AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

Federal Register

4–7–05 Thursday
Vol. 70 No. 66 Apr. 7, 2005

Pages 17583–17886

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.archives.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge as one of the databases on GPO Access, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** *www.gpoaccess.gov/nara,* available through GPO Access, is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward.

For more information about GPO Access, contact the GPO Access User Support Team, call toll free 1-888-293-6498; DC area 202-512-1530; fax at 202-512-1262; or via e-mail at *gpoaccess@gpo.gov.* The Support Team is available between 7:00 a.m. and 9:00 p.m. Eastern Time, Monday–Friday, except official holidays.

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 70 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

FEDERAL REGISTER WORKSHOP

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

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

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.

2. The relationship between the Federal Register and Code of Federal Regulations.

3. The important elements of typical Federal Register documents.

4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, April 19, 2005
9:00 a.m.–Noon—(SESSION FULL)

Tuesday, May 17, 2005
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Printed on recycled paper.

Contents

Federal Register

Vol. 70, No. 66

Thursday, April 7, 2005

Agricultural Marketing Service
PROPOSED RULES
Quality Systems Verification Programs; user-fee schedule, 17611–17616

Agriculture Department
See Agricultural Marketing Service
See Food Safety and Inspection Service
See Rural Business-Cooperative Service
See Rural Utilities Service
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17644

Alcohol, Tobacco, Firearms, and Explosives Bureau
PROPOSED RULES
Firearms:
Machine guns, destructive devices, and certain other firearms; pistol definitions, 17624–17626

Centers for Disease Control and Prevention
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17691–17692
Grants and cooperative agreements; availability, etc.:
Building System Capacity To Apply Law as a Public Health Tool, 17692–17697
Public safety and health protection:
Special Exposure Cohort at Oak Ridge Y-12 Plant; employee class designation, 17697

Centers for Medicare & Medicaid Services
NOTICES
Grants and cooperative agreements; availability, etc.:
Medicare—
Rural Hospice Demonstration, 17697–17698

Coast Guard
RULES
Ports and waterways safety:
Atlantic Intracoastal Waterway, Fernandina Beach, FL, 17608–17609
PROPOSED RULES
Ports and waterways safety:
Cleveland, OH, 17627–17629
NOTICES
Meetings:
National Maritime Security Advisory Committee, 17713–17714

Commerce Department
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration
See Patent and Trademark Office

Customs and Border Protection Bureau
RULES
Air commerce:
Passenger and crew manifests for vessels and aircraft; electronic transmission, 17819–17856

Defense Department
See Navy Department

Election Assistance Commission
NOTICES
Help America Vote Act:
State election plans—
Alaska and Ohio, 17662–17681
Meetings; Sunshine Act, 17681

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Electricity export and import authorizations, permits, etc.:
Rainy River Energy Corp., 17681
WPS Energy Service, Inc., 17681–17682

Environmental Protection Agency
PROPOSED RULES
Air quality implementation plans; approval and promulgation; various States:
Texas, 17640–17643
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17685–17688
Meetings:
Science Advisory Board, 17688–17689
Reports and guidance documents; availability, etc.:
Assessing Susceptibility from Early-Life Exposure to Carcinogens, 17816–17818
Carcinogen Risk Assessment, 17765–17817

Executive Office of the President
See Presidential Documents

Federal Aviation Administration
RULES
Airworthiness directives:
Airbus, 17591–17594
Boeing, 17590–17591, 17596–17604
Bombardier, 17594–17596, 17604–17606
Empresa Brasileira de Aeronautica, S.A. (EMBRAER), 17606–17608
PROPOSED RULES
Airworthiness directives:
Bombardier, 17620–17621
Eurocopter France, 17621–17623
McDonnell Douglas, 17618–17620

Federal Energy Regulatory Commission
NOTICES
Complaints filed:
Adrian Energy Associates, LLC, et al., 17682–17683
Quest Energy, L.L.C, 17683
Electric rate and corporate filings, 17683–17685

Federal Highway Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17753–17754

Federal Reserve System
NOTICES
Banks and bank holding companies:
Change in bank control, 17689–17690
Formations, acquisitions, and mergers, 17690

Federal Retirement Thrift Investment Board
NOTICES
Meetings; Sunshine Act, 17690

Federal Trade Commission
PROPOSED RULES
Trade regulation rules:
Television receiving sets; deceptive advertising as to sizes of viewable pictures shown, 17623–17624

Federal Transit Administration
NOTICES
Grants and cooperative agreements; availability, etc.:
Over-the-Road Bus Accessibility Program, 17754–17763

Fish and Wildlife Service
RULES
Endangered and threatened species:
Florida manatee protection areas, 17863–17879

Food and Drug Administration
NOTICES
Meetings:
International Conference on Harmonization; preparation, 17698–17699

Food Safety and Inspection Service
NOTICES
Meetings:
Codex Alimentarius Commission—
Foods derived from biotechnology; ad hoc intergovernmental task force; new work and priorities proposals, 17644–17645

Government Accountability Office
RULES
Nomenclature changes, 17583

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration
NOTICES
Organization, functions, and authority delegations:
Assistant Secretary for Administration and Management, 17690–17691

Homeland Security Department
See Coast Guard
See Customs and Border Protection Bureau
NOTICES
Reports and guidance documents; availability, etc.:
Privacy impact assessment and privacy policy; Advanced Passenger Information System, 17856–17861

Housing and Urban Development Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17714–17715

Indian Affairs Bureau
NOTICES
American Indian Probate Reform Act of 2004, 17715–17717

Industry and Security Bureau
NOTICES
Export privileges, actions affecting:
Ghashim Group, Inc., et al., 17645–17647

Interior Department
See Fish and Wildlife Service
See Indian Affairs Bureau
See Land Management Bureau
See Surface Mining Reclamation and Enforcement Office

International Trade Administration
NOTICES
Antidumping:
Carbon steel butt-weld pipe fittings and granular polytetrafluoroethylene resin from—
Various countries, 17647–17648
Corrosion resistant carbon steel flat products from—
Canada, 17648
Korea, 17648–17649
Glycine from—
China, 17649–17653
In-shell pistachios from—
Iran, 17653–17655
In-shell raw pistachios from—
Iran, 17655–17656
Stainless steel bar from—
Italy, 17656–17658
Stainless steel sheet and strip coils from—
Taiwan; correction, 17658
Antidumping and countervailing duties:
Iron construction castings, solid urea, and potassium permanganate from—
Various countries, 17647

Justice Department
See Alcohol, Tobacco, Firearms, and Explosives Bureau

Labor Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17717–17720

Land Management Bureau
NOTICES
Meetings:
Pinedale Anticline Working Group task groups, 17717

National Archives and Records Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17720–17721

National Institutes of Health
NOTICES
Inventions, Government-owned; availability for licensing, 17699–17703
Meetings:
National Eye Institute, 17703–17704
National Human Genome Research Institute, 17704
National Institute of Allergy and Infectious Diseases, 17709–17710
National Institute of Child Health and Human Development, 17706, 17708–17709

National Institute of Dental and Craniofacial Research, 17707–17708
National Institute of Diabetes and Digestive and Kidney Diseases, 17705–17706
National Institute of Mental Health, 17706–17707
National Institute of Neurological Disorders and Stroke, 17707
National Institute on Aging, 17708
National Institute on Alcohol Abuse and Alcoholism, 17705–17706, 17709
National Institute on Deafness and Other Communication Disorders, 17704–17705
National Institute on Drug Abuse, 17709–17710
National Library of Medicine, 17710–17711
Scientific Review Center, 17711–17712

National Oceanic and Atmospheric Administration
NOTICES
Environmental statements; notice of intent:
Caribbean, Gulf, and South Atlantic fisheries; Gulf of Mexico charter vessel/headboat permit moratorium, 17658–17659
Meetings:
Pacific Fishery Management Council, 17659–17661
Permits:
Endangered and threatened species, 17661

Navy Department
NOTICES
Meetings:
Chief of Naval Operations Executive Panel, 17661–17662

Nuclear Regulatory Commission
NOTICES
Meetings:
Inspections, tests, and acceptance criteria; categorizing inspection results; workshop, 17722
Nuclear Waste Advisory Committee, 17722–17723
Meetings; Sunshine Act, 17723–17724
Applications, hearings, determinations, etc.:
Duke Cogema Stone & Webster, 17721
Progress Energy Carolinas, Inc., 17721–17722

Patent and Trademark Office
PROPOSED RULES
Patent cases:
Trademark Electronic Application System filing; reduced fee requirement, 17636–17640
Practice and procedure:
Patent applications, reexamination proceedings, etc.; miscellaneous amendments, 17629–17636

Personnel Management Office
PROPOSED RULES
Employment:
Homeland Security Act of 2002; implementation—
Alternative ranking and selection procedures; veterans preference, 17610

Presidential Documents
PROCLAMATIONS
Special observances:
National D.A.R.E. Day (Proc. 7883), 17885–17886
Pan American Day and Pan American Week (Proc. 7882), 17881–17884

Research and Innovative Technology Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17763

Rural Business-Cooperative Service
PROPOSED RULES
Grants and cooperative agreements; availability, etc.:
Business and Industry Guaranteed Loan Program, 17616–17618

Rural Utilities Service
PROPOSED RULES
Grants and cooperative agreements; availability, etc.:
Business and Industry Guaranteed Loan Program, 17616–17618

Securities and Exchange Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17724–17728
Public Utility Holding Company Act of 1935 filings, 17729–17730
Securities:
Suspension of trading—
Homeland Security Network, Inc., 17730
Self-regulatory organizations; proposed rule changes:
American Stock Exchange LLC, 17730–17731
Chicago Board Options Exchange, Inc., 17731–17743
Chicago Stock Exchange, Inc., 17743–17745
National Stock Exchange, 17745
New York Stock Exchange, Inc., 17746–17748
Options Clearing Corp., 17748–17749

Small Business Administration
RULES
Debt Collection Improvement Act of 1996; implementation:
Administrative wage garnishment provisions, 17583–17590
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17749

State Department
NOTICES
Grants and cooperative agreements; availability, etc.:
English Language Fellow Program; correction, 17749
Serbia and Montenegro High School Exchange Program, 17749–17753

Substance Abuse and Mental Health Services Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 17712–17713

Surface Mining Reclamation and Enforcement Office
PROPOSED RULES
Surface coal mining and reclamation operations:
Transfer, assignment, or sale of permit rights, 17626–17627

Surface Transportation Board
NOTICES
Rail carriers:
Waybill data; release for use, 17763

Transportation Department
See Federal Aviation Administration

See Federal Highway Administration
See Federal Transit Administration
See Research and Innovative Technology Administration
See Surface Transportation Board

Separate Parts In This Issue

Part II
Environmental Protection Agency, 17765–17818

Part III
Homeland Security Department, 17856–17861

Part III
Homeland Security Department, Customs and Border Protection Bureau, 17819–17856

Part IV
Interior Department, Fish and Wildlife Service, 17863–17879

Part V
Executive Office of the President, Presidential Documents, 17881–17886

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

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:

7882 17883
7883 17885

4 CFR

Ch. I 17583

5 CFR

Proposed Rules:

337 17610

7 CFR

Proposed Rules:

54 17611
62 17611
4279 17616

8 CFR

217 17820
231 17820
251 17820

13 CFR

134 17583
140 17583

14 CFR

39 (9 documents) 17590, 17591, 17594, 17596, 17598, 17600, 17603, 17604, 17606

Proposed Rules:

39 (3 documents) 17618, 17620, 17621

16 CFR

Proposed Rules:

410 17623

19 CFR

4 17820
122 17820
178 17820

27 CFR

Proposed Rules:

479 17624

30 CFR

Proposed Rules:

701 17626
774 17626

33 CFR

165 17608

Proposed Rules:

165 17627

37 CFR

Proposed Rules:

1 17629
2 17636
3 17629
7 17636
10 17629

40 CFR

Proposed Rules:

52 17640

50 CFR

17 17864

Rules and Regulations

Federal Register
Vol. 70, No. 66
Thursday, April 7, 2005

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.

GOVERNMENT ACCOUNTABILITY OFFICE

4 CFR Chapter I

Nomenclature Changes

AGENCY: Government Accountability Office.

ACTION: Final rule.

SUMMARY: The GAO Human Capital Reform Act of 2004 changed the name of the General Accounting Office to the Government Accountability Office. Accordingly, this technical amendment changes the name of the agency in the heading of the chapter in which the Government Accountability Office's regulations appear, chapter I of title 4 of the Code of Federal Regulations. This document also redesignates all references in chapter I of the Government Accountability Office's regulations. This rulemaking is technical in nature, and merely implements a statutory mandate.

DATES: *Effective Date:* April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Forman, Assistant General Counsel, Government Accountability Office, room 7838D, 441 G Street, NW., Washington, DC 20548, (202) 512–9763.

SUPPLEMENTARY INFORMATION: On July 7, 2004, the President signed the GAO Human Capital Reform Act of 2004 (Pub. L. 108–271), providing the Government Accountability Office with additional flexibilities in its human capital management. Section 8 of Public Law 108–271 changed the name of the General Accounting Office to the Government Accountability Office to more accurately reflect the audit and evaluation work in which the Office engages to assist the Congress in fulfilling its constitutional responsibilities.

This document changes the name of the agency from General Accounting Office to Government Accountability Office. Accordingly, chapter I of title 4 of the Code of Regulations is amended so that in every place in which the name General Accounting Office has appeared the name will now be read as Government Accountability Office. The Government Accountability Office finds good cause for making this final rule effective immediately, since the rule is merely a technical amendment following a statutory change in our name and underlying statute.

■ For the reasons set out above, title 4, chapter I of the Code of Federal Regulations is amended under the authority of section 8 of Pub. L. 108–271, 118 Stat. 814.

CHAPTER I—GENERAL ACCOUNTING OFFICE

■ 1. The heading of chapter I is revised to read as set forth below:

CHAPTER I—GOVERNMENT ACCOUNTABILITY OFFICE

■ 2. In 4 CFR chapter I, remove the words ''General Accounting Office'', and add in their place, the words ''Government Accountability Office'', wherever they appear.

Issued on: April 1, 2005.

Anthony H. Gamboa,

General Counsel.

[FR Doc. 05–6924 Filed 4–6–05; 8:45 am]

BILLING CODE 1610–02–M

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 134 and 140

RIN 3245–AE50

Procedures for Office of Hearings and Appeals, Administrative Wage Garnishment

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Direct final rule.

SUMMARY: This direct final rule implements the administrative wage garnishment provisions contained in the Debt Collection Improvement Act of 1996 (DCIA) in accordance with the regulations issued by the Secretary of the Treasury. By implementing these provisions, SBA will be able to garnish the disposable wages of a person who is indebted to the United States for nontax debts, without first obtaining a court order. This rule also amends SBA's regulations on hearings and appeals in order to expand the scope of those regulations to hearings in administrative wage garnishment cases.

DATES: This rule is effective on June 6, 2005 without further action, unless adverse comment is received by May 9, 2005. If adverse comment is received, SBA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by RIN number 3245–AE50, by any of the following methods: (1) Federal rulemaking portal at *http://www.regulations.gov*; (2) e-mail: *walter.intlekofer@sba.gov*, include RIN number 3245–AE50 in the subject line of the message; (3) mail to: Walter C. Intlekofer, Director Portfolio Management Division, 409 3rd Street, SW., Mail Code: 7021, Washington, DC 20416; and (4) Hand Delivery/Courier: 409 3rd Street, SW., Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Walter C. Intlekofer, Director Portfolio Management Division, (202) 205–7543.

SUPPLEMENTARY INFORMATION:

Background

Section 31001(o) of the Debt Collection Improvement Act of 1996, which is codified at 31 U.S.C. 3720D, authorizes Federal agencies to use an administrative procedure to garnish the disposable pay of an individual to collect delinquent non-tax debt owed to the United States in accordance with regulations promulgated by the Secretary of the Treasury. Wage garnishment is a process whereby an employer withholds amounts from an employee's wages and pays those amounts to the employee's creditor pursuant to a withholding order. Under the DCIA agencies may garnish up to 15% of a delinquent non-tax debtor's disposable wages. Prior to the enactment of the DCIA, agencies were generally required to obtain a court judgment before garnishing the wages of non-Federal employees.

DCIA requires the Secretary of the Treasury to issue regulations implementing the administrative wage garnishment requirements. These implementing regulations, which are at 31 CFR 285.11, provide for due process for nontax debtors and require agencies to publish regulations for administrative wage garnishment hearings. This direct final rule implements that requirement.

