support; Notice

Proposed Collection Entitled Reform of Affirmative Action in Federal Procurement; Notice

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 12, 14, 15, 19, 33, 52, and 53

[FAR Case 97–004]

RIN 9000–AH59

Federal Acquisition Regulation; Reform of Affirmative Action in Federal Procurement

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule with request for comments.

SUMMARY: The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration are proposing amendments to the Federal Acquisition Regulation (FAR) concerning programs for small disadvantaged business concerns. These amendments conform to a Department of Justice (DoJ) proposal to reform affirmative action in Federal procurement. DoJ's proposal is designed to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand Constructors, Inc.* v. *Pena,* 115 S.Ct. 2097 (1995). This proposed rule is not requesting public comments on the DoJ proposal or its disposition of the public comments received. This proposed rule requests public comments only on the FAR implementation of the DoJ proposal. Comments on the DoJ proposal will not be considered. This regulatory action was subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993. This is a major rule under 5 U.S.C. 804.

DATES: Comments on the proposed rule should be submitted to the address below on or before July 8, 1997 to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (MVR), 1800 F Street, NW, Room 4035, Washington, DC 20405.

E-mail comments submitted over Internet should be addressed to: 97–004@www.arnet.gov. Please cite FAR case 97–004 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: Ms. Victoria Moss, Procurement Analyst, Federal Acquisition Policy Division, General Services Administration, telephone (202) 501–4764, or Mike Sipple, Procurement Analyst, Office of the Director of Defense Procurement, Department of Defense, telephone (703) 695–8567. For general information, contact the FAR Secretariat, 1800 F Street, NW, Room 4035, GS Building, Washington, DC 20405 (202) 501–4755. Please cite FAR case 97–004.

SUPPLEMENTARY INFORMATION:

A. Background

In *Adarand,* the Supreme Court extended strict judicial scrutiny to Federal affirmative action programs that use racial or ethnic criteria as a basis for decisionmaking. In procurement, this means that any use of race in the decision to award a contract is subject to strict scrutiny. Under strict scrutiny, any Federal programs that make race a basis for contract decisionmaking must be narrowly tailored to serve a compelling government interest.

DoJ developed a proposed structure to reform affirmative action in Federal procurement designed to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand.* The DoJ proposal was previously published for public notice and invitation for comments (61 FR 26042, May 23, 1996). Its proposal, and its disposition of the public comments which is discussed elsewhere in this publication, are within the purview of DoJ. The DoJ model is expected to be implemented in several parts: Small Business Administration regulations; Department of Commerce regulations; and revisions to the FAR and the FAR supplements. This proposed rule contains the FAR revisions.

B. Regulatory Flexibility Act

This proposed rule may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule provides mechanisms through which small disadvantaged business concerns may be provided a benefit in Federal contracting. An Initial Regulatory Flexibility Analysis (IRFA) has been prepared and may be obtained from the FAR Secretariat. A copy of the IRFA has been submitted to the Chief Counsel for Advocacy of the Small Business Administration. The IRFA is summarized as follows:

This proposed rule would establish in the FAR three procurement mechanisms benefiting small disadvantaged businesses (SDBs). These mechanisms will be authorized in certain two-digit Standard Industrial Classification (SIC) Major Groups authorized by the Administrator of the Office of Federal Procurement Policy (OFPP). The first mechanism is a price evaluation adjustment of up to 10 percent. This price evaluation adjustment would be mandatory for those competitive procurements to which it applied. The second mechanism is a source selection evaluation factor or subfactor for planned SDB participation, primarily at the subcontract level, in the performance of a contract. This evaluation factor or subfactor would be used in competitive, negotiated acquisitions expected to exceed $500,000 ($1,000,000 for construction). A third mechanism provides for a monetary incentive for subcontracting with SDBs.

The main impact of the proposed rule is expected to be on SDBs seeking to obtain from Federal Government agencies, or Federal Government agency prime contractors, contracts and subcontracts that are subject to the procurement mechanisms described above. The best available estimate of the number of such firms is 17,350. The proposed rule would also directly affect, although to a lesser degree, all non-SDB small businesses seeking Federal Government contracts that are subject to any of the procurement mechanisms described above, except the price evaluation adjustment (this mechanism applies only to SDB prime contractors).

Comments are invited. Comments from small entities concerning the affected FAR subparts will be considered in accordance with section 610 of the Act. Such comments must be submitted separately and should cite 5 U.S.C. 601, *et seq.* (FAR case 97–004), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (Public Law 104–13) applies because the proposed rule contains reporting and recordkeeping requirements. This proposed rule provides mechanisms through which businesses may be provided a benefit in Federal contracting through their status as small disadvantaged business concerns or their utilization of small disadvantaged business concerns. In order to obtain these benefits, businesses must provide information supporting their status. In addition, firms claiming an advantage on the basis of their utilization of small disadvantaged business concerns must report on their actual accomplishments.

In addition, this proposed rule requires contractors that submit reports under small, small disadvantaged and women-owned small business subcontracting plans to annually provide a breakout of awards (in dollars) to small disadvantaged business concerns by Standard Industrial Classification Major Group.

A request for approval of the paperwork burden has been submitted to the Office of Management and Budget and a notice of that request appears elsewhere in this issue.

List of Subjects in 48 CFR Parts 12, 14, 15, 19, 33, 52, and 53

Government procurement.

Dated: May 6, 1997.

Edward C. Loeb,

Director, Federal Acquisition Policy Division.

Therefore, it is proposed that 48 CFR Parts 12, 14, 15, 9, 33, 52, and 53 be amended as set forth below:

1. The authority citation for 48 CFR Parts 12, 14, 15, 9, 33, 52, and 53 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 12—ACQUISITION OF COMMERCIAL ITEMS

2. Section 12.303 is amended by revising paragraph (b)(1) to read as follows:

12.303 Contract format.

* * * * *

(b) * * *

(1) Block 10 if set-aside for emerging small businesses, if a price evaluation adjustment for small disadvantaged business concerns is applicable (the contracting officer shall indicate the percentage(s) and applicable line item(s)), or if an incentive subcontracting clause is used (the contracting officer shall indicate the applicable percentage);

* * * * *

PART 14—SEALED BIDDING

14.206 Small business set-asides, and price evaluation adjustments for small disadvantaged business concerns.

3. The section heading for 14.206 is revised to read as set forth above.

4. Section 14.502 is amended by redesignating paragraph (b)(4) as (b)(5) and adding a new (b)(4) to read as follows:

14.502 Conditions for use.

* * * * *

(b) * * *

(4) The use of the price evaluation adjustment for small disadvantaged business concerns (see subpart 19.11).

* * * * *

PART 15—CONTRACTING BY NEGOTIATION

5. Section 15.605 is amended by adding paragraph (b)(1)(v) to read as follows:

15.605 Evaluation factors and subfactors.

* * * * *

(b)(1) * * *

(v) The extent of participation of small disadvantaged business concerns in performance of the contract shall be evaluated in unrestricted acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see 19.201 and 19.1202).

* * * * *

6. Section 15.608 is amended in paragraph (a)(2)(ii) by adding the following sentence after the fourth sentence:

15.608 Proposal evaluation.

(a) * * *

(2) * * *

(ii) * * * Where past performance is to be evaluated, the evaluation should include the past performance of offerors in complying with subcontracting plan goals for small disadvantaged business (SDB) concerns (see subpart 19.7), monetary targets for SDB participation (see 19.1202), and notifications submitted under 19.1202–4(b). * * *

* * * * *

7. Section 15.1003 is amended by revising paragraph (a)(2) to read as follows:

15.1003 Notifications to unsuccessful offerors.

(a) * * *

(2) *Preaward notices for small business set-asides.* (i) In a small business set-aside (see subpart 19.5), or when a small disadvantaged business concern receives a benefit based on its disadvantaged status (see subpart 19.11 and 19.1202) and is the apparently successful offeror, upon completion of negotiations and determinations of responsibility, but prior to award, the contracting officer shall notify each unsuccessful offeror in writing of the name and location of the apparently successful offeror. The notice shall also—

(A) Include, when applicable, the name and address of the organization that certified ownership and control of the small disadvantaged business concern;

(B) State that the Government will not consider subsequent revisions of the unsuccessful offerors proposal; and

(C) State that no response is required unless a basis exists to challenge the disadvantaged status and/or small business size status of the apparently successful offeror.

(ii) The notice is not required when the contracting officer determines in writing that the urgency of the requirement necessitates award without delay.

* * * * *

PART 19—SMALL BUSINESS PROGRAMS

8. Section 19.000 is amended by revising paragraph (a) introductory text; at the end of (a)(6) by removing and; at the end of (a)(7) by removing the period and inserting a semicolon in its place; and adding (a)(8) and (a)(9) to read as follows:

19.000 Scope of part.

(a) This part implements the acquisition-related sections of the Small Business Act (15 U.S.C. 631, *et seq.*), applicable sections of the Armed Services Procurement Act (10 U.S.C. 2302, *et seq.*), the Federal Property and Administrative Services Act (41 U.S.C. 252), section 7102 of the Federal Acquisition Streamlining Act of 1994 (Public Law 103–355), 10 U.S.C. 2323, and Executive Order 12138, May 18, 1979. It covers—

* * * * *

(8) The use of a price evaluation adjustment for small disadvantaged business concerns; and

(9) The Small Disadvantaged Business Participation Program.

* * * * *

9. Section 19.201 is amended by redesignating paragraphs (b), (c), and (d) as (c), (d), and (e), respectively; and adding new paragraphs (b) and (f) to read as follows:

19.201 General policy.

* * * * *

(b) The Administrator of the Office of Federal Procurement Policy (OFPP), based upon a recommendation by the Department of Commerce, will publish on an annual basis, by two-digit Major Groups as contained in the Standard Industrial Classification (SIC) Manual, and by region, if any, the authorized small disadvantaged business (SDB) procurement mechanisms, and their effective dates for new solicitations for the upcoming year. The SDB procurement mechanisms currently authorized are a price evaluation adjustment for SDB concerns (see subpart 19.11), an evaluation factor or subfactor for participation of SDB concerns (see 19.1202), and monetary subcontracting incentive clauses for SDB concerns (see 19.1203). This issuance shall also include the applicable factors, by SIC Major Group, to be used in the price evaluation adjustment for SDB concerns (see 19.1104). The authorized procurement mechanisms shall be applied

consistently with the policies and procedures in this subpart. No SDB procurement mechanisms recommended by the Department of Commerce may be used unless authorized by the Administrator of OFPP. The Department of Commerce, in making its recommendations to the Administrator of OFPP, is not limited to the SDB procurement mechanisms identified in this section where the Department of Commerce has found substantial and persuasive evidence of—

(1) A persistent and significant underutilization of minority firms in a particular industry, attributable to past or present discrimination; and

(2) A demonstrated incapacity to alleviate the problem by using those mechanisms.

* * * * *

(f)(1) Each agency shall designate, at levels it determines appropriate, personnel responsible for determining whether use of the SDB mechanism in subpart 19.11 has caused a particular industry category to bear a disproportionate share of the contracts awarded by a contracting activity of the agency to achieve its goal for SDB concerns. Requests for a determination may be submitted by any individual or business concern to the agency designee. If that person makes an affirmative determination of disproportionate impact, the determination shall be forwarded through agency channels for submittal to the Department of Commerce [*name and address*]. The following information should be included in any submittal:

(i) A determination of disproportionate impact, including proposed corrective action;

(ii) The SIC code(s) affected;

(iii) Supporting information to justify the determination, including dollars and percentages by the contracting activity under the affected SIC code(s) for the previous two fiscal years and current fiscal year to date for—

(A) Total awards;

(B) Total awards to small businesses;

(C) Total awards to SDBs; and

(D) Awards to SDBs categorized as SDB price evaluation adjustment, 8(a), small business set-aside, and other; and

(iv) A discussion of the pertinent findings, including any peculiarities related to the industry, regions, or demographics.

(2) If the determination is approved by the Department of Commerce, the contracting activity shall limit the use of the SDB mechanism in subpart 19.11. This limitation shall not apply to solicitations that already have been synopsized.

Subpart 19.3—Determination of Status as a Small Disadvantaged Business Concern or a Small Business Concern

10. The heading of subpart 19.3 is revised to read as set forth above.

11. Section 19.304 is redesignated as 19.306 and new 19.304 and 19.305 are added to read as follows:

19.304 Disadvantaged business status.

(a) The contracting officer may accept an offeror's representation that it is a small disadvantaged business (SDB) concern for general statistical purposes.

(b) For a prime contractor to be eligible to receive a benefit based on its disadvantaged status, the concern must be a small business and must, no later than the date specified by the contracting officer in the solicitation (see 19.306(b)), qualify as a disadvantaged business concern. The mechanisms that may provide benefits on the basis of disadvantaged status as a prime contractor are a price evaluation adjustment for SDB concerns (see subpart 19.11), and an evaluation factor or subfactor for SDB participation (see 19.1202). Disadvantaged status is determined by two factors: Social and economic disadvantage; and ownership and control by the designated socially and economically disadvantaged individuals. Status as a small business is addressed in 19.301.

(1) The contracting officer shall grant members of designated minority groups (see the provision at 52.219–22, Small Disadvantaged Business Status) a presumption of social and economic disadvantage. An offeror must represent in good faith its minority status. Offerors that are not members of designated minority groups shall be required to establish social and economic disadvantage. For non-presumed offerors, a determination of social and economic disadvantage shall be obtained by the offeror from the Small Business Administration (SBA). When a non-presumed offeror represents that it has a current determination of social and economic disadvantage from the SBA, the contracting officer may assess the validity of the representation of social and economic disadvantage by accessing the SBA's on-line central registry at [*Internet address*].

(2) To claim disadvantaged status, an offeror must also submit to the contracting officer a certification, obtained within the prior three years, that the business is owned and controlled by the designated socially and economically disadvantaged individuals. Such a certification must come from an SBA approved organization, a list of which is maintained by the SBA.

(3) Non-presumed offerors must obtain a determination of social and economic disadvantage, and all offerors claiming a disadvantaged status must provide a certification of ownership and control, no later than the date specified by the contracting officer in the solicitation (see 19.306(b)).

§ 19.305 Protesting a determination of disadvantaged business status.

This section applies to protests of a small business concern's disadvantaged status as a prime contractor. Protests of a small business concern's disadvantaged status as a subcontractor are processed under 19.703(a)(2). Protests of a concern's size as a prime contractor are processed under 19.302. Protests of a concern's size as a subcontractor are processed under 19.703(b). Any offeror, the contracting officer, or the SBA may protest the apparently successful offeror's representation of disadvantaged status if the concern is eligible to receive a benefit based on its disadvantaged status (see subpart 19.11 and 19.1202).

(a) An offeror may protest a concern's representation of disadvantaged status by filing a protest with the contracting officer. The protest—

(1) Must be filed within the times specified in 19.302(d)(1); and

(2) Must contain specific detailed evidence supporting the basis of protest.

(b) The contracting officer or the SBA may protest a concern's representation of disadvantaged status at any time.

(1) If a contracting officer's protest is based on information provided by a party ineligible to protest directly or ineligible to protest under the timeliness standard, the contracting officer must be persuaded by the evidence presented before adopting the grounds for protest as his or her own.

(2) The SBA may protest a concern's representation of disadvantaged status by filing directly with its Office of Program Certification and Eligibility and by notifying the contracting officer.

(c) The contracting officer shall return untimely protests to the protester. This includes protests filed before bid opening or notification of the apparently successful offeror.

(d) Upon receipt of a timely protest, the contracting officer shall withhold award and forward the protest to the SBA Office of Program Certification and Eligibility, Office of Minority Enterprise Development, 409 Third Street, SW, Washington, DC 20416. The contracting officer shall send to SBA—

(1) The protest;

(2) The date the protest was received and a determination of timeliness;

(3) A copy of the protested concern's submittals regarding disadvantaged status; and

(4) The date of bid opening or date on which notification of the apparently successful offeror was sent to unsuccessful offerors.

(e) When the contracting officer makes a written determination that award must be made to protect the public interest, award may be made notwithstanding the protest.