SBA previously published a proposed wage garnishment rule on June 27, 2000, at 65 FR 124. The Agency received no comments. However, since SBA has made changes to the proposed rule to more closely conform it to the Treasury final rule, SBA is issuing this as a direct final rule to provide the public with a final opportunity to comment. SBA must receive comments by the deadline stated above, which is no later than 30 days after this notice appears in the **Federal Register**.

SBA is publishing this rule as a direct final rule because it believes the rule is not controversial as it merely conforms SBA's administrative wage garnishment procedures to those used by the rest of the Government and contains the same substantive and procedural requirements as the Treasury final rule on wage garnishment. The changes implemented by this rule are beneficial to all affected parties by providing exact procedures for SBA's administrative wage garnishment process. SBA believes that this rule will not elicit any significant adverse comments. However, if adverse comments are received, SBA will publish a timely notice of withdrawal in the **Federal Register**.

Section-by-Section Analysis

Part 134

SBA is amending 13 CFR Part 134, Rules of Procedure Governing Cases before the Office of Hearings and Appeals, to expand the scope of the procedures to debt collection cases under DCIA, including administrative wage garnishment cases. SBA is not amending the actual procedural process. SBA is amending the following specific sections of Part 134.

Section 134.102(i) lists the types of cases over which OHA has jurisdiction. SBA is amending this section to add debt collection under DCIA to this list of cases.

Section 134.202 describes how a party, including SBA, may commence a case before OHA and the time period within which a party other than SBA must commence such cases. SBA is amending § 134.202 to add how and when a party may request a hearing on an administrative wage garnishment case.

Section 134.222(a) explains the conditions for obtaining an oral hearing; SBA is amending § 134.222(a) to add when an oral hearing is available for administrative wage garnishment cases.

Section 134.226(b) provides that OHA must render a decision within 60 days after a petition is filed in debt collection cases under the Debt Collection Act of 1982 and Part 140 of the SBA regulations. SBA is amending § 134.226(b) to add debt collection under DCIA to the group of cases in which OHA must render a decision within 60 days.

Section 134.227(a) describes the cases in which OHA's decision constitutes a final agency decision. SBA is amending this section to include debt collection under DCIA to this group of cases.

Part 140

SBA's debt collection regulations can be found at 13 CFR Part 140. SBA is amending this Part to establish procedures for administrative wage garnishment in accordance with DCIA and the Treasury regulations implementing that statute. First, SBA is amending the title to Part 140 to make it more descriptive of the Part's coverage, by changing the title from ''Debt Collection Through Offset'' to ''Debt Collection.'' Second, in order to simplify the organization of Part 140, SBA is dividing it into Subpart A, Overview; Subpart B, Offset; and Subpart C, Administrative Wage Garnishment.

Subpart A will provide an overview of the scope of Part 140. Section 140.1 which currently provides an overview of the coverage of Part 140 will fall under Subpart A and is being amended to add administrative wage garnishment to the scope of cases that are covered by Part 140.

Subpart B will apply to the procedures for debt collection through offset of a federal employee's salary, any money that is due to a debtor from SBA or other Federal agencies and a debtor's IRS tax refund. Existing §§ 140.2 and 140.3 specifically address debt collection through offset and will be part of Subpart B. SBA is not amending these sections at this time.

A new section, designated as 140.11 is being added under Subpart C to establish the rules and procedures for debt collection through administrative wage garnishment.

(a) *General.* Subsection (a) describes the administrative wage garnishment process and provides the statutory authority for SBA to use that process.

(b) *Scope.* Subsection (b)(1) states that § 140.11 provides procedures for SBA to collect delinquent non-tax debt through administrative wage garnishment.

As provided in the DCIA, subsection (b)(2) explains that the wage garnishment provisions in § 140.11 apply despite any State law covering such process.

Subsection (b)(3) explains that SBA's use of this collection tool does not interfere with its discretion to compromise a debt, or to suspend or terminate collection of the debt.

Subsection (b)(4) explains that administrative wage garnishment is one of many debt collection remedies available to SBA and it may use administrative wage garnishment concurrently with other collection remedies, even if the Agency is receiving payments under wage garnishment.

Subsection (b)(5) distinguishes Federal salary offset from administrative wage garnishment. Federal salary offset procedures, whereby Federal salary payments payable to Federal employees who owe debt to the United States are withheld to satisfy that debt, are set forth in 5 U.S.C 5514 and the implementing regulations.

Subsection (b)(6) provides that SBA is not required to duplicate notices or proceedings that are otherwise required.

(c) *Definitions.* Subsection (c) contains the definitions that apply to actions under Part 140.

Agency. The term ''agency'' as used in this section refers to SBA.

Business day. The term ''business day'' means Monday through Friday and will be calculated consistent with Rule 6(a) of the Federal Rules of Civil Procedure.

Day means calendar day and will be calculated consistent with Rule 6(a) of the Federal Rules of Civil Procedure.

Debt or claim. For the purposes of this rule, the terms ''debt'' and ''claim'' refer to delinquent nontax debt. The term ''delinquent nontax debt'' refers to debt that is past-due.

Debtor. The term ''debtor'' refers to an individual who owes a delinquent nontax debt to the United States.

Delinquent non-tax debt refers to any debt other than one owed under the Internal Revenue Code and that has not been paid by the date specified in SBA's initial written demand for payment.

Disposable pay. ''Disposable pay'' is all of a debtor's compensation except health insurance premiums and those amounts required to be withheld by law, such as social security taxes. Lump sum payments, such as bonuses and back pay, are included in disposable pay. For purposes of calculating disposable pay, voluntary withholdings, such as savings allotments, are not deducted from a debtor's compensation.

Employer. The term ''employer'' refers to a person or entity that employs the services of others and includes State and local Governments. For purposes of this section, however, the Federal Government is not an ''employer'' because debts owed by Federal employees are collected in accordance

with the Federal salary offset procedures.

Evidence of Service. This term refers to the information that SBA will retain as proof that it has mailed a given document, including to whom, date of mailing and nature of the document.

Garnishment. The term ''garnishment'' refers to the process of withholding amounts from an employee's pay and forwarding those amounts to a creditor in satisfaction of a withholding order.

Withholding order. The term ''withholding order'' refers to any order for withholding or garnishment of pay, whether issued under the provisions of this section or otherwise. A withholding order may be issued by an agency, or a judicial or administrative body. For purposes of this proposed rule, the terms ''wage garnishment order'' and ''garnishment order'' have the same meaning as ''withholding order.''

(d) *Initiating Proceedings.* Subsection (d) sets forth when SBA may initiate an administrative wage garnishment proceeding.

(e) *Notice Requirements.* Subsection (e)(1) contains the DCIA requirement that SBA give the debtor written notice at least 30 days before initiating garnishment proceedings. The notice will inform the debtor of the nature and amount of the debt and that SBA will collect the debt through deductions from pay, as well as an explanation of the debtor's rights regarding the proposed action.

Subsection (e)(2) explains that pursuant to the DCIA SBA will provide the debtor with an opportunity to inspect and copy records related to the debt, to establish a repayment agreement, and to receive a hearing. This subsection also provides that a debtor is entitled to a hearing only with respect to (1) the existence of the debt; (2) the amount of the debt; or (3) the terms of the proposed repayment schedule under the garnishment order. However, the debtor is not entitled to a hearing on the terms of the proposed repayment schedule if those terms have been established by written agreement between the debtor and SBA.

Subsection (e)(3) states that SBA will keep a copy of the certificate of service.

(f) *Hearing.* Subsection (f)(1) states that OHA's procedural rules also apply to wage garnishment hearings; subsection (f)(2) addresses how a debtor can obtain such a hearing.

Under subsection (f)(3) SBA addresses the two types of hearings that are available; explains when the debtor may receive either a paper hearing or an oral hearing and, if the latter, whether the hearing will be conducted in person or by telephone.

Subsection (f)(4) provides that if a request for hearing is timely received, SBA will not issue a garnishment order until the Judge renders a decision. Timely received means that the request for a hearing is received by SBA on or before the 15th business day following the mailing of the notice described in Subsection (e)(1) of this section. SBA is required to inform the debtor of the deadline for requesting a hearing prior to the issuance of a withholding order.

Subsection (f)(5) addresses hearing requests received after the 15th business day following the mailing of the notice described in Subsection (e)(1) of this section. As provided in the DCIA, SBA does not have to delay issuance of the withholding order prior to conducting a hearing if the request for a hearing is not timely received.

Subsection (f)(6) provides that any Judge as designated by the Assistant Administrator for Hearings and Appeals may be the hearing official.

Subsection (f)(7) requires the Judge to notify the SBA and the debtor about the type of hearing to be held, the date and time of the hearing, and any deadline for the submission of evidence.

Subsection (f)(8) describes the burden of proof on SBA and the debtor. SBA must present evidence as to the existence or amount of the debt. To dispute the debt, the debtor must show by a preponderance of the evidence that no debt exists or that the amount of the debt is incorrect. If the terms of the repayment schedule are an issue, the debtor must show that such terms are unreasonable or unlawful.

Subsection (f)(9) provides that the hearing official will maintain a summary record of the hearing and that testimony at oral hearings will be under oath.

As required by the DCIA, subsection (f)(10) states that the OHA Judge must issue a written decision no later than sixty (60) days after OHA received the request for a hearing. This subsection also explains that if SBA had previously issued a withholding order, the agency must suspend garnishment until the Judge holds a hearing and issues a decision.

Subsection (f)(11) sets forth the information that must be included in the hearing official's written decision.

Subsection (f)(12) states that the OHA Judge's decision is the final agency action for judicial review purposes under the Administrative Procedures Act (5 U.S.C. 701) .

Subsection (f)(13) provides that failure of a debtor to appear at an oral hearing, without showing good cause, will be deemed an untimely filing.

(g) *Wage Garnishment Order.* In accordance with the provisions of the DCIA, Subsection (g)(1) provides that if the debtor did not file a timely request for a hearing, SBA will send the garnishment order to the debtor's employer within 30 days following the 15th business day after SBA mailed the pre-garnishment, or if debtor makes a timely request, 30 days after the Judge renders a final decision to proceed with the garnishment.

Subsection (g)(2) describes the format and content of a withholding order, including debtor's name, address and social security number.

Subsection (g)(3) requires that SBA retain a copy of the certificate of service to show when the agency mailed the withholding order to the debtor's employer.

(h) *Certification by Employer.* When a debtor's employer receives a withholding order, Subsection (h) requires the employer to complete a certification in a form prescribed by the Secretary of the Treasury on matters such as the debtor's employment status and disposable pay available for garnishment.

(i) *Amounts Withheld.* According to subsection (i)(1), a debtor's employer must deduct the amount stated in the garnishment order each pay period.

Subsections (i)(2) and (i)(3) describe the restrictions on the amounts that can be withheld from an employee's pay to satisfy a garnishment order. As provided in the DCIA, under subsection (i)(1) no more than 15% of the debtor's disposable pay for each pay period may be garnished; subsection (i)(2) describes the amount that may be garnished if, at the time of SBA's garnishment order, the debtor's disposable pay is subject to other wage garnishment orders, or where the debtor's wage is also subject to garnishment for family support, even if filed after SBA's order.

For example, if the employer is withholding 15% of a debtor's disposable pay for a family support or prior withholding order, the amount withheld for the subsequent withholding order issued under this section is limited to 10% of the debtor's disposable pay. When the family support or prior withholding order terminates, the amount withheld for the subsequent withholding order issued under this section may be increased to the maximum 15% allowed under (i)(1).

Subsection (i)(4) allows the debtor to consent in writing to withholding a greater amount than provided in subsections (i)(2) and (i)(3).

Under subsection (i)(5), the employer is required to promptly pay to SBA amounts withheld under the garnishment order.

As provided in the DCIA, under subsection (i)(6) an employer is not required to vary its pay cycle to comply with a garnishment order.

Subsection (i)(7) provides that a wage garnishment order issued under this section will take priority over any assignment or allotment by an employee of his wages, except for assignments or allotments made because of a family support judgment or order.

Subsection (i)(8) requires the employer to continue to garnish an employee's wages until the agency notifies the employer that garnishment is no longer required.

(j) *Exclusions from Garnishment.* As required by the DCIA, Subsection (j) provides that SBA may not garnish a debtor's wages if he or she has been involuntarily unemployed during the last 12 months and also advises that the debtor is responsible for notifying SBA of any involuntary unemployment.

(k) *Financial Hardship.* Subsection (k)(1) allows a debtor to request a review by SBA of the amount being garnished under a wage garnishment order based on materially changed circumstances which result in a financial hardship.

Subsection (k)(2) requires the debtor to explain and submit evidence of the materially changed circumstances and the effect of the change on the debtor's ability to pay.

Subsection (k)(3) explains that SBA will adjust the amounts withheld under the garnishment order if a financial hardship is found to exist.

(l) *Ending Garnishment.* Subsection (l)(1) provides that SBA will instruct the employer to discontinue garnishment upon its receipt of the full amount of the debt, including interest, penalties, and administrative costs.

Under subsection (l)(2) once the debtor's account has been paid in full, SBA will review the account to ensure that garnishment has been terminated.

(m) *Prohibited Actions by the Employer.* As mandated by the DCIA, subsection (m) prohibits employers from taking action against a debtor based on the fact that the debtor's wages are subject to garnishment.

(n) *Refunds.* Subsection (n)(1) requires SBA to refund promptly to a debtor amounts improperly withheld from wages.

Subsection (n)(2) provides that, unless required by law or contract, refunds shall not bear interest.

(o) *Right of Action.* As authorized by the DCIA, subsection (o) provides that SBA may sue an employer for the amounts that were not properly withheld from the debtor's wages. SBA may initiate action against an employer only after terminating its collection efforts against the debtor. For purposes of this section, this occurs when SBA (1) has terminated collection action in accordance with the Federal Claims Collection Standards (FCCS) or other applicable standards, or (2) has not received any payments on the debt from any source for at least 1 year.

Finally, since administrative wage garnishment has separate specific authority, SBA is also amending the list of authorities for Part 140 to add 31 U.S.C. 3720D.

Compliance With Executive Orders 12866, 12988, and 13132, the Paperwork Reduction Act (44 U.S.C. Ch. 35) and the Regulatory Flexibility Act (5 U.S.C. 601–12)

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule does not constitute a significant regulatory action under Executive Order 12866.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13132

This regulation will 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, for the purposes of Executive Order 13132, SBA determines that this direct final rule has no federalism implications warranting preparation of a federalism assessment.

Paperwork Reduction Act of 1995

For purposes of the Paperwork Reduction Act, 44 U.S.C., Chapter 35, SBA has determined that this direct final rule does not impose additional reporting or recordkeeping requirements. Although the employer of a delinquent debtor must certify certain information about the debtor, certifications are not collections of information under the Paperwork Reduction Act.

Regulatory Flexibility Act (5 U.S.C. 601–12)

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, small non-profit enterprises, and small local governments. Pursuant to the RFA, when an agency issues a rulemaking, the agency must prepare a regulatory flexibility analysis which describes the impact of the rule on small entities.

This final rule would not have a significant economic impact on a substantial number of small entities. Further, the Administrator, in accordance with the RFA, certifies that this rule, including the certification contained in § 140.11(h), would not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

This rule applies to individuals with outstanding debts to the United States, as well as employers of such individuals. SBA does not believe that a substantial number of small entities will be subject to this regulation and to its certification requirement. SBA has approximately 39,000 Agency-serviced loans that are delinquent or in liquidation status, or are subject to collection processes by the U.S. Department of the Treasury (Treasury). Although SBA cannot predict the number of these loans that will be subject to AWG in the future, SBA estimates, based on the experience of other federal agencies, that no more than one-fourth (less than 10,000) may be subject to wage garnishment procedures. This number is an extremely small percentage of the almost 24 million small businesses in the United States, and consequently the economic impact of compliance with AWG will be minimal.

Further, even though a limited number of small entities may need to comply with these provisions, SBA does not believe that the requirements will have a significant economic impact on these entities. Although a delinquent debtor's employer must certify certain information about the debtor, including the debtor's employment status and earnings, the employer's payroll records already contain this information. Therefore, an employer will not expend significant time or expense completing the certification form. Even if an employer received withholding orders on several employees during the year, the cost to the employer to complete the certifications would not be significant. Employers need not vary normal pay cycles to comply with withholding orders issued under this rule.

Although the new procedures will provide for a hearing if specifically requested by the debtor, employers are not required to participate in the hearing. In addition, SBA certified in

the proposed rule that the rule would not have a significant economic impact on a substantial number of small entities. SBA did not receive any comments from small entities that would indicate that the rule was costly or that the certification was incorrect.