(f) The SBA, Office of Program Certification and Eligibility, will determine the disadvantaged status of the challenged offeror and will notify the contracting officer, the challenged offeror, and the protester. Award may be made on the basis of that determination. The determination is final for purposes of the instant acquisition, unless—

(1) It is appealed; and

(2) The contracting officer receives the SBA's decision on the appeal before award.

(g) If the contracting officer does not receive an SBA determination within 15 business days after the SBA's receipt of the protest, the contracting officer shall presume that the challenged offeror is disadvantaged.

(h) An SBA determination may be appealed by—

(1) The interested party whose protest has been denied;

(2) The concern whose status was protested; or

(3) The contracting officer.

(i) The appeal must be filed with the SBA's Associate Administrator for Minority Enterprise Development within five business days after receipt of the determination. If the contracting officer receives the SBA's decision on the appeal before award, the decision shall apply to the instant acquisition. If the decision is received after award, it will apply to future acquisitions.

12. Newly redesignated 19.306 is amended by redesignating paragraph (b) as (c) and adding a new (b) to read as follows:

19.306 Solicitation provision and contract clause.

* * * * *

(b) The contracting officer shall insert the provision at 52.219–22, Small Disadvantaged Business Status, in solicitations that include the clause at 52.219–23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, or 52.219–25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting. The contracting officer shall insert a date that allows offerors a reasonable time, consistent with the needs of the procurement, to obtain a determination of social and economic disadvantage and a certification of ownership and control.

* * * * *

13. Section 19.703 is amended in paragraph (a)(2) by inserting the following sentence after the first sentence; in the new sixth sentence by removing ''Small Business and Capital Ownership'' and inserting ''Enterprise'' in its place; and in paragraph (b) by removing the first sentence. The new text reads as follows:

19.703 Eligibility requirements for participating in the program.

(a) * * *

(2) * * * A prime contractor, acting in good faith, may accept, for general statistical purposes or for purposes of a subcontracting plan, a subcontractor's representation that it is a small disadvantaged business concern. * * *

* * * * *

14. Section 19.705–1 is amended by inserting the following sentence after the first sentence of the undesignated paragraph to read as follows:

19.705–1 General support of the program.

* * * This subsection does not apply to small disadvantaged business subcontracting (see 19.1203). * * *

19.705–4 [Amended]

15. Section 19.705–4 is amended in the last sentence of paragraph (c) by removing '', small disadvantaged''.

19.708 [Amended]

16. Section 19.708 is amended in the first sentence of paragraphs (c)(1), (c)(2), and (c)(3) by removing '', small disadvantaged''.

17. Section 19.1001 is amended by designating the undesignated introductory paragraph as (a); redesignating paragraphs (a) and (b) as (a)(1) and (a)(2), respectively; and adding paragraph (b) to read as follows:

19.1001 General.

* * * * *

(b) Notwithstanding the Small Business Competitiveness Demonstration Program, the following apply to acquisitions in the designated industry groups if authorized by the Administrator of the Office of Federal Procurement Policy (see 19.201(b)):

(1) A price evaluation adjustment for small disadvantaged business concerns (see subpart 19.11), provided this mechanism may only be used when small business set-asides are authorized in the designated industry groups;

(2) An evaluation factor or subfactor for participation of small disadvantaged business concerns (see 19.1202); and

(3) Monetary subcontracting incentive clauses for small disadvantaged business concerns (see 19.1203).

18. Subparts 19.11 and 19.12, consisting of sections 19.1101 through 19.1204, are added to read as follows:

Subpart 19.11—Price Evaluation Adjustment for Small Disadvantaged Business Concerns

Sec.

19.1101 General.
19.1102 Applicability.
19.1103 Procedures.
19.1104 Solicitation provisions and contract clauses.

19.1101 General.

A price evaluation adjustment for small disadvantaged business concerns shall be applied when authorized by the Administrator of the Office of Federal Procurement Policy (OFPP) (see 19.201(b)). The Administrator of OFPP will publish an annual listing of price evaluation adjustment percentages, by Standard Industrial Classification Major Group, to be used in solicitations for the upcoming year.

19.1102 Applicability.

(a) The price evaluation adjustment shall be used in competitive acquisitions.

(b) The price evaluation adjustment shall not be used in acquisitions that—

(1) Are not greater than the simplified acquisition threshold;

(2) Are awarded pursuant to the 8(a) program;

(3) Are set-aside for small business concerns; or

(4) Are for long distance telecommunications services.

19.1103 Procedures.

(a) Give offers from small disadvantaged business concerns a price evaluation adjustment by adding the factor authorized by OFPP to all offers, except—

(1) Offers from small disadvantaged business concerns that have not waived the evaluation adjustment;

(2) Otherwise successful offers of eligible products under the Trade Agreements Act when the acquisition equals or exceeds the dollar threshold in 25.402;

(3) Offers where application of the factor would be inconsistent with a Memorandum of Understanding or other international agreement with a foreign government.

(b) Apply the factor on a line item basis or apply it to any group of items on which award may be made. Add other evaluation factors such as transportation costs or rent-free use of

Government facilities to the offers before applying the price evaluation adjustment.

(c) Do not evaluate offers using the price evaluation adjustment when it would cause award to be made at a price that exceeds fair market price by more than 10 percent (10 U.S.C. 2323(e)(3) and section 7102(a)(1)(B) of Public Law 103–355).

19.1104 Solicitation provisions and contract clauses.

The contracting officer shall insert the clause at 52.219–23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, in solicitations and contracts when the circumstances in 19.1102 apply. The contracting officer shall insert the authorized price evaluation adjustment factor. The clause shall be used with its Alternate I when the contracting officer determines that there are no small disadvantaged business manufacturers that can meet the requirements of the solicitation. This clause does not apply to the Department of Defense, the National Aeronautics and Space Administration, or the Coast Guard.

Subpart 19.12—Small Disadvantaged Business Participation Program

Sec.

19.1201 General.
19.1202 Evaluation factor or subfactor.
19.1202–1 General.
19.1202–2 Applicability.
19.1202–3 Considerations in developing an evaluation factor or subfactor.
19.1202–4 Procedures.
19.1203 Incentive subcontracting with small disadvantaged business concerns.
19.1204 Solicitation provisions and contract clauses.

19.1201 General.

This subpart addresses the evaluation of the extent of participation of small disadvantaged business (SDB) concerns in performance of contracts in the Standard Industrial Classification (SIC) Major Groups authorized by the Administrator of the Office of Federal Procurement Policy (OFPP) (see 19.201(b)) and to the extent authorized by law. Two mechanisms are addressed in this subpart:

(a) An evaluation factor or subfactor for the participation of SDB concerns in performance of the contract; and

(b) An incentive subcontracting program for SDB concerns.

19.1202 Evaluation factor or subfactor.

19.1202–1 General.

The extent of participation of SDB concerns in performance of the contract, in the SIC Major Groups authorized by the Administrator of OFPP and to the extent authorized by law, shall be evaluated consistent with this section. Participation in performance of the contract includes joint ventures, teaming arrangements, and subcontracts. Credit under the evaluation factor or subfactor is not available to SDB concerns that receive a price evaluation adjustment under subpart 19.11. If an SDB concern waives the price evaluation adjustment at subpart 19.11, participation in performance of that contract includes the work expected to be performed by the SDB concern at the prime contract level.

19.1202–2 Applicability.

(a) Except as stated in paragraph (b) of this subsection, the extent of participation of SDB concerns in performance of the contract in the authorized SIC Major Groups shall be evaluated in competitive, negotiated acquisitions expected to exceed $500,000 ($1,000,000 for construction).

(b) The extent of participation of SDB concerns in performance of the contract in the authorized SIC Major Groups (see paragraph (a) of this subsection) shall not be evaluated in—

(1) Small business set-asides (see subpart 19.5);

(2) 8(a) acquisitions (see subpart 19.7);

(3) Negotiated acquisitions where source selection is based on cost or price competition between proposals that meet the Government's minimum requirements stated in the solicitation (see 15.602); or

(4) Contract actions that will be performed entirely outside of any State, territory, or possession of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

19.1202–3 Considerations in developing an evaluation factor or subfactor.

In developing an SDB participation evaluation factor or subfactor, agencies may consider: The extent to which such concerns are specifically identified; the extent to which identified concerns have obtained disadvantaged status (for example, non-presumed offerors that have already obtained disadvantaged status (*i.e.*, obtained a determination of social and economic disadvantage and a certification of ownership and control) are to receive greater consideration than non-presumed offerors that have only applied for disadvantaged status)); the extent of commitment to use such concerns (for example, enforceable commitments are to be weighted more heavily than non-enforceable ones); the complexity and variety of the work small disadvantaged concerns are to perform; the realism of the proposal; past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation; and the extent of participation of such firms in terms of the value of the total acquisition.

19.1202–4 Procedures.

(a) The solicitation shall describe the SDB participation evaluation factor or subfactor. The solicitation shall require offerors to provide, with their offers, targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized SIC Major Groups, and total targets for SDB participation segregated by joint venture partners, team members, and subcontractors. The solicitation shall require an SDB offeror that waives the SDB price evaluation adjustment in the clause at 52.219–23 to provide with its offer a target for the work that it intends to perform as the prime contractor. The solicitation shall state that any targets will be incorporated into and become part of any contract. Contractors with SDB participation targets shall be required to report SDB participation.

(b) When an evaluation includes an SDB participation evaluation factor or subfactor that considers the extent to which SDB firms are specifically identified, the SDBs considered in the evaluation shall be listed in the contract, and the contractor shall be required to notify the contracting officer of any substitutions of firms that are not SDB concerns.

19.1203 Incentive subcontracting with small disadvantaged business concerns.

The contracting officer may encourage increased subcontracting opportunities in the SIC Major Groups authorized by the Administrator of OFPP for SDB concerns in negotiated acquisitions by providing monetary incentives (see the clause at 52.219–26, Incentive Subcontracting Program for Small Disadvantaged Business Concerns, and 19.1204(c)). Monetary incentives shall be based on actual achievement as compared to proposed monetary targets for SDB subcontracting (see 19.1202) or award fee contracting. The incentive subcontracting program is separate and distinct from the establishment, monitoring, and enforcement of SDB subcontracting goals in a subcontracting plan.

19.1204 Solicitation provisions and contract clauses.

(a) The contracting officer may insert a provision substantially the same as the provision at 52.219–24, Small

Disadvantaged Business Participation Targets, in solicitations that consider the extent of participation of SDB concerns in performance of the contract. The contracting officer may vary the terms of this provision consistent with the policies in 19.1202–4.

(b) The contracting officer shall insert the clause at 52.219–25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting, in solicitations and contracts that consider the extent of participation of small disadvantaged business concerns in performance of the contract.

(c) The contracting officer may, when contracting by negotiation, insert in solicitations and contracts containing the clause at 52.219–25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting, a clause substantially the same as the clause at 52.219–26, Incentive Subcontracting Program for Small Disadvantaged Business Concerns, when authorized (see 19.1203). The contracting officer may include an award fee provision in lieu of the incentive; in such cases, however, the contracting officer shall not use the clause at 52.219–26.

PART 33—PROTESTS, DISPUTES, AND APPEALS

19. Section 33.102 is amended by revising the last sentence of paragraph (a) to read as follows:

33.102 General.

(a) * * * (See 19.302 for protests of small business status and 19.305 for protests of disadvantaged business status.)

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

52.212–2 [Amended]

20. Section 52.212–2 is amended by revising the provision date; and in the parenthetical following paragraph (a) of the provision by inserting ''; (iv) small disadvantaged business participation;'' after ''(see FAR 15.605)''.

21. Section 52.212–3 is amended by revising the provision date; and adding two sentences at the end of paragraph (c)(2) to read as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.

* * * * *

Offeror Representations and Certifications—Commercial Items (Date)

* * * * *

(c) * * *

(2) * * * See the clause at 52.212–5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items. If the Contracting Officer has checked 52.219–23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, or 52.219–25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting, and the offeror desires a benefit based on its disadvantaged status, the offeror shall submit a completed copy of the provision at 52.219–22, Small Disadvantaged Business Status, together with any documents required by that provision.

* * * * *

22. Section 52.212–5 is amended by revising the clause date; redesignating paragraphs (b)(6) through (b)(17) as (b)(9) through (b)(20), respectively; and adding paragraphs (b)(6), (b)(7), and (b)(8) to read as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (Date)

* * * * *

(b) * * *

_____ (6) 52.219–23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (Pub. L. 103–355, section 7102). (_____Alternate I). If the offeror elects to waive the adjustment, it shall so indicate in its offer.

_____ (7) 52.219–25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting.

_____ (8) 52.219–26, Incentive Subcontracting Program for Small Disadvantaged Business Concerns.

* * * * *

23. Section 52.219–9 is amended by revising the clause date and paragraph (d)(10)(iii); and by adding paragraph (j) to read as follows:

52.219–9 Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan.

* * * * *

Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan (Date)

* * * * *

(d)(10) * * * (iii) submit Standard Form (SF) 294, Subcontracting Report for Individual Contracts, and/or SF 295, Summary Subcontract Report, in accordance with the instructions on the forms and in paragraph (j) of this clause, and * * *

* * * * *

(j) The Contractor shall submit the following reports:

(1) *Standard Form 294, Subcontracting Report for Individual Contracts.* This report shall be submitted to the Contracting Officer semiannually and at contract completion. The reports cover subcontract award data related to this contract. This report is not required for company-wide or division-wide subcontracting plans.

(2) *Standard Form 295, Summary Subcontract Report.* This report encompasses all the contracts with the awarding agency. It must be submitted semi-annually for contracts with the Department of Defense and annually for contracts with civilian agencies. If the reporting activity is covered by a company-wide or division-wide plan, the reporting activity must report annually all subcontract awards under that plan. All reports submitted at the close of each fiscal year (both individual and company-wide or division-wide plans) shall include a breakout of subcontract awards, in whole dollars, to small disadvantaged business concerns by Standard Industrial Classification (SIC) Major Group. For a company-wide or division-wide plan, the Contractor may obtain from each of its subcontractors a predominant SIC code and report all awards to that subcontractor under its predominant SIC code.

* * * * *

52.219–10 [Amended]

24. Section 52.219–10 is amended by revising the clause date; and in the first sentence of paragraph (b) of the clause by inserting ''for small business concerns and women-owned small business concerns'' after the word ''goals''.

25. Sections 52.219–22 through 52.219–26 are added to read as follows:

52.219–22 Small Disadvantaged Business Status.

As prescribed in 19.306(b), insert the following provision:

Small Disadvantaged Business Status (Date)

(a) *Definition. Small disadvantaged business concern,* as used in this provision, means—

(1) A small business concern that—

(i) Is at least 51 percent unconditionally owned by one or more individuals who are both socially and economically disadvantaged, or a publicly owned business having at least 51 percent of its stock unconditionally owned by one or more socially and economically disadvantaged individuals;

(ii) Has its management and daily business controlled by one or more such individuals; and

(iii) For the Department of Defense, National Aeronautics and Space Administration, and Coast Guard only, the majority of earnings of which accrue to such individuals; or

(2) A small business concern that is at least 51 percent unconditionally owned by an economically disadvantaged Indian tribe or Native Hawaiian Organization, or a publicly owned business having at least 51 percent of its stock unconditionally owned by one or more of these entities, which has its management and daily business controlled by members of an economically disadvantaged Indian tribe or Native Hawaiian Organization, and which meets the requirements of 13 CFR Part 124.

(b) *General.* This provision is used to assess an offeror's small disadvantaged business status for the purpose of obtaining a benefit as a result of this solicitation. Status as a small business concern and status as a small disadvantaged business concern for general statistical purposes is covered by the provision at 52.219–1, Small Business Program Representation. Offerors claiming disadvantaged business status must demonstrate social and economic disadvantage and ownership and control by the designated individuals. [The offeror shall check one of the following:]

_____ The offeror is not claiming disadvantaged business status.

_____ The offeror is claiming disadvantaged business status. [*The offeror shall enter the name(s), title(s) and business address(es) of the socially and economically disadvantaged individuals and paragraphs (b)(1) and (b)(2) of this provision.*] The socially and economically disadvantaged individual(s) are:

_____

_____

_____

(1) *Social and Economic Disadvantage.* Individuals who are members of the groups named in paragraph (b)(1)(i) of this provision are entitled to a presumption of social and economic disadvantage and must check the applicable categories. However, these presumptions are rebuttable (see the criteria for social disadvantage at 13 CFR 124.105 and economic disadvantage at 13 CFR 124.106). Individuals who are not members of the named groups must complete paragraph (b)(1)(ii) of this provision.