Treasury published regulations for AWG in 1998 and employers have been subject to collections through AWG since then. The U.S. Department of Education has been using administrative wage garnishment under the Higher Education Act for over a decade. Consequently, employers have been complying with administrative wage garnishments for student loans for many years. Treasury reports that it has not received any complaints that the garnishment procedure is overly taxing or costly for entities affected. Accordingly, SBA concludes that this rule will not have a significant economic impact.

List of Subjects

13 CFR Part 134

Administrative practice and procedure, Claims, Equal access to justice, Lawyers, Organization and functions (government agencies).

13 CFR Part 140

Claims, Debts, Garnishment, Government employees, Income taxes, Wages.

■ For the reasons stated in the preamble and under the authority contained in 5(b)(6) of the Small Business Act, 15 U.S.C. 634(b)(6), SBA amends 13 CFR parts 134 and 140 as follows:

PART 134—RULES OF PROCEDURE GOVERNING CASES BEFORE THE OFFICE OF HEARINGS AND APPEALS

■ 1. The authority citation for part 134 continues to read as follows:

Authority: 5 U.S.C. 504; 15 U.S.C. 632, 634(b)(6), 637(a), 648(l), 656(i), and 687(c); E.O. 12549, 51 FR 6370.

■ 2. Amend § 134.102 by revising paragraph (i) to read as follows:

§ 134.102 Jurisdiction of OHA.

* * * * *

(i) Collection of debts owed to SBA and the United States under the Debt Collection Act of 1982, the Debt Collection Improvement Act of 1996, and part 140 of this chapter;

* * * * *

■ 3. Amend § 134.202 by revising paragraph (a)(2) to read as follows:

§ 134.202 Commencement of cases.

(a) * * *

(2) In proceedings for debt collection under part 140 of this chapter: no later than 15 days after receipt of a notice of indebtedness and intention to collect such debt by salary or administrative offset; in accordance with the time frames specified in § 140.11 of this chapter with respect to administrative wage garnishment;

* * * * *

■ 4. Amend § 134.222 by adding paragraph (a)(3) to read as follows:

§ 134.222 Oral hearing.

* * * * *

(a) * * *

(3) The Judge determines that an oral hearing is necessary in administrative wage garnishment proceedings conducted pursuant to § 140.11 of this chapter.

* * * * *

■ 5. Amend § 134.226 by revising paragraph (b) to read as follows:

§ 134.226 The decision.

* * * * *

(b) *Time Limits.* Decisions pertaining to the collection of debts owed to SBA and the United States under the Debt Collection Act of 1982, the Debt Collection Improvement Act of 1996, and Part 140 of this chapter must be made within 60 days after a petition is filed. Time limits for decisions in other types of cases, if any, are indicated either in the applicable program regulations or in other subparts of this part 134.

* * * * *

■ 6. Amend § 134.227 by revising paragraph (b)(1) to read as follows:

§ 134.227 Finality of decisions.

* * * * *

(b) * * *

(1) Collection of debts owed to SBA and the United States under the Debt Collection Act of 1982, Debt Collection Improvement Act of 1996, and part 140 of this chapter;

* * * * *

PART 140—DEBT COLLECTION

■ 7. Revise the heading of part 140 to read as set forth above.

■ 8. Revise the authority citation of part 140 to read as follows:

Authority: 5 U.S.C. 5514; 15 U.S.C. 634(b)(6); 31 U.S.C. 3711, 3716, 3720, 3720A and 3720D.

■ 9. Add subpart A, consisting of existing § 140.1 to read as follows:

Subpart A—Overview

■ 10. Revise § 140.1 to read:

§ 140.1 What does this part cover?

This part establishes procedures which SBA may use in the collection, through offset or administrative wage garnishment, of delinquent debts owed to the United States. SBA's failure to comply with any provision of the regulations in this part is not available to any debtor as a defense against collection of the debt through judicial process or otherwise.

■ 11. Add subpart B, consisting of existing §§ 140.2 and 140.3, to read as follows:

Subpart B—Offset

■ 12. Add subpart C consisting of a new § 140.11 to read as follows:

Subpart C—Administrative Wage Garnishment

§ 140.11 What type of debt is subject to administrative wage garnishment, and how can SBA administratively garnish your pay?

(a) *General.* SBA may order your employer to pay SBA a portion of your disposable pay to satisfy delinquent non-tax debt you owe to the United States. This process is called ''administrative wage garnishment'' and is authorized by 31 U.S.C. 3720D.

(b) *Scope.* (1) This section provides procedures for SBA to collect delinquent non-tax debts through administrative wage garnishment.

(2) This section applies despite any State law.

(3) Nothing in this section prevents SBA from settling for less than the full amount of a debt. See, for example, the Federal Claims Collection Standards (FCCS), 31 CFR parts 900–904.

(4) SBA's receipt of payments under this section does not prevent SBA from pursuing other debt collection remedies. SBA may pursue debt collection remedies separately or together with administrative wage garnishment.

(5) This section does not apply to the collection of delinquent non-tax debt owed to the United States from the wages of Federal employees. Federal pay is subject to the Federal salary offset procedures set forth in 5 U.S.C. 5514 and other laws, including subpart B of this part.

(6) Nothing in this section requires SBA to duplicate notices or administrative proceedings required by contract, other laws, or regulations.

(c) *Definitions.* In this section the following definitions apply:

Agency means the SBA.

Business day means Monday through Friday excluding Federal legal holidays.

Day means calendar day. For purposes of computation, the last day of the period will be included unless it is a Saturday, a Sunday, or a Federal legal holiday.

Debt or *claim* means any amount of money, funds or property that has been

determined by an appropriate official of the Federal Government to be owed to the United States by an individual, including debt administered by a third party as an agent for the Federal Government. Debt also includes accrued interest, administrative costs incurred in collection efforts by SBA or a lender participating in an SBA loan program, and penalties imposed pursuant to law or contract.

Debtor or you means an individual who owes a delinquent non-tax debt to the United States.

Delinquent non-tax debt means any debt not related to an obligation under the Internal Revenue Code of 1986, as amended, that has not been paid by the date specified in SBA's initial written demand for payment, or applicable agreement, unless other satisfactory payment arrangements have been made. For purposes of this section, the terms ''debt'' and ''claim'' are synonymous and refer to delinquent non-tax debt.

Disposable pay means that part of the debtor's compensation (including, but not limited to, salary, bonuses, commissions, and vacation pay) from an employer remaining after the deduction of health insurance premiums and any amounts required by law to be withheld. For purposes of this section, ''amounts required by law to be withheld'' include amounts for deductions such as social security taxes and withholding taxes, but do not include any amount withheld pursuant to a court order.

Employer means a person or entity that employs the services of others and that pays their wages or salaries. The term employer includes, but is not limited to, State and local Governments, but does not include an agency of the Federal Government.

Evidence of service means information retained by the SBA indicating the nature of the document to which it pertains, the date of mailing of the document, and to whom the document is being sent. Evidence of service may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

Garnishment means the process of withholding amounts from an employee's disposable pay and the paying of those amounts to a creditor in satisfaction of a withholding order.

Withholding order means any order for withholding or garnishment of pay issued by an agency, or judicial or administrative body. For purposes of this section, the terms ''wage garnishment order'' and ''garnishment order'' have the same meaning as ''withholding order.''

(d) *When may the SBA initiate administrative wage garnishment proceedings?* Whenever SBA determines you owe a delinquent non-tax debt, SBA may initiate administrative wage garnishment proceedings to withhold a portion of your wages to satisfy the debt.

(e) *What notice must the SBA give you before beginning an administrative wage garnishment?* (1) SBA will send a written notice by first-class mail to your last known address at least 30 days before initiating garnishment. This pre-garnishment notice will inform you of:

(i) The type and amount of the debt;

(ii) SBA's intent to collect the debt by making deductions from your pay until the debt is paid in full;

(iii) An explanation of your rights, including those listed below, and the timeframe within which you may exercise your rights.

(2) You have the right to:

(i) Inspect and copy non-privileged SBA records related to the debt;

(ii) Enter into a written repayment agreement with SBA under terms agreeable to SBA; and

(iii) Have a hearing at SBA's Office of Hearings and Appeals (OHA) in accordance with paragraph (f) of this section concerning the existence or the amount of the debt or the terms of the proposed repayment schedule under the garnishment order. However, you are not entitled to a hearing concerning the terms of the proposed repayment schedule if those terms have been established by written agreement under paragraph (e)(2)(ii) of this section.

(3) SBA will retain evidence of service showing when SBA mailed the pre-garnishment notice.

(f) *What type of hearing must SBA give me?* (1) *Procedural rules.* Unless they expressly conflict with this section, the rules of procedure governing cases before OHA apply to administrative wage garnishment hearings.

(2) *Request for hearing.* You will be provided with a hearing, if you request one in writing disputing either the existence or amount of the debt or the terms of the repayment schedule (except a repayment schedule you and SBA agreed to in writing).

(3) *Type of hearing or review.* (i) You will have the right to an oral hearing only if the Judge determines that the issues in dispute cannot be resolved solely by review of the documentary evidence, for example, when the Judge finds that the validity of the claim turns on the issue of credibility or veracity.

(ii) If the Judge determines an oral hearing is needed, he or she will set the time and location. You may choose whether the oral hearing is conducted in person or by telephone. You must pay all travel expenses for yourself and your witnesses to attend an in-person hearing. SBA will pay telephone charges for telephone hearings.

(iii) If no oral hearing is needed, the Judge will accord you a ''paper hearing,'' that is, the Judge will decide the issues in dispute based upon a review of the written record. The Judge will set a reasonable deadline for the submission of evidence.

(4) *Effect of timely request for hearing.* Subject to paragraph (f)(13) of this section (failure to appear), if the Judge determines your written request for a hearing was received at OHA by the 15th business day after SBA mailed the pre-garnishment notice, SBA will not issue a garnishment order before the Judge renders a decision.

(5) *Untimely request for hearing.* If the Judge determines your written request for a hearing was not received at OHA by the 15th business day after SBA mailed the pre-garnishment notice, SBA will provide a hearing to you. However, SBA may proceed with the issuance of a garnishment order and acceptance of payments unless the Judge determines that the delay in filing the request was caused by factors over which you had no control, or that information received justifies a delay or cancellation of the garnishment order.

(6) *Hearing official.* A hearing official may be any Judge, as designated by the Assistant Administrator for Hearings and Appeals.

(7) *Procedure.* After you request a hearing, the Judge will decide what type of hearing to hold and will notify you and the SBA of:

(i) The date and time of a telephonic hearing;

(ii) The date, time, and location of an in-person oral hearing; or

(iii) The deadline for the submission of evidence for a written hearing.

(8) *Burden of proof.* (i) The SBA will have the burden of going forward to prove the existence or amount of the debt.

(ii) Thereafter, if you dispute the existence or amount of the debt, you must establish by a preponderance of the evidence that no debt exists or that the amount of the debt is incorrect. In addition, you may present evidence that the terms of the repayment schedule are unlawful, would cause you a financial hardship, or that collection of the debt may not be pursued due to operation of law.

(9) *Record.* The Judge must maintain a summary record of any hearing provided under this section. A hearing is not required to be a formal evidentiary-type hearing; however, witnesses who testify in oral hearings will do so under oath or affirmation.

(10) *Date of decision.* The Judge must render a written decision within 60 days of the date on which your request for a hearing was received by OHA. If the Judge's decision is not rendered within that time, and SBA had previously issued a garnishment order, SBA must suspend garnishment beginning on the 61st day. This suspension must continue until the Judge renders a decision.

(11) *Content of decision.* The written decision shall include:

(i) A summary of the facts presented;

(ii) The Judge's findings, analysis and conclusions; and

(iii) The terms of any repayment schedule, if applicable.

(12) *Final agency action.* The Judge's decision will be the final agency action for the purposes of judicial review under the Administrative Procedure Act (5 U.S.C. 701 *et seq.*).

(13) *Failure to appear.* In the absence of good cause shown, a debtor who fails to appear at an oral hearing will be deemed as not having timely filed a request for a hearing.

(g) *Garnishment order.* (1) Unless SBA receives an adverse decision from the Judge or information it believes justifies delaying or canceling garnishment, SBA will send the garnishment order to your employer by first-class mail, within the following time frames:

(i) If you did not make a timely request for a pre-garnishment hearing, within 30 days following the 15th business day after SBA mailed the pre-garnishment notice;

(ii) If you did make a timely request for a pre-garnishment hearing, within 30 days after the Judge renders a final decision to proceed with garnishment; or,

(iii) As soon as reasonably possible thereafter.

(2) The garnishment order will be in a form prescribed by the Secretary of the Treasury, and will contain the signature of, or the image of the signature of, SBA's Administrator or his/her delegatee. The garnishment order will contain only the information necessary for compliance, including your name, address, and social security number, the instructions for garnishing your pay, and the address for sending payments.

(3) SBA will retain evidence of service showing when it mailed the garnishment order.

(h) *Certification by employer.* Along with the garnishment order, SBA will send your employer a certification, in a form determined by the Secretary of the Treasury. Your employer must complete and return this certification to us within the time stated in the certification instructions. The certification will include information about your employment status and the amount of your disposable pay available for garnishment.

(i) *Amounts withheld.* (1) Your employer must deduct the garnishment amount from your disposable pay during each pay period.

(2) Except as shown in paragraphs (i)(3) and (i)(4) of this section, the amount of garnishment will be the lesser of:

(i) The amount stated on the garnishment order, not to exceed 15% of your disposable pay; or,

(ii) The amount in 15 U.S.C. 1673(a)(2) (Restriction on Garnishment). This is the amount by which your disposable pay exceeds an amount equivalent to thirty times the minimum wage. See 29 CFR 870.10.

(3) If your pay is subject to other garnishment orders, the following applies:

(i) Unless otherwise provided by Federal law, SBA garnishment orders must be paid in the amounts in paragraph (i)(2) of this section, and will have priority over other garnishment orders issued later. However, withholding orders for family support have priority over SBA garnishment orders.

(ii) If amounts are being withheld from your pay because of a garnishment order issued before SBA's garnishment order, or because of a garnishment order for family support issued at any time, the earlier or family support order will have priority, and the amount withheld because of the SBA garnishment order will be the lesser of:

(A) The amount calculated under paragraph (i)(2) of this section, or

(B) An amount equal to 25% of your disposable pay minus the amount withheld under the garnishment order(s) with priority.

(iii) If you owe more than one delinquent non-tax debt, SBA may issue multiple garnishment orders if the amount withheld from your pay does not exceed the amount in paragraph (i)(2) of this section.

(4) You may give written consent for SBA to garnish from your pay an amount greater than that in paragraphs (i)(2) and (i)(3) of this section.

(5) Your employer must promptly pay to SBA all amounts withheld under a withholding order.

(6) Your employer is not required to change normal pay cycles to comply with the garnishment order.

(7) No assignment or allotment of your earnings that you have requested may interfere with or prohibit execution of SBA's garnishment order. The one exception to this rule is that you may assign or allot earnings because of a family support judgment or order.

(8) The garnishment order will state a reasonable time period within which your employer must begin wage garnishment. Your employer must withhold the designated amount from your wages each pay period until SBA notifies your employer to stop wage garnishment.

(j) *Exclusions from garnishment.* SBA may not garnish your wages if SBA knows you have been involuntarily unemployed at any time during the last 12 months. You are responsible for informing SBA of the facts and circumstances of your unemployment.

(k) *Financial hardship.* (1) If your wages are subject to a garnishment order issued by SBA, you may, at any time, request a review of the amount being withheld from your wages based on a material change in circumstances that causes you financial hardship, such as disability, divorce, or catastrophic illness. You may send your request to the Director of SBA's loan servicing center in Birmingham, Alabama.

(2) If you request review under paragraph (k)(1) of this section, you must specifically state why the current amount of garnishment causes you financial hardship and you must send documentation supporting your claim.

(3) If SBA finds financial hardship, SBA will decide how much and how long to reduce the amount garnished from your pay. SBA will notify your employer of any reductions.

(l) *Ending garnishment.* (1) After SBA has recovered the amount you owe, including interest, penalties, and administrative costs consistent with the FCCS, SBA will send a notice to your employer to stop wage garnishment with a copy to you.

(2) SBA will review your account to ensure that garnishment has stopped if you have paid your debt in full.

(m) *Prohibited actions.* No employer may fire, refuse to employ, or take disciplinary action against you because of a withholding order issued by SBA.