(i) *Individuals with a Presumption of Social and Economic Disadvantage.* The offeror represents that its ownership falls within at least one of the following categories [*the offeror shall check the applicable categories*]:

_____ Black American;

_____ Hispanic American;

_____ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians);

_____ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, the Philippines, U.S. Trust Territory of the Pacific Islands (Republic of Palau), Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru);

_____ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal).

_____ Individual/concern, other than one of the preceding, currently certified for participation in the Minority Enterprise Development Program under section 8(a) of the Small Business Act (15 U.S.C. 637(a)).

(ii) *Individuals without a Presumption of Social and Economic Disadvantage.* Offerors must obtain a determination of social and economic disadvantage from the Small Business Administration dated no earlier than three years prior to the date of the solicitation. The offeror shall check one of the following:

_____ The offeror represents, as part of its offer, that the Small Business Administration has made a determination concerning the individual's or individuals' status as socially and economically disadvantaged. The offeror certifies that it was found by the Small Business Administration to be socially and economically disadvantaged as a result of that determination and that no circumstances have changed to alter that determination.

_____ The offeror represents that it will obtain a determination of social and economic disadvantage from the Small Business Administration by _____ [*contracting officer shall insert date*] or forego any benefits based on disadvantaged status.

(2) *Ownership and Control.* Both presumed and non-presumed offerors must demonstrate ownership and control by providing a certification from an organization approved by the Small Business Administration dated no earlier than three years prior to the date of the solicitation. [*The offeror shall check one of the following:*]

_____Attached is a certification of ownership and control. The offeror certifies that no circumstances have changed to alter the validity of the certification.

_____The offeror represents that it will provide a certification of ownership and control from an organization approved by the Small Business Administration by _____ [*contracting officer shall insert date*] or forego any benefits based on disadvantaged status.

(c) *Penalties and Remedies.* Anyone who misrepresents any aspects of the disadvantaged status of a concern for the purposes of securing a contract or subcontract shall—

(1) Be punished by imposition of a fine, imprisonment, or both;

(2) Be subject to administrative remedies, including suspension and debarment; and

(3) Be ineligible for participation in programs conducted under authority of the Small Business Act.

(End of provision)

52.219–23 Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns.

As prescribed in 19.1104, insert the following clause:

Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (Date)

(a) *Definitions. Small disadvantaged business concern,* as used in this clause, means—

(1) A small business concern that—

(i) Is at least 51 percent unconditionally owned by one or more individuals who are both socially and economically disadvantaged, or a publicly owned business having at least 51 percent of its stock unconditionally owned by one or more socially and economically disadvantaged individuals; and

(ii) Has its management and daily business controlled by one or more such individuals; or

(2) A small business concern that is at least 51 percent unconditionally owned by an economically disadvantaged Indian tribe or Native Hawaiian Organization, or a publicly owned business having at least 51 percent of its stock unconditionally owned by one or more of these entities, which has its management and daily business controlled by members of an economically disadvantaged Indian tribe or Native Hawaiian Organization, and which meets the requirements of 13 CFR Part 124.

United States, as used in this clause, means the United States, its territories and possessions, the Commonwealth of Puerto Rico, the U.S. Trust Territory of the Pacific Islands, and the District of Columbia.

(b) *Evaluation adjustment.* (1) Offers will be evaluated by adding a factor of _____ [*percentage to be inserted by the contracting officer*] percent to the price of all offers, except—

(i) Offers from small disadvantaged business concerns that have not waived the adjustment;

(ii) Otherwise successful offers of eligible products under the Trade Agreements Act when the dollar threshold for application of the Act is exceeded (see section 25.402 of the Federal Acquisition Regulation); and

(iii) Offers where application of the factor would be inconsistent with a Memorandum of Understanding or other international agreement with a foreign government.

(2) The factor shall be applied on a line item basis or to any group of items on which award may be made. Other evaluation factors described in the solicitation shall be applied before application of the factor. The factor may not be applied if using the adjustment would cause the contract award to be made at a price that exceeds the fair market price by more than 10 percent.

(c) *Waiver of evaluation adjustment.* A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of this clause do not apply to offers that waive the adjustment.

_____ Offeror elects to waive the adjustment.

(d) *Agreements.* (1) A small disadvantaged business concern, that did not waive the adjustment, agrees that in performance of the contract, in the case of a contract for

(i) Services, except construction, at least 50 percent of the cost of personnel for contract performance will be spent for employees of the concern.

(ii) Supplies (other than procurement from a nonmanufacturer of such supplies), at least 50 percent of the cost of manufacturing, excluding the cost of materials, will be performed by the concern.

(iii) General construction, at least 15 percent of the cost of the contract, excluding the cost of materials, will be performed by employees of the concern.

(iv) Construction by special trade contractors, at least 25 percent of the cost of the contract, excluding the cost of materials, will be performed by employees of the concern.

(2) A small disadvantaged business concern submitting an offer in its own name agrees to furnish in performing this contract only end items manufactured or produced by small disadvantaged business concerns in the United States. This paragraph does not apply in connection with construction or service contracts.

(End of clause)

Alternate I (Date). As prescribed in 19.1104, substitute the following paragraph (d)(2) for paragraph (d)(2) of the basic clause:

(d)(2) A small disadvantaged business concern submitting an offer in its own name agrees to furnish in performing this contract only end items manufactured or produced by small business concerns in the United States. This paragraph does not apply in connection with construction or service contracts.

52.219–24 Small Disadvantaged Business Participation Targets.

As prescribed in 19.1204(a), insert a provision substantially as follows:

Small Disadvantaged Business Participation Targets (Date)

(a) This solicitation contains a source selection factor or subfactor related to the participation of small disadvantaged business (SDB) concerns in the contract. Credit under that evaluation factor or subfactor is not available to an SDB concern that qualifies for a price evaluation adjustment under the clause at FAR 52.219–23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, unless the SDB concern specifically waives the price evaluation adjustment.

(b) In order to receive credit under the source selection factor or subfactor, the offeror must provide, with its offer, targets, expressed as dollars and percentages of total contract value, for SDB participation in any of the Standard Industrial Classification (SIC) Major Groups for which the Administrator of the Office of Federal Procurement Policy has authorized the use of an evaluation factor or subfactor for SDB participation. A listing of those SIC codes may be found at: gopher://www.sbaonline.sba.gov:70/00/Government-Contracting/Size/sizeall.txt. The targets may provide for participation by a prime contractor, joint venture partner, teaming arrangement member, or subcontractor; however, the targets for subcontractors must be listed separately.

(End of provision)

52.219–25 Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting.

As prescribed in 19.1204(b), insert the following clause:

Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (Date)

(a) *Disadvantaged status for joint venture partners, team members, and subcontractors.* This clause addresses disadvantaged status for joint venture partners, teaming arrangement members, and subcontractors and is applicable if this contract contains small disadvantaged business (SDB) participation targets. Disadvantaged status consists of a determination of social and economic disadvantage, and a certification of ownership and control by the designated socially and economically disadvantaged individuals.

(1) *Social and economic disadvantage.* The Contractor, acting in good faith, may rely on the representations of joint venture partners, teaming arrangement members, and subcontractors regarding membership in designated minority groups. Representations shall be obtained from joint venture partners, teaming arrangement members, and subcontractors by way of a provision substantially the same as the provision at FAR 52.219–22, Small Disadvantaged Business Status. The Contractor shall grant members of designated minority groups a presumption of social and economic disadvantage. The Contractor shall also consider individuals to be socially and economically disadvantaged if they have obtained a determination of social and economic disadvantage from the Small Business Administration (SBA). The Contractor shall assess the validity of the determination by accessing the SBA's on-line registry at [INTERNET ADDRESS].