(n) *Refunds.* (1) SBA must promptly refund any amount collected by administrative wage garnishment if either—

(i) A Judge, after a hearing held under paragraph (f) of this section, determines you do not owe a debt to the United States; or

(ii) SBA determines that your employer continued submitting to SBA withheld wages after you had paid your debt in full.

(2) Refunds of amounts collected will not earn interest unless required by federal law or contract.

(o) *Right of action.* SBA may sue your employer for any amount that the employer fails to withhold from wages owed and payable to you in accordance with paragraphs (g) and (i) of this section. However, SBA may not file such a suit until the collection action involving you has ended unless earlier filing is necessary to avoid expiration of any applicable statute of limitations period. For purposes of this section, the collection action involving you ends when SBA stops the collection action in accordance with the FCCS or other applicable standards. In any event, the collection action involving you will be deemed ended if SBA has not received any payments from you to satisfy your debt, in whole or in part, for a period of one (1) year.

Hector V. Barreto,

Administrator.

[FR Doc. 05–6898 Filed 4–6–05; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20026; Directorate Identifier 2004–NM–150–AD; Amendment 39–14040; AD 2005–07–16]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–400ER, 777–200, and 777–300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Boeing Model 767–400ER, 777–200, and 777–300 series airplanes. This AD requires replacing, with new parts, the existing tie-down fitting studs that secure galleys, purser work stations, and closets to the seat tracks. This AD is prompted by a report that tie-down fitting studs were found damaged. We are issuing this AD to prevent a galley, purser work station, or closet from detaching from the tie-down fitting studs during an emergency landing, which could injure passengers or crewmembers, or obstruct escape routes and impede emergency evacuation.

DATES: This AD becomes effective May 12, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of May 12, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2005–20026; the directorate identifier for this docket is 2004–NM–150–AD.

FOR FURTHER INFORMATION CONTACT: Robert Kaufman, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6433; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for certain Boeing Model 767–400ER, 777–200, and 777–300 series airplanes. That action, published in the **Federal Register** on January 12, 2005 (70 FR 2064), proposed to require replacing, with new parts, the existing tie-down fitting studs that secure galleys, purser work stations, and closets to the seat tracks.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comment that has been submitted on the proposed AD. The commenter supports the proposed AD.

Explanation of Change to Proposed AD

We have changed the number of airplanes in the Costs of Compliance paragraph to reflect information received from the airplane manufacturer.

Conclusion

We have carefully reviewed the available data, including the comment that has been submitted, and determined that air safety and the public interest require adopting the AD with the change described previously. We have determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

There are about 355 airplanes of the affected design in the worldwide fleet, including about 124 U.S.-registered airplanes. The following table provides the estimated costs for U.S. operators to comply with this proposed AD, at an average labor rate of $65 per hour.

ESTIMATED COSTS

Airplane model	Work hours	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
767–400ER	10	$6,221	$6,871	6	$41,226
777–200 and –300	6–30 (depending on configuration).	1,464–19,761	1,854–21,711	118	218,772–2,561,898

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on

products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(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) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–16 Boeing: Amendment 39–14040. Docket No. FAA–2005–20026; Directorate Identifier 2004–NM–150–AD.

Effective Date

(a) This AD becomes effective May 12, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 767–400ER series airplanes, certificated in any category, having Variable Numbers VQ071 through VQ076 inclusive; and Model 777–200 and –300 series airplanes, certificated in any category, as identified in Boeing Service Bulletin 777–25–0217, dated July 17, 2003.

Unsafe Condition

(d) This AD was prompted by a report that tie-down fitting studs were found damaged. We are issuing this AD to prevent a galley, purser work station, or closet from detaching from the tie-down fitting studs during an emergency landing, which could injure passengers or crewmembers, or obstruct escape routes and impede emergency evacuation.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement

(f) Within 60 months after the effective date of this AD: Replace, with new parts, the existing tie-down fitting studs that secure galleys, purser work stations, and floor-mounted closets to the seat tracks, by doing all of the actions specified in the Accomplishment Instructions of Boeing Service Bulletin 767–25–0338, dated October 9, 2003 (for Boeing Model 767–400ER series airplanes); or Boeing Service Bulletin 777–25–0217, dated July 17, 2003 (for Boeing Model 777–200 and –300 series airplanes); as applicable.

Replacements Accomplished According to Previous Issue of Service Bulletin

(g) For Boeing Model 777–200 and –300 series airplanes: Replacements accomplished before the effective date of this AD according to Boeing Service Bulletin 777–25–0217, dated July 18, 2002, are considered acceptable for compliance with the corresponding action specified in this AD.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(i) You must use Boeing Service Bulletin 767–25–0338, dated October 9, 2003; or Boeing Service Bulletin 777–25–0217, dated July 17, 2003; as applicable; to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on March 24, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6684 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19762; Directorate Identifier 2004–NM–168–AD; Amendment 39–14038; AD 2005–07–14]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Model A318, A319, A320, and A321 series airplanes. This AD requires an inspection of the spoiler servo control for certain part numbers, and corrective action if necessary. This AD is prompted by a report of a broken piston rod bearing of the spoiler servo control. We are issuing this AD to prevent breakage of the piston rod bearing, which could cause loss of the associated hydraulic system and spoiler extension, and could result in reduced controllability of the airplane.

DATES: This AD becomes effective May 12, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of May 12, 2005.

ADDRESSES: For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401,

Washington, DC. This docket number is FAA–2004–19762; the directorate identifier for this docket is 2004–NM–168–AD.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with an AD for all Airbus Model A318, A319, A320, and A321 series airplanes. That action, published in the **Federal Register** on December 7, 2004 (69 FR 70568), proposed to require an inspection of the spoiler servo control for certain part numbers and corrective action if necessary.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD.

Request To Change Applicability

One commenter asks that the applicability statement in the proposed AD be changed. The commenter states that, as written, the applicability does not limit the effectivity, but instead applies to every Model A318, A319, A320, and A321 series airplane previously delivered or that is yet to be delivered. The commenter adds that the proposed visual inspection would have to be done regardless of the documented status of the spoiler servo controls, which introduces unnecessary maintenance activity. The commenter notes that paragraph (j) of the proposed AD prohibits installation of an affected spoiler servo control on any airplane; therefore, the applicability statement could be altered to limit the effectivity to those airplanes affected by the service bulletins referenced therein. The commenter states that limiting the applicability would apply if supporting documentation is provided which verifies that no spoiler servo control has been changed before the effective date of the AD. The commenter adds that this change would provide assurance that all affected spoiler servo controls are removed from service and would also eliminate unnecessary maintenance activity. The commenter operates 148 Model A319 and A320 series airplanes, but of those airplanes, only one spoiler servo control is affected. The commenter states that the applicability statement, as written, would require that the general visual inspection be done on all 148 airplanes. In conclusion, the commenter states that the applicability should be limited to Model A318, A319, A320, and A321 series airplanes, all certified models, all serial numbers, on which Goodrich spoiler actuators with part number (P/N) 31077–050, –060, –070, –110, or –112 are installed.

We do not agree to change the applicability identified in the proposed AD. As specified in the Differences section of the proposed AD, ''French airworthiness directive F–2004–122, dated July 21, 2004, has an effectivity of 'AIRBUS A318, A319, A320 and A321 aircraft, all certified models, all serials numbers, fitted with GOODRICH spoiler actuators P/N 31077–050, –060, –070, –110 or –112.' However, because spoiler actuators are interchangeable on Airbus Model A318, A319, A320, and A321 series airplanes, airplanes not fitted with the spoiler actuators P/N 31077–050, –060, –070, –110 or –112 may have a spoiler actuator P/N 31077–050, –060, –070, –110 or –112 installed in the future by operators during normal maintenance. Therefore, the applicability of this proposed AD includes all Airbus Model A318, A319, A320, and A321 series airplanes. Both the proposed AD and French airworthiness directive require an inspection for the part number of the spoiler actuator (spoiler servo control).''

We do agree to allow a review of the airplane maintenance records instead of accomplishing the Phase 1 or Phase 2 inspection. We have changed paragraphs (f) and (g) of this final rule to allow a review of the airplane maintenance records to determine the part number of the spoiler servo controls. However, if the part number cannot be positively identified from the records review, the inspection will need to be done.

Request To Reference New Service Information

One commenter asks that Airbus Service Bulletins A320–27–1158 and A320–27–1159; both Revision 01; both dated September 3, 2004; be included as the sources of service information for accomplishing the inspections in the proposed AD. The original issues of those service bulletins were referenced as the appropriate sources of service information for accomplishing the actions specified in the proposed AD.

We agree with the commenter's request. We have added Revision 01, which is the most current source of service information for the actions in this AD, to this final rule as the source of service information for accomplishing those actions. Revision 01 adds no further work to the original issues of the service bulletin; operators are merely informed that the revised service bulletins are mandatory. We have also added a new paragraph (i) to this final rule which allows credit for actions done in accordance with the original issue of the service bulletins. We have re-identified subsequent paragraphs accordingly.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection	3–5	$65	$195–$325	648	$126,360–$210,600

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(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) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–14 Airbus: Amendment 39–14038. Docket No. FAA–2004–19762; Directorate Identifier 2004–NM–168–AD.

Effective Date

(a) This AD becomes effective May 12, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Airbus Model A318, A319, A320, and A321 series airplanes; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a report of a broken piston rod bearing of the spoiler servo control. We are issuing this AD to prevent breakage of the piston rod bearing, which could cause loss of the associated hydraulic system and spoiler extension, and could result in reduced controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Phase 1 Inspection or Review of Maintenance Records

(f) Within 12 months after the effective date of this AD, do a general visual inspection for the part number (P/N) of the spoiler servo control at the applicable locations specified in Table 1 of this AD, in accordance with Airbus Service Bulletin A320–27–1158, Revision 01, excluding Appendices 01 and 02, dated September 3, 2004. Instead of inspecting the spoiler servo control, a review of the airplane maintenance records is acceptable if the P/N of the spoiler servo control can be conclusively determined from that review.

Note 1: For the purposes of this AD, a general visual inspection is: ''A visual examination of an interior or exterior area, installation or assembly to detect obvious damage, failure or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all surfaces in the inspection area. This level of inspection is made under normal available lighting conditions such as daylight, hangar lighting, flashlight or droplight and may require removal or opening of access panels or doors. Stands, ladders or platforms may be required to gain proximity to the area being checked.''

TABLE 1.—PHASE 1 SPOILER SERVO CONTROL INSPECTION

For airbus model—	Inspect spoiler servo controls at—
A318 and A319 series airplanes	Positions 2, 3, 4, and 5.
A320 series airplanes	Position 2.
A321 series airplanes	Positions 2, 3, and 4.

Phase 2 Inspection or Review of Maintenance Records

(g) Within 30 months after the effective date of this AD, do a general visual inspection for the P/N of the spoiler servo control at the applicable locations specified in Table 2 of this AD, in accordance with Airbus Service Bulletin A320–27–1159, Revision 01, excluding Appendices 01 and 02, dated September 3, 2004. Instead of inspecting the spoiler servo control, a review of the airplane maintenance records is acceptable if the P/N of the spoiler servo control can be conclusively determined from that review.

TABLE 2.—PHASE 2 SPOILER SERVO CONTROL INSPECTION

For airbus model—	Inspect spoiler servo controls at—
A318 and A319 series airplanes	Position 1.
A320 series airplanes on which Airbus modification 26335 and Airbus Service Bulletin A320–27–1115, dated October 27, 1997; and Revision 01, dated June 22, 1999; has not been done.	Positions 1 and 3.
A320 series airplanes on which Airbus modification 26335 or Airbus Service Bulletin A320–27–1115, dated October 27, 1997; or Revision 01, dated June 22, 1999; has been done.	Positions 1, 3, 4, and 5.
A321 series airplanes	Positions 1 and 5.

Corrective Action

(h) If, during any inspection specified in paragraph (f) or (g) of this AD, P/N 31077–050, –060, –070, –110, or –112 is found or if unable to determine the P/N, before further flight, replace the spoiler servo control with a new or modified spoiler servo control, in accordance with Airbus Service Bulletin A320–27–1158 or A320–27–1159; both Revision 01; both excluding Appendices 01 and 02; both dated September 3, 2004; as applicable.

Note 2: Airbus Service Bulletins A320–27–1158, Revision 01; and A320–27–1159, Revision 01; refer to Goodrich Service Bulletin 31077–27–14, dated May 24, 2004; as an additional source of service information for modifying the spoiler servo control.

Actions Accomplished Per Previous Issues of Service Information

(i) Actions accomplished before the effective date of this AD in accordance with Airbus Service Bulletin A320–27–1158; or Airbus Service Bulletin A320–27–1159; both excluding Appendices 01 and 02; both dated May 26, 2004; are considered acceptable for compliance with the corresponding actions required by this AD.

Reporting Not Required

(j) Although Airbus Service Bulletin A320–27–1158, Revision 01, dated September 3, 2004; and Airbus Service Bulletin A320–27–1159, Revision 01, dated September 3, 2004; specify to submit certain information to the manufacturer, this AD does not include that requirement.

Parts Installation

(k) As of the effective date of this AD, no person may install a spoiler servo control, P/N 31077–050, –060, –070, –110, or –112, on any airplane, unless it has been modified according to Airbus Service Bulletin A320–27–1158 or A320–27–1159; both Revision 01; both excluding Appendices 01 and 02; both dated September 3, 2004.

Alternative Methods of Compliance (AMOCs)

(l) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(m) French airworthiness directive F–2004–122, dated July 21, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(n) You must use Airbus Service Bulletin A320–27–1158, Revision 01, excluding Appendices 01 and 02, dated September 3, 2004; and Airbus Service Bulletin A320–27–1159, Revision 01, excluding Appendices 01 and 02, dated September 3, 2004; as applicable; to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, go to Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. To view the AD docket go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW, room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on March 24, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6685 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20222; Directorate Identifier 2004–NM–230–AD; Amendment 39–14041; AD 2005–07–17]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model DHC–8–102, –103, –106, –201, –202, –301, –311, and –315 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier Model DHC–8–102, –103, –106, –201, –202, –301, –311, and–315 airplanes. This AD requires revising the airplane flight manual to include applicable procedures to follow when the flightcrew receives abnormal indications of airspeed, altitude, or vertical airspeed. This AD also requires modifying the static system. This AD is prompted by a report of a leak in the static pressure system, which could result in loss of the static systems and consequent erroneous data displayed on the pilot's flight instruments. We are issuing this AD to advise the flightcrew of applicable procedures in the event of abnormal indications of airspeed, altitude, or vertical airspeed; and to prevent leaks in the static system, which could result in the loss of critical flight information that could result in reduced controllability of the airplane or controlled flight into terrain.

DATES: This AD becomes effective May 12, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of May 12, 2005.

ADDRESSES: For service information identified in this AD, contact Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2005–20222; the directorate identifier for this docket is 2004–NM–230–AD.

FOR FURTHER INFORMATION CONTACT: Ezra Sasson, Aerospace Engineer, Systems and Flight Test Branch, ANE–172, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, suite 410, Westbury, New York 11590; telephone (516) 228–7320; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for certain Bombardier Model DHC–8–102, –103, –106, –201, –202, –301, –311, and –315 airplanes. That action, published in the **Federal Register** on February 1, 2005 (70 FR 5078), proposed to require revising the airplane flight manual (AFM) to include applicable procedures to follow when the flightcrew receives abnormal indications of airspeed, altitude, or vertical airspeed. That action also proposed to require modifying the static system.

Comments

We provided the public the opportunity to participate in the development of this AD. No comments have been submitted on the proposed AD or on the determination of the cost to the public.

Conclusion

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Revise AFM	1	$65	None	$65	181	$11,765
Modify static system	2	65	100–200	230–330	181	41,630–59,730

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(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) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–17 Bombardier, Inc. (Formerly de Havilland, Inc.): Amendment 39–14041. Docket No. FAA–2005–20222; Directorate Identifier 2004–NM–230–AD.

Effective Date

(a) This AD becomes effective May 12, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Bombardier Model DHC–8–102, –103, –106, –201, –202, –301, –311, and –315 airplanes, certificated in any category; serial numbers 003 through 598 inclusive.

Unsafe Condition

(d) This AD was prompted by a report of a leak in the static pressure system, which could result in loss of the static systems and consequent erroneous data displayed on the pilot's flight instruments. We are issuing this AD to advise the flightcrew of applicable procedures in the event of abnormal indications of airspeed, altitude, or vertical airspeed; and to prevent leaks in the static system, which could result in the loss of critical flight information that could result in reduced controllability of the airplane or controlled flight into terrain.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Revision to Airplane Flight Manual

(f) Within 10 days after the effective date of this AD, revise the Normal and Abnormal Procedures sections of the applicable de Havilland Dash 8 Flight Manual to include the following statement in paragraph 4.11.1 of 4.11 Pitot—Static and Stall Warning System Failures. This may be done by inserting a copy of this AD into the applicable flight manual.

''4.11.1 ABNORMAL INDICATIONS OF AIRSPEED, ALTITUDE AND VERTICAL AIRSPEED.

1. Appropriate STATIC SOURCE selector—ALTERNATE. If switching the STATIC SOURCE selector to ALTERNATE does not correct the abnormal indications:

2. Rely on the flight instruments on the opposite side and land as soon as practicable.''

Note 1: When a statement identical to that in paragraph (f) of this AD has been included in the general revisions of the applicable flight manual, the general revisions may be inserted into the flight manual, and the copy of this AD may be removed from the flight manual.

Modification of the Static System

(g) For airplanes having serial numbers 003 through 590 inclusive: Within 24 months after the effective date of this AD, modify the static system in accordance with Part A and Part C of the Accomplishment Instructions of Bombardier Service Bulletin 8–34–221, Revision 'A,' dated September 15, 2003.

(h) For airplanes having serial numbers 591 through 598 inclusive: Within 24 months after the effective date of this AD, modify the static system in accordance with Part B and Part C of the Accomplishment Instructions of Bombardier Service Bulletin 8–34–221, Revision 'A,' dated September 15, 2003.

Modifications Done According to Previous Issue of Service Bulletin

(i) Modifications done before the effective date of this AD in accordance with Bombardier Service Bulletin 8–34–221, dated May 27, 2003, are acceptable for compliance with the applicable modifications specified in paragraphs (g) and (h) of this AD.

Alternative Methods of Compliance (AMOCs)

(j) The Manager, New York Aircraft Certification Office, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(k) Canadian airworthiness directive CF–2003–25, dated October 10, 2003, also addresses the subject of this AD.

Material Incorporated by Reference

(l) You must use Bombardier Service Bulletin 8–34–221, Revision 'A,' dated September 15, 2003, to perform the actions

that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, contact Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on March 24, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6687 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–18997; Directorate Identifier 2004–NM–19–AD; Amendment 39–14036; AD 2005–07–12]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–100, –200, –200C, –300, –400, and –500 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This AD requires repetitive detailed and eddy current inspections to detect cracking of the frame web around the cutout for the doorstop intercostal strap at the aft side of the body station 291.5 frame at stringer 16R, and corrective actions if necessary. This AD is prompted by reports of fatigue cracks in the web of the body station 291.5 frame near the forward galley door. We are issuing this AD to detect and correct fatigue cracking of the aft frame and frame support structure of the forward galley door, which could result in a severed fuselage frame web, rapid decompression of the airplane, and possible loss of the forward galley door.

DATES: This AD becomes effective May 12, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of May 12, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2004–18997; the directorate identifier for this docket is 2004–NM–19–AD.

FOR FURTHER INFORMATION CONTACT: Howard Hall, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6430; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with an AD for certain Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. That action, published in the **Federal Register** on September 3, 2004 (69 FR 53858), proposed to require repetitive detailed and eddy current inspections to detect cracking of the frame web around the cutout for the doorstop intercostal strap at the aft side of the body station 291.5 frame at stringer 16R, and corrective actions if necessary.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD.

Request To Delay Issuing AD

Several commenters note that the proposed AD does not provide a terminating action for the repetitive inspections specified in the proposed AD. Two commenters suggest that a terminating action be included in either the final AD action or in the instructions of the structural inspection document. One commenter requests that the FAA delay issuing the final AD action until Boeing Alert Service Bulletin 737–53A1241, dated June 13, 2002, has been revised to include a terminating modification. (That service bulletin was referenced in the proposed AD as the appropriate source of service information for accomplishing the repetitive inspections.) One commenter states that the proposed repetitive intervals will allow enough time for accomplishment of the inspections during its fleet's heavy maintenance visits, but that it would be helpful if terminating action instructions were provided.

We agree that a terminating action for the repetitive inspections would benefit operators. The airplane manufacturer is currently developing a terminating action. Once the proposed terminating action has been submitted to us for review, and we have approved the proposed action as terminating action for the requirements of the AD, anyone may use that terminating action as an alternative method of compliance (AMOC) under the provisions of paragraph (h) of this AD. We do not agree that we should delay issuing this AD until a terminating action is developed. We have determined that an unsafe condition exists, and we do not have any technical justification for delaying the release of this AD. We have not changed this AD regarding this issue.

One commenter requests that operators be allowed to review the additional service history information referenced in the proposed AD before the FAA issues the final AD action. The commenter states that it has requested that Boeing disseminate that additional history information to all operators. The commenter notes that the initial inspection threshold specified in the proposed AD is 20 percent lower than the threshold specified in Boeing Alert Service Bulletin 737–53A1241. The commenter concludes that the additional history information had an obvious impact on the FAA's decision to include a lowered initial inspection threshold in the proposed AD.

We agree with the intent of the commenter's request. As stated in the ''Differences Between the Proposed AD and Service Bulletin'' section of the proposed AD, the service bulletin includes an initial inspection threshold of 50,000 total flight cycles, and the proposed AD includes an initial inspection threshold of 40,000 total flight cycles. The threshold specified in the service bulletin is based on the first two reported cracks, which were found on an airplane that had accumulated more than 54,000 total flight cycles. After the release of the service bulletin, a subsequent crack was reported on an

airplane that had accumulated only 44,153 total flight cycles. In light of this additional service history, we met with Boeing and determined that a threshold of 40,000 total flight cycles was appropriate for the initial inspection. We do not agree to delay issuing this AD until operators have had the opportunity to review the additional service history referenced in the proposed AD. We do not have any technical justification for such a delay. We have not changed this AD regarding this issue.

Request To Revise Repetitive Inspection Interval

Two commenters state that the repetitive inspection interval specified in the proposed AD is not synchronized with their maintenance programs, and that doing the inspection at the interval specified in the proposed AD would be a significant burden for operators that need to remove the galley to do an inspection. We infer that the commenters are requesting that the repetitive inspection interval of ''not to exceed 4,500 flight cycles,'' which is specified in the proposed AD, be increased so the interval is synchronized with the commenters' maintenance programs.

We agree that it would be a significant burden if operators have to remove the galley outside of a scheduled maintenance visit in order to perform an inspection. We do not agree to revise this AD so the repetitive inspection interval is synchronized with the maintenance programs of specific operators. In developing the repetitive inspection interval for this AD we considered the manufacturer's recommendation, the degree of urgency associated with the subject unsafe condition, and the practical aspect of accomplishing the required inspection at an interval that corresponds to the normal scheduled maintenance for most affected operators. However, under the provisions of paragraph (h) of this AD, we may approve requests to adjust the repetitive interval if the request includes data that justify that a different interval would provide an acceptable level of safety. We have not changed this AD regarding this issue.

Request To Address Inspection of Areas With Existing Repairs

One commenter notes that the proposed AD does not address inspection requirements if a repair exists in the subject areas. We infer that the commenter is requesting that we revise the proposed AD to include information regarding the inspection of areas with existing repairs.

We acknowledge that special inspection procedures may be required if a previously installed repair prevents an operator from accomplishing the actions required by this AD. It is not possible to foresee all possible repair configurations and to provide an appropriate inspection. If this is the case, the operator must apply for an AMOC as provided by paragraph (h) of this AD. We have not changed this AD regarding this issue.

Request To Revise Costs of Compliance

Several commenters state that the estimated costs for compliance stated in the proposed AD are misleading. The commenters note that inspecting the subject areas may only take 2 hours per inspection cycle to accomplish, but the time for accessing and closing the inspection area may take an additional 20 hours per inspection cycle. The commenters state that these access and closing costs would be attributable to the proposed AD because the proposed compliance time would not allow for doing the proposed actions during a scheduled maintenance visit when the galley would be removed. We infer that the commenters are requesting that the estimated costs of compliance be revised to include labor hours for accessing and closing the inspection area.

We do not agree to revise the ''Costs of Compliance'' section of this AD. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. This AD requires repetitive detailed and eddy current inspections. We recognize that in accomplishing the requirements of any AD, operators may incur incidental costs in addition to the direct costs. However, the cost analysis in AD rulemaking actions typically does not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions. Because incidental costs may vary significantly from operator to operator, they are almost impossible to calculate.

Explanation of Change to the Proposed AD

Boeing has received a Delegation Option Authorization (DOA). We have revised this AD to delegate the authority to approve an AMOC for any replacement required by this AD to the Authorized Representative (AR) for the Boeing DOA Organization rather than the Designated Engineering Representative.

We have revised paragraph (h) of this AD to provide the option of requesting an AMOC from either the Manager, Seattle Aircraft Certification Office (ACO), FAA, or an approved AR of the Boeing DOA Organization who has been authorized by the Manager, Seattle ACO, to make such findings.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

This AD affects about 3,113 airplanes worldwide. The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection, per inspection cycle.	2	$65	None	$130, per inspection cycle	876	$113,880, per inspection cycle.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII,

Part A, Subpart III, Section 44701, ''General requirements.''

Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(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) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–12 Boeing: Amendment 39–14036. Docket No. FAA–2004–18997; Directorate Identifier 2004–NM–19–AD.

Effective Date

(a) This AD becomes effective May 12, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes; certificated in any category; as identified in Boeing Alert Service Bulletin 737–53A1241, dated June 13, 2002.

Unsafe Condition

(d) This AD was prompted by reports of fatigue cracks in the web of the body station 291.5 frame near the forward galley door. We are issuing this AD to detect and correct fatigue cracking of the aft frame and frame support structure of the forward galley door, which could result in a severed fuselage frame web, rapid decompression of the airplane, and possible loss of the forward galley door.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Initial and Repetitive Inspections

(f) Prior to the accumulation of 40,000 total flight cycles, or within 2,250 flight cycles after the effective date of this AD, whichever occurs later: Do a detailed inspection and an eddy current inspection to detect cracking of the frame web around the cutout for the doorstop intercostal strap at the aft side of the body station 291.5 frame at stringer 16R, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1241, dated June 13, 2002. If no cracking is found, repeat the inspections thereafter at intervals not to exceed 4,500 flight cycles.

Note 1: For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

Corrective Action

(g) If any crack is found during any inspection required by this AD, and the bulletin specifies to contact Boeing for appropriate action: Before further flight, repair the crack according to a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or according to data meeting the certification basis of the airplane approved by an Authorized Representative (AR) for the Boeing Delegation Option Authorization (DOA) Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically reference this AD.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any inspection required by this AD, if it is approved by an AR for the Boeing DOA who has been authorized by the Manager, Seattle ACO, to make those findings. For an inspection method to be approved, the approval must specifically refer to this AD.

Material Incorporated by Reference

(i) You must use Boeing Alert Service Bulletin 737–53A1241, dated June 13, 2002, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, go to Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on March 25, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6688 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19989; Directorate Identifier 2004–NM–151–AD; Amendment 39–14037; AD 2005–07–13]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–300 and –400ER Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Boeing Model 767–300 and –400ER series airplanes. This AD requires replacing the in-flight entertainment cooling card, located in the P50 card file

in the main equipment center, with a new, improved cooling card. This AD is prompted by a report of an improperly designed component on the in-flight entertainment (IFE) cooling card, which may cause the IFE cooling system to incorrectly interpret signals from airplane system interfaces. We are issuing this AD to prevent failure of the IFE cooling card to configure itself correctly in response to input signals from airplane system interfaces during a forward cargo fire, which could result in the IFE cooling fan causing smoke to penetrate occupied areas of the airplane.

DATES This AD becomes effective May 12, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of May 12, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility Office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2004–19989; the directorate identifier for this docket is 2004–NM–151–AD.

FOR FURTHER INFORMATION CONTACT: Clint Jones, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6471; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with an AD for certain Boeing Model 767–300 and –400ER series airplanes. That action, published in the **Federal Register** on January 5, 2005 (70 FR 725), proposed to require replacing the in-flight entertainment cooling card, located in the P50 card file in the main equipment center, with a new, improved cooling card.

Comments

We provided the public the opportunity to participate in the development of this AD. No comments have been submitted on the proposed AD or on the determination of the cost to the public.

Conclusion

We have carefully reviewed the available data and determined that air safety any the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 32 airplanes of the affected design in the worldwide fleet. The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Replacement	1	$65	$9,500	$9,565	16	$153,040

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD;

(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) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air Transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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.

§ 3913 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–13 Boeing: Amendment 39–14037. Docket No. FAA–2004–19989; Directorate Identifier 2004–NM–151–AD.

Effective Date

(a) This AD becomes effective May 12, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 767–300 series airplanes as listed in Boeing Special Attention Service Bulletin 767–21–0188, dated May 27, 2004; and Boeing Model 767–400ER series airplanes, as listed in Boeing Special Attention Service Bulletin

767–21–0189, dated May 27, 2004; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a report of an improperly designed component on the in-flight entertainment (IFE) cooling card, which may cause the IFE cooling system to incorrectly interpret signals from airplane system interfaces. We are issuing this AD to prevent failure of the IFE cooling cared to configure correctly in response to input signals from airplane system interfaces during a forward cargo fire, which could result in the IFE cooling fan causing smoke to penetrate occupied areas of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement of IFE Cooling Card

(f) Within 18 months after the effective date of this AD: Replace the IFE cooling card, part number (P/N) 285T1198–101, located in the P50 card file in the main equipment center, with a new, improved cooling card, P/N 285T1198–102. Do the replacement by accomplishing all of the actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 767–21–0189 (for Boeing Model 767–400ER series airplanes); or 767–21–0189 (for Boeing Model 767–400ER series airplanes); both dated May 27, 2004; as applicable. Where the service bulletins state that the replacement may be done using an ''operator's equivalent procedure,'' the replacement must be done according to the procedures in the chapter/subject of the applicable Boeing 767 Airplane Maintenance Manual specified in the service bulletins.

Parts Installation

(g) As of the effective date of this AD, no person may install an IFE cooling card, P/N 285T1198–101, on any airplane.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this Ad, if requested in accordance with the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(i) You must use Boeing Special Attention Service Bulletin 767–21–0188, dated May 27, 2004; or Boeing Special Attention Service bulletin 767–21–0189, dated May 27, 2004; as applicable, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. You may view the AD docket at the Docket management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archieves.gov/federal register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on March 25, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6689 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19003; Directorate Identifier 2003–NM–245–AD; Amendment 39–14044; AD 2005–07–19]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–100, –200C, –300, –400, and –500 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This AD requires repetitive inspections for cracks in the fuselage skin, doubler, bearstrap, and frames surrounding the main, forward, and aft cargo doors; and repair of any cracking. This AD also requires inspections of certain existing repairs for cracking, and related corrective action if cracking is found. This AD is prompted by reports of multiple fatigue cracks in the fuselage skin and bonded skin doubler, bearstrap, and doorway frames surrounding the forward and aft cargo doors. We are issuing this AD to find and fix fatigue cracking in the fuselage skin, doubler, bearstrap, and frames, which could result in reduced structural integrity of the frames, possible loss of a cargo door, and consequent rapid decompression of the fuselage.

DATES: This AD becomes effective May 12, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of May 12, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. You can examine this information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2004–19003; the directorate identifier for this docket is 2003–NM–245–AD.

FOR FURTHER INFORMATION CONTACT: Howard Hall, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6430; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with an AD for all Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. That action, published in the **Federal Register** on September 7, 2004 (69 FR 54058), proposed to require repetitive inspections for cracks in the fuselage skin, doubler, bearstrap, and frames surrounding the main, forward, and aft cargo doors; and repair of any cracking. That action also proposed to require inspections of certain existing repairs for cracking, and related corrective action if cracking is found.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD.

Supportive Comment

One commenter states that the proposed AD will affect only its 737–200C and –400 fleets, and adds that the proposed detailed inspections and compliance intervals will allow compliance at heavy check maintenance visits. The commenter stipulates that these requirements are acceptable provided there are adequate replacement parts available if discrepancies are found.

We have discussed the issue of obtaining replacement parts with the airplane manufacturer and we anticipate no difficulty in getting the parts to accomplish repairs.

Request for Credit for Accomplishing AD 93–14–10

One commenter, the airplane manufacturer, asks that we add a sentence to paragraph (f) of the proposed AD that gives credit for accomplishing the inspections and repairs required by AD 93–14–10, amendment 39–8634 (58 FR 43547, August 17, 1993). The commenter states that the requirements of the proposed AD are equivalent to, or more conservative than, the requirements in AD 93–14–10.