(2) *Ownership and control.* To claim disadvantaged status, a joint venture partner, teaming arrangement member or subcontractor must submit to the Contractor a certification that the business is owned and controlled by the designated socially and economically disadvantaged individuals. Such a certification must come from an SBA approved organization dated no earlier than three years from the date of the joint venture or teaming arrangement or subcontract solicitation. A list of approved certifying organizations is maintained by the SBA.

(b) *Reporting requirement.* If this contract contains SDB participation targets, the Contractor shall report on the participation of SDB concerns at contract completion, or as otherwise provided in this contract. Reporting may be on the Optional Form XX, Small Disadvantaged Business Participation Report, or in the Contractor's own format providing the same information. This report is required for each contract containing SDB participation targets. If this contract contains an individual Small, Small Disadvantaged and Women-owned Small Business Subcontracting Plan, reports may be submitted with the final Subcontracting Report for Individual Contracts (Standard Form 294) at the completion of the contract.

(End of clause)

52.219–26 Incentive Subcontracting Program for Small Disadvantaged Business Concerns.

As prescribed in 19.1204(c), insert the following clause:

Incentive Subcontracting Program for Small Disadvantaged Business Concerns (Date)

(a) Of the total dollars it plans to spend under subcontracts, the Contractor has committed itself in its offer to try to award a certain amount to small disadvantaged business concerns in the Standard Industrial Classification (SIC) Major Groups authorized by the Administrator of the Office of Federal Procurement Policy.

(b) If the Contractor exceeds its total monetary target for subcontracting to small disadvantaged business concerns in the authorized SIC Major Groups, it will receive _____ [*insert the appropriate number between 0 and 10*] percent of the dollars in excess of the monetary target, unless the Contracting Officer determines that the excess was not due to the Contractor's efforts (*e.g.*, a subcontractor cost overrun caused the actual subcontract amount to exceed that estimated in the offer, or the excess was caused by the award of subcontracts that had been planned but had not been disclosed in the offer during contract negotiations). Determinations made under this paragraph are not subject to the Disputes clause.

(c) If this is a cost-plus-fixed-fee contract, the sum of the fixed fee and the incentive fee earned under this contract may not exceed the limitations in Subpart 15.9 of the Federal Acquisition Regulation.

(End of clause)

PART 53—FORMS

26. Section 53.219 is amended by adding paragraph (c) to read as follows:

§ 53.219 Small business programs.

* * * * *

(c) *OF XX (DATE), Small Disadvantaged Business Participation Report.* (See subpart 19.12.)

27. Section 53.302–XX is added to read as follows:

53.302–XX OF XX, Small Disadvantaged Business Participation Report.

BILLING CODE 6820–EP–U

SMALL DISADVANTAGED BUSINESS PARTICIPATION REPORT

OMB No: 9000-xxxx
Expires xx/xx/xx

Page of

Public reporting burden for this collection of information is estimated to average 8.66 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the FAR Secretariat (MVRS), Office of Governmentwide Policy, Federal Acquisition Policy Division, GSA, Washington, DC 20405.

1. Contractor name and address

2. Contract number

3. Total participation of small disadvantaged businesses in the contract $

4. SDB participation at prime contract level

Industry category $

5. Breakdown of SDB participation at subcontract level by industry category

A. Major Category	B. Dollars	C. Percent	A. Major category	B. Dollars	C. Percent

6. Name of individual who prepared report	7. Telephone	8. Date

Authorized for local reproduction.

Optional Form XX
Prescribed by ....

GENERAL INSTRUCTIONS

1. This form collects data on the participation of small disadvantaged business concerns in contracts that contain the clause at FAR 52.219-26, Small Disadvantaged Business Participation Program - Disadvantaged Status and Reporting. This form may also be used to report the breakout of subcontracting with small disadvantaged business concerns under the clause at FAR 52.219-9, Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan.

2. Reports may be submitted on this form, or in any other format that includes all the required information.

3. Submit this report to the contracting officer. If your organization is required to report subcontracting data under an individual subcontracting plan, you may attach this report to the final SF 294 report submitted under the contract.

4. Report in whole dollars.

SPECIFIC INSTRUCTIONS:

Block 3: Report the total dollar amount of participation of small disadvantaged business concerns under the contract cited in Block 2. Participation may be through subcontracting, teaming arrangement, joint ventures, or as the prime contractor (provided the prime contractor waived its right to a price evaluation adjustment).

Block 4. Report the participation, if any, by small disadvantaged business concerns in this contract at the prime contract level. All prime contract dollars must be reported under the Major Group (first two digits of the SIC code) assigned to the prime contract. Report the dollar amount and percentage of the total contract value.

Block 5. Report, by major group, the participation by small disadvantaged business concerns in this contract at the subcontract level. Report the dollar amount and percentage of the total contract value.

Blocks 6 and 7. Provide the name and telephone number of the individual who can answer questions related to this report.

[FR Doc. 97–12264 Filed 5–8–97; 8:45 am]
BILLING CODE 6820–EP–U

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0007]

Proposed Collection; Comment Request Entitled Summary Subcontract Support

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding a revision of an existing OMB clearance (9000–0007).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision of a currently approved information collection requirement concerning Summary Subcontract Report.

DATES: Comment Due Date: July 8, 1997.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat, 1800 F Street, NW, Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000–0007, Summary Subcontract Report, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Victoria Moss, Office of Federal Acquisition Policy, GSA (202) 501–4764.

SUPPLEMENTARY INFORMATION:

A. Purpose

The proposed rule contemplates revisions to the FAR to implement the Department of Justice (DOJ) proposal to reform affirmative action in Federal procurement. DOJ's proposal is designed to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand Constructors, Inc.* v. *Pena,* 115 S.Ct. 2097 (1995). In *Adarand*, the Supreme Court extended strict judicial scrutiny to Federal affirmative action programs that use racial or ethnic criteria as a basis for decisionmaking. In Federal procurement, this means that any use of race in the decision to award a contract is subject to strict scrutiny. Under strict scrutiny, any Federal programs that make race a basis for contract decisionmaking must be narrowly tailored to serve a compelling government interest.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *16.77* hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents, *4,253*; responses per respondent, *1.66*; total annual responses, *7,098*; preparation hours per response, *16.77*; and total response burden hours, *119,070*.

Obtaining Copies of Justifications

Requester may obtain a copy of the justification from the General Services Administration, FAR Secretariat (MVRS), Room 4037, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0007, Summary Subcontract Support, in all correspondence.

Dated: April 22, 1997.

Sharon A. Kiser,

FAR Secretariat.

[FR Doc. 97–12266 Filed 5–8–97; 8:45 am]

BILLING CODE 6820–EP–U

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[FAR Case 97–004]

Comment Request; Proposed Collection Entitled Reform of Affirmative Action in Federal Procurement

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding a new information collection requirement.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat plans to submit to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement concerning Reform of Affirmative Action in Federal Procurement (FAR Case 97–004).

DATES: Comment Due Date: July 8, 1997.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat, 1800 F Street, NW, Room 4037, Washington, DC 20405. Please cite FAR case 97–004, Reform of Affirmative Action in Federal Procurement, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Ms. Victoria Moss, Office of Federal Acquisition Policy, GSA (202) 501–4764.

SUPPLEMENTARY INFORMATION:

A. Purpose

The proposed rule contemplates revisions to the FAR to implement the Department of Justice (DOJ) proposal to reform affirmative action in Federal procurement. DOJ's proposal is designed to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand Constructors, Inc.* v. *Pena,* 115 S.Ct. 2097. In *Adarand*, the Supreme Court extended strict judicial scrutiny to Federal affirmative action programs that use racial or ethnic criteria as a basis for decisionmaking. In Federal procurement, this means any use of race in the decision to award a contract is subject to strict scrutiny. Under strict scrutiny, any Federal programs that make race a basis for contract decisionmaking must be narrowly tailored to serve a compelling Government interest.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *2.09* hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents *20,430*; responses per respondent, *8.97*; total annual responses, *182,470*; preparation hours per response, *2.09*; and total response burden hours, *381,305*.

Obtaining Copies of Justifications

Requester may obtain a copy of the justification from the General Services

Administration, FAR Secretariat (MVRS), Room 4037, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite FAR case 97–004, Reform of Affirmative Action in Federal Procurement, in all correspondence.

Dated: April 17, 1997.

Sharon A. Kiser,

FAR Secretariat.

[FR Doc. 97–12265 Filed 5–8–97; 8:45 am]

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Federal Register

Vol. 62, No. 90

Friday, May 9, 1997

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The United States Government Manual **523–5227**

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Privacy Act Compilation **523–3187**

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FEDERAL REGISTER PAGES AND DATES, MAY

23613–23938 1
23939–24324 2
24325–24558 5
24559–24796 6
24797–25106 7
25107–25420 8
25421–25798 9

CFR PARTS AFFECTED DURING MAY

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.

3 CFR

Proclamations:
6996 24555
6997 24557
6998 25105
6999 25421

Administrative Orders:
Presidential Determinations:
No. 97–21 of April 24, 1997 23939
Memorandums:
April 24, 1997 24797

5 CFR

530 25423
531 25423
591 25423
1312 25426
3801 23941

Proposed Rules:
1603 25558
1640 25559

7 CFR

29 24559
226 23613
301 ..... 23620, 23943, 24746, 24753
340 ..... 23628, 23945
401 25107
454 23628
457 ..... 23628, 25107
718 25433
723 24799
729 25433
1464 24799
1493 24560
1494 24560
1755 ..... 23958, 25017
1930 25062
1944 ..... 25062, 25071
1951 25062
1965 25062

Proposed Rules:
Ch. XIII 24849, 25140
319 ..... 24849, 25561
321 24849
330 24849
401 23675
405 25140
416 23680
425 23685
437 23690
457 ..... 23675, 23680, 23685, 23690, 25140
1137 24610

8 CFR

292 23634

9 CFR

77 24801
92 23635
94 ..... 24802, 25439
160 25444
161 25444
304 23639
308 23639
310 23639
327 23639
381 23639
416 23639
417 23639

Proposed Rules:
3 24611

10 CFR

703 24804
1023 24804

Proposed Rules:
71 25146
435 24164

11 CFR

Proposed Rules:
100 24367
104 24367
109 24367
110 24367

12 CFR

617 24562
620 24808
630 24808

Proposed Rules:
IX 25563

13 CFR

121 24325

14 CFR

39 ..... 23640, 23642, 24009, 24013, 24014, 24015, 24017, 24019, 24021, 24022, 24325, 24567, 24568, 24570, 24809, 24810
71 ..... 23643, 23644, 23646, 23647, 34648, 23649, 23651, 23652, 23653, 23654, 23655, 23656, 24024, 25110, 25112, 25445, 25448
95 25448
97 ..... 24025, 25110
187 ..... 24286, 24552

Proposed Rules:
11 24288
21 24288
25 24288
39 ..... 23695, 23697, 24851, 25130, 25563, 25565, 25566
71 ..... 23699, 25568

15 CFR

730 25451

732 25451
734 25451
736 25451
738 25451
740 25451
742 25451
744 25451
750 25451
752 25451
754 25451
756 25451
758 25451
762 25451
764 25451
768 25451
770 25451
772 25451
950 24812

16 CFR

Proposed Rules:
1015 24614

17 CFR

1 ..... 24026, 25470
15 24026
16 24026
17 24026
230 24572

Proposed Rules:
230 24160
239 24160
270 ..... 24160, 24161
274 24160

18 CFR

Proposed Rules:
154 24853
430 25569

19 CFR

122 24814

Proposed Rules:
111 24374
163 24374

20 CFR

429 24328

21 CFR

Proposed Rules:
Ch. I 24619
178 25475
511 ..... 25212, 25153
514 25152
558 25477
898 25477
1308 24620

22 CFR

41 ..... 24331, 24332, 24334

24 CFR

5 24334
573 24573
950 24334
3280 24337
3282 24337

Proposed Rules:
960 25728
966 25728
3500 25740

26 CFR

1 ..... 23657, 25498, 25502
301 25498
602 25502

27 CFR

Proposed Rules:
9 24622

28 CFR

0 23657
45 23941
544 25098

29 CFR

Proposed Rules:
4231 23700

30 CFR

Proposed Rules:
251 23705
253 24375

31 CFR

351 24280
356 ..... 25113, 25224

Proposed Rules:
207 25572
356 24375

32 CFR

706 23658

33 CFR

117 ..... 24338, 25514
154 25115
155 25115
156 25115
165 ..... 23659, 24339
334 24034

Proposed Rules:
96 23705
100 24377
110 24378
167 25576

34 CFR

685 25515

Proposed Rules:
1100 24860

36 CFR

Proposed Rules:
7 24624

37 CFR

Proposed Rules:
1 24865
2 24865

38 CFR

Proposed Rules:
3 23724
17 23731
36 ..... 24872, 24874

39 CFR

20 ..... 25136, 25515
111 ..... 24340, 25752

Proposed Rules:
3001 25578

40 CFR

52 ..... 24035, 24036, 24341, 24574, 24815, 24824, 24826
60 24824
81 ..... 24036, 24038, 24552, 24826
87 25356
180 ..... 24040, 24045, 24835, 24839, 25518, 25524
244 24051
372 23834

Proposed Rules:
52 ..... 24060, 24380, 24632, 24886, 24887
60 ..... 24212, 24887
63 ..... 24212, 25370
80 24776
81 24065
87 25368
180 24065
260 24212
261 24212
264 24212
265 24212
266 24212
270 24212
271 24212
372 24887

41 CFR

Proposed Rules:
101–47 24383

44 CFR

64 24343

Proposed Rules:
62 23736

45 CFR

1626 ..... 24054, 24159

46 CFR

13 25115
15 25115
30 25115
35 25115
98 25115
105 25115
108 23894
110 23894
111 23894
112 23894
113 23894
159 25525
160 25525
161 23894
169 25525
199 25525

Proposed Rules:
2 23705
31 23705
71 23705
91 23705
107 23705
115 23705
126 23705
175 23705
176 23705
189 23705

47 CFR

0 24054
1 24576
2 24576
64 ..... 24583, 24585
68 24587
73 ..... 24055, 24842, 24843, 24844, 25557
101 24576

Proposed Rules:
Ch. I 25157
2 24383
25 24073
73 24896

48 CFR

1831 24345

Proposed Rules:
12 25786
14 25786
15 25786
19 25786
33 25786
32 23740
52 ..... 23740, 25786
53 25786
252 23741

49 CFR

1 23661
8 23661
10 23666
107 24055
171 24690
172 24690
173 24690
175 24690
176 24690
178 24690
190 24055

Proposed Rules:
Ch. X 24896
1121 23742
1150 23742

50 CFR

91 24844
222 24345
227 ..... 24345, 24588
600 23667
622 23671
648 25138
660 ..... 24355, 24845
670 24058
679 ..... 24058, 25138

Proposed Rules:
17 ..... 24387, 24388, 24632
600 ..... 23744, 24897
622 25158
648 24073

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT MAY 9, 1997

AGRICULTURE DEPARTMENT

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Veterinarian accreditation, etc.:

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AGRICULTURE DEPARTMENT

Farm Service Agency

Farm marketing quotas, acreage allotments, and production adjustments:

Peanuts; published 5-9-97

COMMERCE DEPARTMENT

Export Administration Bureau

Export administration regulations:

Restructuring, reorganization, and simplification; published 5-9-97

ENVIRONMENTAL PROTECTION AGENCY

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Cyfluthrin; published 5-9-97

FEDERAL COMMUNICATIONS COMMISSION

Radio stations; table of assignments:

Missouri; published 5-9-97

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Animal drugs, feeds, and related products:

Semduramicin; published 5-9-97

Food additives:

Adjuvants, production aids, and sanitizers—

High-purity furnace black; published 5-9-97

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Community development block grants:

Hispanic-serving institutions work study program; published 4-9-97

PERSONNEL MANAGEMENT OFFICE

Federal Employee Travel Reform Act of 1996; implementation:

Location-based pay entitlements; official duty station determinations; published 5-9-97

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Airbus Industrie; published 4-4-97

Bell; published 4-4-97

Jetstream; published 4-4-97

Raytheon; published 3-13-97

Correction; published 5-2-97

Airworthiness standards:

Special conditions—

Lockheed Martin Aerospace Corp. model L382J airplane; published 4-9-97

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Arbitrage and related restrictions on tax-exempt bonds; guidance for complying; published 5-9-97

Partnership termination; published 5-9-97¶

RULES GOING INTO EFFECT MAY 10, 1997

TRANSPORTATION DEPARTMENT

Coast Guard

Ports and waterways safety:

Tampa Bay, FL; safety zone; published 5-5-97

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Potatoes (Irish) grown in—

Washington; comments due by 5-14-97; published 4-14-97

Raisins produced from grapes grown in California; comments due by 5-14-97; published 4-14-97

AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

Poultry improvement:

National Poultry Improvement Plan and auxiliary provisions—

New program classifications and new or modified sampling and testing procedures for participants and participating flocks; establishment; comments due by 5-12-97; published 3-11-97

AGRICULTURE DEPARTMENT

Federal Crop Insurance Corporation

Crop insurance regulations:

Safflower seed; comments due by 5-12-97; published 4-11-97

AGRICULTURE DEPARTMENT

Farm Service Agency

Federal Agriculture Improvement and Reform Act of 1996; implementation:

Delinquent account servicing provisions; comments due by 5-13-97; published 3-5-97

AGRICULTURE DEPARTMENT

Food Safety and Inspection Service

Meat and poultry inspection:

Cooked roast beef products; sorbitol use; comments due by 5-13-97; published 3-14-97

AGRICULTURE DEPARTMENT

Grain Inspection, Packers and Stockyards Administration

Packers and Stockyard Act:

Poultry grower contracts, scales, weighing; comments due by 5-12-97; published 2-10-97

AGRICULTURE DEPARTMENT

Rural Business-Cooperative Service

Federal Agriculture Improvement and Reform Act of 1996; implementation:

Delinquent account servicing provisions; comments due by 5-13-97; published 3-5-97

AGRICULTURE DEPARTMENT

Rural Housing Service

Federal Agriculture Improvement and Reform Act of 1996; implementation:

Delinquent account servicing provisions; comments due by 5-13-97; published 3-5-97

AGRICULTURE DEPARTMENT

Rural Utilities Service

Rural development:

Distance learning and telemedicine loan and grant program; comments due by 5-16-97; published 4-16-97

COMMERCE DEPARTMENT

International Trade Administration

Uruguay Round Agreements Act (URAA):

Antidumping and countervailing duties, conformance and Federal regulatory review; comments due by 5-12-97; published 4-23-97

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

Atlantic highly migratory species fisheries—

Atlantic bluefin tuna; comments due by 5-16-97; published 4-21-97

Highly migratory species advisory panels establishment; combination of Atlantic shark, swordfish, and tunas fishery management plans; comments due by 5-15-97; published 4-4-97

Northeastern United States fisheries—

Summer flounder, scup, and Black Sea bass; comments due by 5-14-97; published 4-15-97

Marine mammals:

Commercial fishing authorizations—

Take reduction plan and emergency regulations; hearings; comments due by 5-15-97; published 4-24-97

Incidental taking—

North Atlantic right whale, etc.; take reduction plan; comments due by 5-15-97; published 4-7-97

Subsistence taking—

Northern fur seals; harvest estimates; comments due by 5-12-97; published 4-11-97

CONSUMER PRODUCT SAFETY COMMISSION

Poison prevention packaging:

Household products containing petroleum distillates and other hydrocarbons; comments

due by 5-12-97; published 2-26-97

DEFENSE DEPARTMENT

Acquisition regulations:

Duty-free entry of supplies; guidance clarification; comments due by 5-12-97; published 3-11-97

ENERGY DEPARTMENT

Nuclear waste repositories; site recommendations; general guidelines; comments due by 5-16-97; published 4-29-97

ENERGY DEPARTMENT

Federal Energy Regulatory Commission

Rulemaking petitions:

Pipeline Customer Coalition and Interstate Natural Gas Association of America; interstate natural gas pipelines services; expedited complaint procedures; comments due by 5-16-97; published 4-28-97

ENVIRONMENTAL PROTECTION AGENCY

Air pollution; standards of performance for new stationary sources:

Phosphate fertilizer industry; granular triple superphosphate storage facilities; comments due by 5-15-97; published 4-15-97

Air programs:

Ambient air quality surveillance; ozone monitoring season modification for Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont; comments due by 5-16-97; published 4-16-97

Air quality implementation plans; approval and promulgation; various States:

California; comments due by 5-14-97; published 4-14-97

New Jersey; comments due by 5-12-97; published 4-11-97

Ohio; comments due by 5-16-97; published 4-16-97

Tennessee; comments due by 5-14-97; published 4-14-97

Vermont; comments due by 5-12-97; published 4-10-97

Virginia; comments due by 5-13-97; published 4-29-97

Air quality implementation plans; √A√approval and promulgation; various States; air quality planning purposes; designation of areas:

Indiana; comments due by 5-13-97; published 3-14-97

Air quality planning purposes; designation of areas:

Maine; comments due by 5-16-97; published 4-16-97

Solid wastes:

Recovered materials advisory notice; availability; comments due by 5-14-97; published 4-14-97

Water programs and sewage sludge:

State sewage sludge management programs; streamlining; comments due by 5-12-97; published 3-11-97

FEDERAL COMMUNICATIONS COMMISSION

Practice and procedure:

Pole attachments—

Cable operators; maximum just and reasonable rates utilities charge; comments due by 5-12-97; published 4-14-97

Radio stations; table of assignments:

Tennessee; comments due by 5-12-97; published 3-26-97

Television broadcasting:

Cable television systems—

Navigation devices; commercial availability; comments due by 5-16-97; published 3-5-97

Television stations; table of assignments:

Pennsylvania; comments due by 5-12-97; published 3-25-97

FEDERAL TRADE COMMISSION

Trade regulation rules:

Telecommunications Act of 1996—

900-number rules; pay-per-call services advertising and operation and billing dispute procedures establishment; comments due by 5-12-97; published 3-12-97

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Community development block grants:

State program income requirements and miscellaneous amendments; reporting and recordkeeping requirements; comments due by 5-12-97; published 3-11-97

INTERIOR DEPARTMENT

Fish and Wildlife Service

Endangered and threatened species:

Flat-tailed horned lizard; comments due by 5-12-97; published 3-5-97

Migratory bird hunting:

Migratory bird harvest information program; participating States; comments due by 5-13-97; published 3-14-97

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Acquisition regulations:

Protests to agency; comments due by 5-12-97; published 3-11-97

NATIONAL CREDIT UNION ADMINISTRATION

Credit unions:

Credit union service organizations; comments due by 5-12-97; published 3-13-97

Federal credit unions bylaws and Federal credit union standard bylaw amendments; revision; comments due by 5-12-97; published 3-13-97

Interpretive rulings and policy statements; revision; comments due by 5-12-97; published 3-13-97

NORTHEAST DAIRY COMPACT COMMISSION

Over-order price regulations:

Compact over-order price regulation for Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont; comments due by 5-12-97; published 4-28-97

PENSION BENEFIT GUARANTY CORPORATION

Single-employer plans:

Termination regulations; amendments; comments due by 5-13-97; published 3-14-97

TRANSPORTATION DEPARTMENT

Coast Guard

Drawbridge operations:

Massachusetts; comments due by 5-12-97; published 4-11-97

Regattas and marine parades:

Laughlin Aquamoto Sports Challenge and Expo; comments due by 5-12-97; published 3-26-97

TRANSPORTATION DEPARTMENT

Economic regulations:

Domestic passenger manifest information; comments due by 5-12-97; published 3-13-97

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Airbus Industrie; comments due by 5-12-97; published 4-1-97

Boeing; comments due by 5-12-97; published 3-13-97

Jetstream; comments due by 5-15-97; published 4-4-97

New Piper Aircraft, Inc.; comments due by 5-16-97; published 2-19-97

Pilatus Britten-Norman Ltd.; comments due by 5-12-97; published 3-6-97

Class D airspace; comments due by 5-15-97; published 4-9-97

Class E airspace; comments due by 5-15-97; published 4-21-97

TRANSPORTATION DEPARTMENT

Federal Highway Administration

Motor carrier safety standards:

Federal regulatory review; comments due by 5-12-97; published 3-27-97

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