We agree with the commenter that accomplishing the requirements in paragraph (f) of the proposed AD ends the requirements in AD 93–14–10 (referenced as related rulemaking in the preamble of the proposed AD). As specified in the preamble of the proposed AD, during structural inspections, cracks were found in the bearstrap under the fuselage frame flanges at the edges of the forward cargo door. In two cases, cracks were found in the fuselage frames of the aft cargo door where steel repair doublers had been installed using the requirements of AD 93–14–10; therefore, the requirements in this AD exceed the requirements of AD 93–14–10. We have changed paragraph (f) of this AD by adding credit for previously accomplishing AD 93–14–10.

Request To Add Inspection Type to Paragraph (f) of the Proposed AD

The same commenter states that the first sentence in paragraph (f) specifies, in part, ''Do the applicable detailed, general visual, and low and high frequency eddy current inspections for cracks * * *'' The commenter asks that a reference to the mid-frequency eddy current (MFEC) inspection be added to paragraph (f). The commenter notes that this inspection is specified in the referenced service bulletin.

We agree with the commenter that the MFEC inspection should be added to paragraph (f), for clarification. An internal MFEC inspection is specified in the referenced service bulletin as an option to accomplishing the detailed visual inspections, and would extend the compliance time for the repetitive inspections, but was not identified in the proposed AD. Paragraph (f) of the proposed AD specified doing the ''applicable'' inspections for cracks as specified in the referenced tables. However, to clarify the type of inspection, we have changed paragraph (f) of this final rule to include the MFEC inspection.

Request for Clarification of Location of Inspections for Existing Repairs

One commenter asks for clarification regarding accomplishing inspections of existing repairs around the cargo doors in accordance with the referenced service bulletin. The commenter states that it is unclear which inspection is required if repairs are of a different configuration than those referenced in the figures in the service bulletin. The commenter notes, for example, that a repair of the cargo door lower corner per Boeing Structural Repair Manual 737–100/200, Figure 46, Detail IV, does not match the Figure 8 repair in the service bulletin. The commenter adds that verbiage needs to be added clarifying whether the ''intent'' of the service bulletin is to accomplish a MFEC inspection of all outer row fasteners of the repair doubler, no matter what the configuration.

We agree that clarification is necessary. The repairs shown in Figures 8, 9, and 10 of the referenced service bulletin are conceptual illustrations of typical doubler/tripler type repairs. These figures are intended to indicate that the location of the detailed visual or MFEC inspections for cracking is the skin or bearstrap at the outer row fasteners common to the outer edge of the repair. We have added a note after paragraph (f) of the final rule for further clarification.

Request for Certain Repair Instructions

One commenter states that repair instructions that are similar to those currently available for Model 737–100 and –200 series airplanes for damaged skin, doubler, and bearstrap around the cargo doors should also be available for Model 737–300, –400, and –500 series airplanes. The commenter adds that it is crucial to limit downtime of aircraft as much as possible, an coordinating repair procedures with Boeing extends the out-of-service time for affected airplanes.

We agree that repair instructions should be made available for Model 737–300, –400 and –500 series airplanes. However, until repair instructions are published for Model 737–300, –400 and –500 series airplanes, the repair must be accomplished according to a method approved by the Manager, Settle Aircraft Certification Office or an Authorized Representative for the Boeing Delegation Option Authorization (DOA) Organization. Repair procedures have been developed for incorporation into the next revision of the 737–300/400/500 SRM and will be submitted to us by Boeing soon. As provided by paragraph (i) of this AD, we will consider approving these repairs as an alternative method of compliance for paragraph (g) of this AD. We have made no change to the final rule in this regard.

Clarification of Applicability

One commenter asks why the proposed AD isn't applicable to Model 737–300C series airplanes with a main cargo door installed by PEMCO. The commenter notes that the proposed AD includes Model 737–200C series airplanes with a main cargo door, and asks if excluding the 737–300C is normal.

We acknowledge the commenter's concern and offer clarification. The proposed AD is applicable to Model 737–100, –200, –200C, –300, –400, –500 series airplanes, including airplanes modified to include a main cargo door. We infer that the commenter's reference to a ''Model 737–300C'' is an informal designation for a Model 737–300 series airplane that has been modified to include a main cargo door per a supplemental type certificate. However, no model 737–300C series airplane is identified in the type certificate data sheet. Thus, an airplane with that configuration would be subject to the AD requirements for Model 737–300 series airplanes. In comparison, the Model 737–200C series airplane is identified in the type certificate data sheet.

Explanation of Changer to Proposed AD

Boeing has received a DOA. We have revised paragraph (i)(2) of this final rule to delegate the authority to approve an alternative method of compliance for any repair required by this AD to the Authorized Representative for the Boeing DOA Organization rather than the Designated Engineering Representative.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD with the change described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

There are about 3,132 airplanes of the affected design in the worldwide fleet. We estimate that 870 airplanes of U.S. registry will be affected by this AD. We provide the following cost estimates to

comply with this AD, per inspection cycle:

Group	Work hours	Hourly labor rate	Parts	Cost per airplane
1	24	$65	$0	$1,560
2 and 4	28	65	0	1,820
3 and 5	30	65	0	1,950
6 and 7	28	65	0	1,820

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(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) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporated by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–19 Boeing: Amendment 39–14044. Docket No. FAA–2004–19003; Directorate Identifier 2003–NM–245–AD.

Effective Date

(a) This AD becomes effective May 12, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Model 737–100, –200, –200C, –300, –400, and –500 series airplanes; certified in any category.

Unsafe Condition

(d) This AD was prompted by reports of multiple fatigue cracks in the fuselage skin and bonded skin doubler, bearstrap, and doorway frames surrounding the forward and aft cargo doors. We are issuing this AD to find and fix fatigue cracking in the fuselage skin, doubler, bearstrap, and frames, which could result in reduced structural integrity of the frames, possible loss of a cargo door, and consequent rapid decompression of the fuselage.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Initial and Repetitive Inspections/Corrective Action

(f) Do the applicable detailed, general visual, and low-, mid-, and high-frequency eddy current inspections for cracks in the fuselage skin, doubler, bearstrap, and frames surrounding the main, forward, and aft cargo doors, and for cracks in existing repairs, as specified in Tables 1, 2, and 3, as applicable, of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1228, dated July 10, 2003. Do the inspections at the initial compliance times listed in Tables 1, 2, and 3, as applicable, of paragraph 1.E., ''Compliance,'' of the service bulletin; except, where the service bulletin specifies a compliance time after the service bulletin date, this AD requires compliance within the specified compliance time after the effective date of this AD. Do the inspections in accordance with the Accomplishment Instructions of the service bulletin. Repeat the inspections within the repetitive inspection intervals listed in Tables 1, 2, 3 of paragraph 1.E., ''Compliance,'' of the service bulletin. Accomplishing the requirements in this paragraph ends the requirements in AD 93–14–10, amendment 39–8634 (58 FR 43547. August 17, 1993).

Note 1: At existing repairs around the forward and aft cargo door cutouts: The location for the specified detailed or mid-frequency eddy current inspections for cracking of the skin or bearstrap is at the outer row of fasteners common to the repair, as illustrated in Figures 8, 9, and 10 of Boeing Alert Service Bulletin 737–53A1228, dated July 10, 2003.

(g) If any crack is found during any inspection: Repair before further flight in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1228, dated July 10, 2003. Where the service bulletin specifies contacting the manufacturer for disposition of certain repair conditions, repair before further flight in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or an Authorized Representative for the Boeing Delegation Option Authorization (DOA) Organization who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically refer to this AD.

No Reporting Required

(h) Although the service bulletin referenced in this AD recommends reporting any discrepancies to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing

DOA Organization who has been authorized by the Manager, Seattle ACO, to make those findings.

Material Incorporated by Reference

(j) You must use Boeing Alert Service Bulletin 737–53A1228, dated July 10, 2003, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on March 30, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6763 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19986; Directorate Identifier 2004–NM–247–AD; Amendment 39–14045; AD 2005–07–20]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–600, –700, –800, and –900 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Boeing Model 737–600, –700, –800, and –900 series airplanes. This AD requires installing and testing an updated version of the operational program software of the flight control computers. This AD is prompted by a report of an airplane pitching up with rapidly decreasing indicated airspeed after the flightcrew set a new altitude into the autopilot. We are issuing this AD to prevent anomalous autopilot operation that produces a hazardous combination of airplane attitude and airspeed, which could result in loss of control of the airplane.

DATES: This AD becomes effective May 12, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of May 12, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2004–19986; the directorate identifier for this docket is 2004–NM–247–AD.

FOR FURTHER INFORMATION CONTACT: Gregg Nesemeier, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6479; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with an AD for certain Boeing Model 737–600, –700, –800, and –900 series airplanes. That action, published in the **Federal Register** on January 5, 2005 (70 FR 733), proposed to require installing and testing an updated version of the operational program software of the flight control computers.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD.

Support for the Proposed AD

Two commenters support the AD as proposed. A third commenter supports the intent of the proposed AD.

Request To Prohibit Testing in Revenue Service

One commenter requests that we prohibit testing of the updated software in revenue service. The commenter provides no justification for the request. We infer that the commenter believes the proposed AD would require a flight test of the updated software installation, and that performing a flight test during revenue service would pose undue hazard to airplane occupants.

We do not agree because we believe the commenter has misunderstood the testing requirement of this AD. The test of the updated version of the operational program (OPS) software is a ground test performed by maintenance personnel, not a flight test. This test, which must be satisfactorily accomplished before returning an airplane to service, is adequate for ensuring that the OPS software is properly installed and updated. Therefore, no change to this final rule is necessary in this regard.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 155 airplanes of the affected design in the worldwide fleet. This AD affects about 34 airplanes of U.S. registry. The actions take about 2 work hours per airplane, at an average labor rate of $65 per work hour. Required parts cost about $0 per airplane. Based on these figures, the estimated cost of this AD for U.S. operators is $4,420, or $130 per airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(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) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–20 Boeing: Amendment 39–14045. Docket No. FAA–2004–19986; Directorate Identifier 2004–NM–247–AD.

Effective Date

(a) This AD becomes effective May 12, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 737–600, –700, –800, and –900 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 737–22A1164, dated May 20, 2004.

Unsafe Condition

(d) This AD was prompted by a report of an airplane pitching up with rapidly decreasing indicated airspeed after the flightcrew set a new altitude into the autopilot. We are issuing this AD to prevent anomalous autopilot operation that produces a hazardous combination of airplane attitude and airspeed, which could result in loss of control of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Install and Test Updated Software

(f) Within 12 months after the effective date of this AD, install and test an updated version of the operational program software of the enhanced digital flight control system (EDFCS) flight control computers (FCCs), in accordance with Boeing Alert Service Bulletin 737–22A1164, dated May 20, 2004.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(h) You must use Boeing Alert Service Bulletin 737–22A1164, dated May 20, 2004, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on March 30, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6762 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19761; Directorate Identifier 2003–NM–167–AD; Amendment 39–14039; AD 2005–07–15]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier Model CL–600–2B19 (Regional Jet Series 100 and 440) airplanes. This AD requires modification of the Auxiliary Power Unit (APU) cooling air exhaust. This AD is prompted by reports of incomplete drainage of the APU enclosure. We are issuing this AD to prevent a negative pressure condition from developing in the APU enclosure when the APU is operating on the ground, which could create a potential fire hazard if flammable liquid leakage occurs inside the APU enclosure and cannot be drained overboard.

DATES: This AD becomes effective May 12, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of May 12, 2005.

ADDRESSES: For service information identified in this AD, contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, Washington, DC. This docket number is FAA–2004–19761; the directorate identifier for this docket is 2003–NM–167–AD.

FOR FURTHER INFORMATION CONTACT: James E. Delisio, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, suite 410, Westbury, New York 11590; telephone (516) 228–7321; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for certain Bombardier Model CL–600–2B19 (Regional Jet Series 100 and 440) airplanes. That action, published in the **Federal Register** on December 7, 2004 (69 FR 70566), proposed to require modification of the Auxiliary Power Unit cooling air exhaust.

Comments

We provided the public the opportunity to participate in the

development of this AD. We have considered the single comment that has been submitted on the proposed AD.

Request To Clarify Applicability

The commenter asks that the airplane serial numbers be listed in the applicability paragraph of the final rule, rather than referencing the service bulletin. The commenter states that this request is consistent with similar airworthiness directives and presents a quicker reference for establishing applicability.

We agree to provide further clarification in the applicability section of this final rule. Although the applicability section in the proposed AD already identifies the referenced service bulletin, which specifies the airplane serial numbers in the effectivity section, we have listed the serial numbers in the applicability section in paragraph (c) of this final rule.

Editorial Change/Clarification Regarding Appendix A of Bombardier Service Bulletin 601R–49–015

We changed all service bulletin references in this final rule from ''Bombardier Service Bulletin S.B. 601R–49–015'' to ''Bombardier Service Bulletin 601R–49–015.'' The letters ''S.B.'' are not part of the service bulletin number.

Note 1 of this final rule specifies that Avica Service Bulletin 10S145–49–01 and Canadair Kit Drawing K601R97150 are included as Appendix A of Bombardier Service Bulletin 601R–49–015. In paragraph (j) of this final rule, we have ''excluded'' Appendix A from the citation for Bombardier Service Bulletin 601R–49–015 for the purpose of incorporation by reference of the service bulletin. However, as stated in Note 1, our intent is that the references in Appendix A still be used as additional sources of service information for doing the modification specified in paragraph (f) of this final rule.

These changes were made to comply with the Office of the Federal Register's guidelines for material incorporated by reference.

Conclusion

We have carefully reviewed the available data, including the comment that has been submitted, and determined that air safety and the public interest require adopting the AD with the changes described previously. These changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

This AD will affect about 120 airplanes of U.S. registry. The actions will take about 10 work hours per airplane, at an average labor rate of $65 per work hour. There is no charge for parts that may be required to perform the actions required by this AD. Based on these figures, the estimated cost of the AD for U.S. operators is $78,000, or $650 per airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(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) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–15 Bombardier, Inc. (Formerly Canadair): Amendment 39–14039. Docket No. FAA–2004–19761; Directorate Identifier 2003–NM–167–AD.

Effective Date

(a) This AD becomes effective May 12, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Bombardier Model CL–600–2B19 (Regional Jet Series 100 and 440) airplanes; certified in any category; serial numbers 7003 through 7067 inclusive and 7069 through 7254 inclusive.

Unsafe Condition

(d) This AD is prompted by reports of incomplete drainage of the Auxiliary Power Unit (APU) enclosure. We are issuing this D to prevent a negative pressure condition from developing in the APU enclosure when the APU is operating on the ground, which could create a potential fire hazard if flammable fluid leakage occurs inside the APU enclosure and cannot be drained overboard.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Modify APU Cooling Air Exhaust

(f) Within 2,000 flight hours after the effective date the AD, or within 16 months after the effective date of this AD, whichever occurs first: Modify the APU cooling air exhaust by doing all of the actions in the Accomplishment Instructions of Bombardier Service Bulletin 601R–49–015, dated November 6, 1998, except that submitting a comment sheet and a compliance sheet are not required by this AD.

Note 1: Bombardier Service Bulletin 601R–49–015, dated November 6, 1998, refers to Avica Service Bulletin 10S145–49–01, dated July 15, 1998, and Canadair Kit Drawing K601R97150, Rev NC, as additional sources of service information for doing the modification. The Avica service bulletin and the Canadair Kit Drawing are included as Appendix A of the Bombardier service bulletin.

Parts Installation

(g) As of the effective date of this AD, no person may install an APU enclosure having Canadair part number (P/N) 601R97150–13, or Avica P/N 15A104–101, on any airplane, unless he unit has been modified in accordance with paragraph (f) of this AD.

Alternative Methods of Compliance

(h) The Manager, New York Aircraft Certification Office, FAA, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(i) Canadian airworthiness directive CF–2002–21, dated March 21, 2002, also addresses the subject of this AD.

Materials Incorporated by Reference

(j) You must use Bombardier Service Bulletin 601R–49–015, excluding Appendix A, dated November 6, 1998, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. You may view the Ad docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on March 24, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6686 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20883; Directorate Identifier 2005–NM–064–AD; Amendment 39–14047; AD 2005–07–22]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 series airplanes. This AD requires revising the Limitations section of the airplane flight manual to advise the flightcrew to make sure the correct instrument landing system (ILS) identifier is included on the flight management system (FMS) flight plan before the flightcrew initiates an approach to landing with the autopilot engaged. This AD is prompted by reports that the airplane's autopilot may apply large-amplitude control inputs while following ILS guidance to a runway that is not included on the FMS flight plan. We are issuing this AD to prevent hazardous maneuvers close to the ground, which could result in an impact with an obstacle or terrain.

DATES: Effective April 22, 2005. We must receive comments on this AD by June 6, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street SW, Nassif Building, room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343–CEP 12.225, Sao Jose dos Campos—SP, Brazil.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20883; the directorate identifier for this docket is 2005–NM–064–AD.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: The Departmento de Aviacao Civil (DAC), which is the airworthiness authority for Brazil, notified the FAA that an unsafe condition may exist on all Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 series airplanes. The DAC advises that it has received several reports that the airplane's autopilot applied large-amplitude control inputs while following instrument landing system (ILS) guidance to runways that were not included on the flight management system (FMS) flight plan. This condition, if not corrected, could cause hazardous maneuvers close to the ground, and result in an impact with an obstacle or terrain.

Brazilian Airworthiness Directive

The DAC issued Brazilian airworthiness directive 2005–03–01, dated March 21, 2005, which mandates modification of the autopilot-coupled ILS approach procedures by revising the Limitations section of the airplane flight manual to advise the flightcrew to make sure the correct ILS identifier is included on the FMS flight plan before the flightcrew initiates an approach to landing with the autopilot engaged. The DAC issued airworthiness directive 2005–03–01 to ensure the continued airworthiness of these airplanes in Brazil.

FAA's Determination and Requirements of This AD

This airplane model is manufactured in Brazil and is 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 DAC has kept the FAA informed of the situation described above. We have examined the DAC's findings, evaluated all pertinent information, and determined that we need to issue an AD

for products of this type design that are certificated for operation in the United States.

Therefore, we are issuing this AD to prevent hazardous maneuvers close to the ground, which could result in an impact with an obstacle or terrain. This AD requires revising the Limitations section of the airplane flight manual to advise the flightcrew to make sure the correct ILS identifier is included on the FMS flight plan before the flightcrew initiates an approach to landing with the autopilot engaged.

Interim Action

We consider this AD interim action. If final action is later identified, we may consider further rulemaking then.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD; therefore, providing notice and opportunity for public comment before the AD is issued is impracticable, and good cause exists to make this AD effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any relevant written data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20883; Directorate Identifier 2005–NM–064–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of our docket Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, *etc.*). You can review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that the 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. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. *See* the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–07–22 Empresa Brasileira de Aeronautica S.A. (EMBRAER): Amendment 39–14047. Docket No. FAA–2005–20883; Directorate Identifier 2005–NM–064–AD.

Effective Date

(a) This AD becomes effective April 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 series airplanes, certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports that the airplane's autopilot may apply large-amplitude control inputs while following instrument landing system (ILS) guidance to a runway that is not included on the flight management system (FMS) flight plan. The FAA is issuing this AD to prevent hazardous maneuvers close to the ground, which could result in an impact with an obstacle or terrain.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Airplane Flight Manual Revision

(f) Within 15 days after the effective date of this AD, revise the Limitations section of the EMBRAER Model ERJ 170 airplane flight manual (AFM) to include the following statement in the ''Autopilot'' subsection. This may be done by inserting a copy of this AD in the AFM.

''Before initiating an approach to landing with AUTOPILOT engaged, make sure the correct ILS identifier has been inserted on the FMS PROGRESS PAGE 1/3, Lines 5L and 5R.''

Note 1: When a statement identical to that in paragraph (f) of this AD has been included in the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(h) Brazilian airworthiness directive 2005–03–01, dated March 21, 2005, also addresses the subject of this AD.

Material Incorporated by Reference

(i) None.

Issued in Renton, Washington, on March 31, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6909 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP Jacksonville 05–033]

RIN 1625–AA00

Safety Zone; Atlantic Intracoastal Waterway, Fernandina Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary fixed safety zone on the Atlantic Intracoastal Waterway, Fernandina Beach, FL, for the Isle of Eight Flags Shrimp Festival. The safety zone is needed to protect boaters from the hazards associated with fireworks demonstrations. Anchoring, mooring, or transiting within this zone is prohibited, unless authorized by the Captain of the Port, Jacksonville, FL.

DATES: This rule is effective from 8:30 p.m. to 9:30 p.m. on April 29, 2005. A rain date has been set that would make this rule effective from 8:30 p.m. to 9:30 p.m. on April 30, 2005.

ADDRESSES: Documents mentioned in this preamble as being available in the docket, are part of docket [COTP Jacksonville 05–033] and are available for inspection and copying at Coast Guard Marine Safety Office Jacksonville, 7820 Arlington Expressway, Suite 400, Jacksonville, Florida, 32211, between 8 a.m. and 4 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Carol Swinson at Coast Guard Marine Safety Office Jacksonville, FL, tel: (904) 232–2640, ext. 155.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553 (b)(B), the Coast Guard finds that good cause exists for not publishing a NRPM. Publishing a NPRM, which would incorporate a comment period before a final rule could be issued, and delaying the rule's effective date is contrary to public safety because immediate action is necessary to protect the public and waters of the United States. Moreover, a NPRM is unnecessary due to the limited amount of time this rule will be in effect.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard will issue a broadcast notice to mariners and may place Coast Guard vessels in the vicinity of this zone to advise mariners of the restriction.

Background and Purpose

This rule is needed to protect spectator craft in the vicinity of the fireworks presentation from the hazards associated with transport, storage, and launching of fireworks. Anchoring, mooring, or transiting within this zone is prohibited, unless authorized by the Captain of the Port, Jacksonville, FL. The temporary safety zone encompasses all waters within a 500-yard radius around the fireworks platform during the storage, preparation, transport, and launching of fireworks. During the fireworks show, the platform will be located at approximate position 30°40.00′ N, 081°27.00′ W.

Regulatory Evaluation

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential cost and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has exempted it from review under the order. It is not significant under the regulatory policies and procedures of the Department of Homeland Security (DHS) because these regulations will only be in effect for a short period of time, and the impacts on routine navigation are expected to be minimal.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominate in their field, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under section 5 U.S.C. 605(b) that this rule will not have a significant economic impact upon a substantial number of small entities because the regulation will only be enforced for approximately one and a half hours the day it is in effect and the impact on routine navigation are expected to be minimal because traffic may transit safely around the zone and traffic may enter upon permission of the Captain of the Port or his representative.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Although this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. Under figure 2–1, paragraph (34)(g), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165, as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T07–033 is added to read as follows:

§ 165.T07–033 Safety Zone Atlantic Intracoastal Waterway, Fernandina Beach, FL.

(a) *Regulated area.* The Coast Guard is establishing a temporary safety zone on the Atlantic Intracoastal Waterway, Fernandina Beach, FL. The temporary safety zone encompasses all waters within a 500-yard radius around the fireworks platform located at approximate position 30°40.00′ N, 081°27.00′ W.

(b) *Regulations.* In accordance with the general regulations in § 165.23 of this part, anchoring, mooring or transiting in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Jacksonville, FL.

(c) *Dates.* This rule is effective from 8:30 p.m. to 9:30 p.m. on April 29, 2005. A rain date has been set that would make this rule effective from 8:30 p.m. to 9:30 p.m. on April 30, 2005.

Dated: March 25, 2005.

David. L. Lersch,

Captain, U.S. Coast Guard, Captain of the Port Jacksonville.

[FR Doc. 05–6955 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–15–P

Proposed Rules

Federal Register
Vol. 70, No. 66
Thursday, April 7, 2005

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 337

RIN 3206–AK35

Examining System

AGENCY: Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing a proposed regulation to designate two sections of the Alternative Ranking and Selection Procedures from the Chief Human Capital Officers Act of 2002 (Title XIII of the Homeland Security Act) as veterans' preference requirements for purposes of a prohibited personnel practice violation, thereby aligning these sections with other statutory provisions covering veterans' preference.

DATES: Comments will be considered if received by May 9, 2005.

ADDRESSES: Send, deliver or fax comments to Mark Doboga, Deputy Associate Director for Talent and Capacity Policy, U.S. Office of Personnel Management, Room 6551, 1900 E Street, NW., Washington, DC 20415–9700; e-mail at *employ@opm.gov*; or fax at (202) 606–2329.

Comments may also be sent through the Federal eRulemaking Portal at: *http://www.regulations.gov*. All submissions received through the Portal must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Watson by telephone at (202) 606–0830; by fax at (202) 606–2329; by TTY at (202) 418–3134; or by e-mail at *linda.watson@opm.gov*.

SUPPLEMENTARY INFORMATION: On June 15, 2004, OPM published final regulations at 69 FR 33271, to implement provisions of the Chief Human Capital Officers Act of 2002 (Act), Public Law 107–296. This Act provides Federal agencies with a number of human resources flexibilities to enhance their recruitment and hiring programs. These flexibilities include the alternative (category) rating and selection procedures.

The alternative ranking and selection procedures were codified in section 3319 of title 5, United States Code (U.S.C.). This section provides agencies with the authority to develop a category-based rating method to assess and rate job applicants for positions filled through the competitive examining process. Traditionally, applicants for Federal jobs are assigned numerical scores, including veterans' preference points, if appropriate, and are considered for selection based on the ''rule of three'' (5 U.S.C. 3318(a)).

Section 3319(b) protects the rights of veterans by placing them ahead of non-preference eligibles within each category in lieu of adding veterans' preference points or applying the ''rule of three.'' For all positions other than scientific and professional positions at GS–9 (equivalent or higher), qualified preference eligibles that have a compensable service-connected disability of at least 10 percent must be listed in the highest quality category.

Section 3319(c)(2) prohibits appointing officials from passing over a preference eligible in the same quality category from which a selection is made to select a non-preference eligible unless the requirements of section 3317(b) or 3318(b) are satisfied.

OPM is issuing a proposed regulation designating sections 3319(b) and (c)(2) as veterans' preference requirements for purposes of section 2302(b)(11). OPM's authority to designate in regulation a provision of law as a ''veterans' preference requirement'' is prescribed in section 2302(e)(1)(G).

Section 2302(b) defines actions that constitute prohibited personnel practices. Section 2302(b)(11)(A) provides that an employee shall not, ''knowingly take, recommend, or approve any personnel action if the taking of such action would violate a veterans' preference requirement''. Section 2302(b)(11)(B) provides that an employee shall not ''knowingly fail to take, recommend, or approve any personnel action if the failure to take such action would violate a veterans' preference requirement''. As a result of this designation, failure to comply with section 3319(b) or (c)(2) constitutes a prohibited personnel practice under section 2302(b)(11).

The purpose of this designation is to align sections 3319(b) and (c)(2) with the other statutory provisions covering veterans' preference that are listed in section 2302(e)(1) as constituting veterans' preference requirements.

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities (including small businesses, small organizational units, and small governmental jurisdictions) because they would only apply to Federal agencies and employees.

List of Subjects in 5 CFR Part 337

Government employees.

U.S. Office of Personnel Management.

Dan G. Blair,

Acting Director.

Accordingly, OPM is proposing to amend 5 CFR part 337 as follows:

PART 337—EXAMINING SYSTEM

1. Revise the authority citation for part 337 to read as follows:

Authority: 5 U.S.C. 1104(a)(2), 1302, 2302, 3301, 3302, 3304, 3319, 5364; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218; 33 FR 12423, Sept. 4, 1968; 45 FR 18365, Mar. 21, 1980; and Section 1413 of Pub. L. 108–136.

Subpart C—Alternative Rating and Selection Procedures

2. Add new paragraph (c) to § 337.304 to read as follows:

§ 337.304 Veterans' preference.

* * * * *

(c) Sections 3319(b) and 3319(c)(2) of title 5 U.S.C. constitute veterans' preference requirements for purposes of 5 U.S.C. 2302(b)(11)(A) and (B).

[FR Doc. 05–6841 Filed 4–6–05; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 54 and 62

[No. LS–02–10]

RIN #0581–AC12

Quality Systems Verification Programs

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service (AMS) is proposing to establish a separate user-fee schedule for the Quality Systems Verification Programs (QSVP) and expand the scope of the QSVP to include all agricultural products and services within the responsibility of the Livestock and Seed (LS) Program. A new Part 62 would be established for QSVP services. QVSP are a collection of voluntary, audit-based, user-fee programs authorized under the Agricultural Marketing Act of 1946. QSVP facilitate the global marketing and trade of agricultural products; provide consumers the opportunity to distinguish specific characteristics involved in the production and processing of agricultural products; and ensure that product consistently meets program requirements.

DATES: Written comments must be received by May 9, 2005. Comments regarding the information collection requirements that would result from this proposal must be received by June 6, 2005.

ADDRESSES: Send comments concerning this proposed rule to James L. Riva, Chief; USDA, AMS, LS, ARC Branch; STOP 0294, Room 2627–S, 1400 Independence Avenue, SW., Washington, DC 20250–0248; by FAX to 202–690–1038; or by e-mail to: *ARCBranch@usda.gov*. Comments may also be submitted electronically through *http://www.regulations.gov*. Comments should reference the date and page number of this issue of the **Federal Register**. Comments will be posted at: *http://www.ams.usda.gov/lsg/rulemaking.htm* and will be made available for public inspection during normal business hours at the above address. Comments concerning the information collection should be sent to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Room 725, Washington, DC 20503; or by e-mail to: *OIRA_submissions@OMB.eop.gov*.

FOR FURTHER INFORMATION CONTACT: James L. Riva, Chief, Audit, Review, and Compliance (ARC) Branch, telephone 202–720–1124, or e-mail *James.Riva@usda.gov*.

SUPPLEMENTARY INFORMATION:

Background and Discussion

The Agricultural Marketing Act of 1946 (AMA), as amended, (7 U.S.C. 1621, *et seq.*), gives AMS the authority to provide services so that agricultural products may be marketed to their best advantage, that trade may be facilitated, and that consumers may be able to ascertain characteristics involved in the production and processing of products and obtain the quality of product they desire. AMA also provides for the collection of fees from users of these services that are reasonable and cover the cost of providing services.

The QSVP were developed in 1995 and have since grown to include several value-added marketing programs. The QSVP have grown steadily over the past few years, with auditors conducting 385 assessments in FY 2001, 562 assessments in FY 2002, and 715 assessments in 2003, and 915 assessments in 2004. Presently, 14 full-time auditors conduct assessments for the LS Program.

QSVP are voluntary, audit-based, user-fee funded programs developed and conducted at the request of industry and others as a cost-effective alternative to conventional product certification. QSVP use International Organization for Standardization's (ISO) Guidelines and standards as a format for evaluating program documentation to ensure consistent assessment practices and promote international recognition of assessment results.

Currently, QSVP user-fees are based on the approved hourly rate established for meat grading and certification services provided by the Meat Grading and Certification (MGC) Branch pursuant to 7 CFR part 54. Following the initial program development period, LS Program management conducted a detailed cost analysis of QSVP services and determined that the existing hourly rate established for meat grading and certification services did not sufficiently cover the cost of providing QSVP services. Due to the complexity of planning, performing and interpreting the results of assessments, auditor positions are classified at the GS–11/12 pay grade, in contrast to the GS–5/7/9 pay grade classifications of most MGC Branch full-time positions.

Upon considering all QSVP operational expenses, the LS Program determined that the actual cost of QSVP services, excluding travel costs, to be $108 per hour. LS Program management considered employee salaries and benefits; Agency and LS Program overhead; total revenue hours available to the ARC Branch; and included other anticipated costs such as, federally mandated pay raises through FY 2005, rent, communications, utilities, contractual services, supplies, and equipment in their analysis.

The LS Program considered alternatives to creating a separate user-fee for QSVP services, but found that none were sufficient. Maintaining the same user-fee for QSVP services currently used for conventional meat grading and certification services would not sufficiently cover the cost of providing QSVP services. Another option was to terminate all QSVP services, which would adversely affect producers, businesses, and consumers who desire QSVP services and those entities with already-established programs.

The QSVP were administered through the LS Program's MGC Branch pursuant to 7 CFR part 54 using the user-fee schedule established for meat grading and certification services. In 2001, the administration of QSVP was moved by the LS Program to the Audit, Review, and Compliance (ARC) Branch. This proposed rule would establish a separate user-fee of $108 per hour for QSVP services under a new part 62. Additionally, this proposed rule would expand the scope of QSVP services to include all agricultural products or services within the responsibility of the LS Program, such as livestock, meat, meat products, seed, feedstuffs, as well as processes involving the production of these products, agricultural product data storage, product traceability and identification. Currently, Part 54 only provides for services dealing with meat and meat products. A new Part 62 would be established for QSVP services.

Executive Order 12866

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect and would not preempt or supersede any State or local laws, regulations, or policies, unless they present an irreconcilable conflict. There are no administrative procedures that must be exhausted prior to any

judicial challenge to the provisions of this rule.

Regulatory Flexibility Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA)(5 U.S.C. 601 *et seq.*), the Agricultural Marketing Service (AMS) has considered the economic effect of this action on small entities and has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

AMS, through the LS Program's ARC Branch, provides voluntary assessment services to approximately 415 businesses, including 152 livestock slaughterers, 72 meat processors, 46 livestock producers feeders, 135 organic certifying companies, 4 trade associations, and 4 State and Federal entities. Seventy-five percent (*i.e.*, 346) of these businesses are classified as small entities and generate approximately 65 percent of the ARC Branch's revenue. The Small Business Administration (SBA) (13 CFR 121.201) defines small agricultural producers as those having annual receipts of less than $750,000; small agricultural service firms as those whose annual receipts are less than $5 million; and small meat packers as those that have less than 500 employees. No entity, small or large, is obligated to use voluntary QSVP services provided under the authority of AMA.

AMS regularly reviews its user-fee-financed programs to determine if the fees are adequate to cover the cost of the services provided. The most recent review determined that the existing hourly rate that the ARC Branch charges for QSVP services would not generate sufficient revenues to recover operating costs for current and near-term periods while maintaining a 4-month operating reserve of $275,000. In FY 2004, the ARC Branch incurred a $330,000 operating loss; and without a fee increase, FY 2004 operating losses are projected to reach $421,000. These combined losses will deplete the ARC Branch's operating reserve and place the ARC Branch in an unstable financial position that will adversely affect its ability to provide QSVP services.

While the ARC Branch has utilized existing automated information management systems for data collection, retrieval, dissemination, applicant billing, and disbursement of employee entitlements, the ARC Branch has continued to lose revenue due to the cost of providing QSVP services utilizing auditors classified at the GS–11/12 pay grade while charging a user-fee that is based on a lower GS–5/7/9 pay grade classification.

The ARC Branch operating costs increased as a result of higher salaries associated with higher grade employees; congressionally mandated salary increases for all Federal Government employees in 2004 and 2005; ongoing information system technology upgrades necessary to remain compatible with customer and Agency systems; inflation of non-salary operating expenses; and office maintenance expenses.

AMS estimates that this proposed action will provide the ARC Branch with an additional $420,000 for FY 2005. Of this $420,000, small businesses would pay an average of $878 more per year per applicant or a total of $273,000 of the total increase. This proposed fee increase coupled with a projected increase in revenue hours would increase total revenues by $420,000 per year and offset FY 2004 operating losses of $330,000. Currently, without a fee increase, the ARC Branch is projected to lose $420,000 in FY 2005. The proposed increase will create a 4-month operating reserve of $275,000, as required by the Agency.

The proposed Part 62 includes sections on definitions; sections related to providing services, including availability and how to apply for services; and suspension, denial, or cancellation of service and other sections relating to fees. These sections are similar to, or the same as, provisions that currently apply to Quality Systems Verification Programs.

Paperwork Reduction Act

This proposed rule contains submission and recordkeeping requirements subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. Chapter 35).

OMB Number: 0581–0124.

Expiration Date: October 31, 2006.

Type of Request: Revision of currently approved collection.

Abstract: The QSVP are voluntary, audit-based programs developed at the request of the livestock industry and other interested parties as a cost-effective alternative to conventional product certification. This proposed rule would permit the LS Program to carry out independent assessments of applicant's programs for any agricultural product or service within the scope of the LS Program. This action is necessary to provide continued, seamless, and efficient distribution of highly differentiated agricultural products and services to customers who require production and marketing process assessments by an authorized government entity. The information collection and recordkeeping requirements in this proposed rule are essential to maintaining these voluntary programs. Only authorized representatives of the USDA, including AMS, LS Program, ARC Branch staff use the collected information in the performance of their official duties.

The AMA, as amended, authorizes the USDA to provide services that facilitate the marketing of agricultural products. Currently, the LS Program provides QSVP services for livestock, meat, and meat products, pursuant to 7 CFR part 54. This proposed rule would define QSVP services to include other agricultural products within the scope of the LS Program in a new part, part 62 to Title 7 of the Code of Federal Regulations.

Applicants may request QSVP services through submission of the currently approved form LS–313 to the ARC Branch. This existing form requires the minimum information necessary to effectively carry out the requirements of the proposed rule including: firm name, address, telephone number, and other information necessary to identify the applicant, and other pertinent information necessary to determine if the firm is eligible to apply and receive QSVP services. Applicants are required to complete the form only when initially applying for QSVP service. There is no annual requirement for resubmission. The form can be supplied without data processing equipment or outside technical expertise. AMS estimates the one-time burden for submission of Form LS–313 to average 0.200 hours (12 minutes) per applicant at $20.00 per hour. The total one-time burden if 50 applicants applied under this proposed rule is estimated to be $200.00.

Applicants may obtain form LS–313 by (1) Contacting James L. Riva, Chief; USDA, AMS, LS, ARC Branch; STOP 0294, Room 2627–S; 1400 Independence Ave., SW., Washington, DC 20250–0294; (2) downloading a printable version at the ARC Branch Web site: *http://www.ams.usda.gov/lsg/arc/audit.htm;* or (3) accessing a Web-based version at the AMS Electronic Forms Web site: *http://151.121.3.189/EManager/new.htm.*

Applicants may submit form LS–313 by (1) mail to: James L. Riva, Chief; USDA, AMS, LS, ARC Branch; STOP 0294, Room 2627–S, 1400 Independence Avenue, SW., Washington, DC 20250–0248; (2) FAX to: (202) 690–1038; or e-mail to: *ARCBranch@usda.gov.*

Under this proposed rule, applicants would be required to submit a cover letter and a complete copy of the applicant's program documentation when a request for service is made. This is a one-time requirement per service request. The PRA also requires the agency to measure the recordkeeping burden. The proposed rule would also require applicants to retain records and documents necessary to support the requested service for the period of at least one calendar year following the year the record was created and long enough to assess conformance of the product though the applicant's quality management system. Additionally, applicants must ensure that such records and documents are readily available and easily accessible. The recordkeeping burden is the amount of time needed to prepare, store, and maintain documents.

Based on its experience with QSVP, AMS understands that applicants develop and maintain complete documentation of their programs as a normal business practice. AMS believes the cost burden associated with submission of complete program documentation to be limited to the time needed for the applicant to review the documentation for completeness and accuracy. AMS estimates this time to average 24 hours per applicant at $20.00 per hour for a total one-time burden per applicant of $480.00. The total one-time burden if 50 applicants applied under this proposed rule is estimated to be $24,000.

Based on its experience, AMS believes that the documents and records required to be retained are normally retained by applicants as part of their normal business practices. However, if record keepers were compensated for their time, AMS estimates that the time required for each applicant to retain these records and documents in a manner required in the proposed rule to average 6 hours per year at $20.00 per hour for a total annual burden of $120.00 per applicant. Assuming that 50 applicants were retained under this proposed rule, the total annual burden is estimated to be $6,000.

(1) Application for Service form LS–313.

Estimate of Burden: The proposal to expand the scope of the QSVP to include all agricultural products and services within the responsibility of the LS Program will increase the approved burden by 1210 hours. Using the currently approved form LS–313, the public reporting burden for this proposed collection of information is estimated to average 0.20 hours (12 minutes) per response.

Respondents: Livestock, meat industry, and other businesses that produce, process, or handle agricultural products or services.

Estimated Number of Respondents: 50.

Estimated Number of Responses per Respondent: 1.

Estimated Total Number of Responses: 50.

Estimated Total Annual Burden on Respondents: 10.00 hours.

Estimated Total Cost: $200.00.

(2) Review and Submission of Program Documentation.

Estimate of Burden: Public reporting burden for this proposed collection of information is estimated to average 24 hours per respondent.

Respondents: Livestock, meat industry, and other businesses that produce, process or handle agricultural products or services.

Estimated Number of Respondents: 50.

Estimated Number of Responses per Respondent: 1.

Estimated Total Number of Responses: 50.

Estimated Total Annual Burden on Respondents: 1200 hours.

Estimated Total Cost: $24,000.

Comments are invited on: (1) Whether the 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 burden estimate of the 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments should reference OMB No. 0581–0124, the QSVP, and be sent to (1) Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Room 725, Washington, DC 20503; or by e-mail to: *OIRA_submissions@OMB.eop.gov* and (2) James L. Riva, Chief; USDA, AMS, LS, ARC Branch; STOP 0294, Room 2627–S, 1400 Independence Avenue, SW., Washington, DC 20250–0248; or FAX (202) 690–1038; or e-mail *ARCBranch@usda.gov.* A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

All comments will be posted on the Internet at *http://www.ams.usda.gov/lsg/rulemaking.htm* and will be made available for public inspection in the above offices during regular business hours.

A 30-day comment period is provided for interested persons to comment on this proposed rule. This comment period is deemed appropriate in order to implement this rule, if adopted, as soon as possible so that program costs are covered by revenue.

All responses to this proposed rule will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

List of Subjects

7 CFR Part 54

Meats, Prepared meats, and Meat products.

7 CFR Part 62

Food grades and standards, Food labeling, Meat and meat products.

For the reasons set forth in the preamble, it is proposed that chapter 1 of title 7 of the Code of Federal Regulations be revised by amending part 54 and adding part 62 to read as follows:

PART 54—[AMENDED]

1. The authority citation for part 54 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

§ 54.4 [Amended]

2. In § 54.4, paragraph (5) is removed.

3. Part 62 is added to read as follows:

PART 62—LIVESTOCK, MEAT, AND OTHER AGRICULTURAL COMMODITIES (QUALITY SYSTEMS VERIFICATION PROGRAMS)

Subpart A—Quality Systems Verification Programs

Definitions

Sec.
62.000 Meaning of terms.

Administration

62.100 Administrator.

Service

62.200 Services.
62.201 Availability of service.
62.202 How to apply for service.
62.203 How to withdraw service.
62.204 Authority to request service.
62.205 Conflict of interest.
62.206 Access to program documents and activities.
62.207 Official assessment.
62.208 Publication of QSVP assessment status.
62.209 Reassessment.

62.210 Denial, suspension, or cancellation of service.
62.211 Appeals.
62.212 Official assessment reports.
62.213 Official identification.

Charges for Service

62.300 Fees and other costs for service.
62.301 Payment of fees and other charges.

Miscellaneous

OMB Control Number

62.400 OMB control number assigned pursuant to the Paperwork Reduction Act.

Subpart B—[Reserved]

Authority: 7 U.S.C. Sec. 1621–1627.

Subpart A—Quality Systems Verification Programs

Definitions

§ 62.000 Meaning of terms.

Words used in this Subpart in the singular form shall be deemed to impart the plural, and vice versa, as the case may demand. For the purposes of such regulations, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

Administrator. The Administrator of the Agricultural Marketing Service (AMS), or any officer or employee of AMS to whom authority has heretofore been delegated or to whom authority may hereafter be delegated, to act in the Administrator's stead.

Agricultural Marketing Service. The Agricultural Marketing Service of the U.S. Department of Agriculture.

Applicant. Any individual or business with financial interest in QSVP services who has applied for service under this Part.

Assessment. A systematic review of the adequacy of program or system documentation, or the review of the completeness of implementation of a documented program or system.

Auditor. Person authorized by the Livestock and Seed Program to conduct official assessments.

Branch. The Audit, Review, and Compliance Branch of the Livestock and Seed Program.

Chief. The Chief of the ARC Branch, or any officer or employee of the Branch to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in the Chief's stead.

Conformance. A user's quality manual and supporting documentation.

Deputy Administrator. The Deputy Administrator of the Livestock and Seed Program, or any officer or employee of the Livestock and Seed Program to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in the Deputy Administrator's stead.

Financially interested person. Any individual, partnership, corporation, other legal entity, or Government agency having a financial interest in the involved product or service.

Livestock. Bovine, ovine, porcine, caprine, bison or class of Osteichthyes.

Official mark. Official mark or other official identification means any form of mark or other identification, used under the regulations to show the conformance of products with applicable program requirements, or to maintain the identity of products for which service is provided under the regulations.

Official memoranda or assessment reports. Official memorandum means any assessment report of initial or final record of findings made by an authorized person of services performed pursuant to the regulations.

Products. Includes all agricultural commodities and services within the scope of the Livestock and Seed Program This includes livestock, meat, meat products, seed, feedstuffs, as well as processes involving the production of these products, agricultural product data storage, product traceability and identification.

QSVP Procedures. Audit rules and guidelines set forth by the Agricultural Marketing Service regarding the development, documentation, and implementation of QSVP.

Quality Manual. A collection of documents that describe the applicant's quality management system, as it applies to the requested service.

Quality Systems Verification Programs (QSVP). A collection of voluntary, audit-based, user-fee programs that allow applicants to have program documentation and program processes assessed by AMS auditor(s) and other USDA officials under this Part.

Regulations. The regulations in this Part.

USDA. The U.S. Department of Agriculture.

Administration

§ 62.100 Administrator.

The LS Program Deputy Administrator is charged with the administration of official assessments conducted according to the regulations in this Part and approved LS Program QSVP procedures.

Service

§ 62.200 Services.

QSVP, under this regulation, provide applicants, the ability to have USDA assess documented processes or systems.

(a) Assessment services provided under the regulations shall consist of:

(1) A review of the adequacy of an applicant's quality manual against LS Program QSVP procedures, internationally recognized guidelines, or other requirements as approved by the LS Program;

(2) An onsite assessment of the applicant's program to ensure implementation of provisions within the quality manual and the applicant's conformance with applicable program requirements and LS Program QSVP procedures; and

(3) A reassessment of the applicant's program to ensure continued implementation of provisions within the quality manual and the applicant's conformance with program requirements and applicable LS Program QSVP procedures;

(b) Developmental assistance in the form of training to explain LS Program QSVP procedures is available upon request.

§ 62.201 Availability of service.

QSVP services under these regulations are available to international and domestic government agencies, private agricultural businesses and any finically interested person.

§ 62.202 How to apply for service.

Applicants may apply for QSVP services by submitting the following information to the ARC Branch headquarters office at USDA, AMS, LSP, ARC Branch, 1400 Independence Avenue, SW., STOP 0294, Room 2627–S, Washington, DC, 20250–0294; by fax to: (202) 690–1038, or e-mail to: *ARCBranch@usda.gov.*

(a) The original completed form LS–313, Application for Service;

(b) A letter requesting QSVP services; and

(c) A complete copy of the applicant's program documentation, as described in the LS Program QSVP procedures.

§ 62.203 How to withdraw service.

Service may be withdrawn by the applicant at any time; provided that, the applicant notifies the ARC Branch in writing of his/her desire to withdraw the application for service and pays any expenses the Department has incurred in connection with such application.

§ 62.204 Authority to request service.

Any person requesting service may be required to prove his/her financial interest in the product or service at the discretion of the Deputy Administrator.

§ 62.205 Conflict of interest.

No USDA official shall review any program documentation or determine conformance of any documented process or system in which the USDA official has financial holdings.

§ 62.206 Access to program documents and activities.

(a) The applicant shall make its products and program documentation available and easily accessible for assessment, with respect to the requested service. Auditors and other USDA officials responsible for maintaining uniformity and accuracy of service under the regulations shall have access to all parts of facilities covered by approved applications for service under the regulations, during normal business hours or during periods of production, for the purpose of evaluating products or processes. This includes products in facilities which have been or are to be examined for program conformance or which bear any official marks of conformance. This further includes any facilities or operation that is part of an approved program.

(b) Documentation and records relating to an applicant's program must be retained for at least one calendar year following the calendar year during which the record was created.

§ 62.207 Official assessment.

Official assessment of an applicant's program shall include:

(a) *Documentation assessment.* Auditors and other USDA officials shall review the applicant's program documentation and issue finding of the review to the applicant.

(b) *Program assessment.* Auditors and USDA officials shall conduct an onsite assessment of the applicant's program to ensure provisions of the applicant's program documentation have been implemented and conform to LS Program QSVP procedures.

(c) *Program Determination.* Applicant's determined to meet or not meet LS Program QSVP procedures or the applicant's program requirements shall be notified of their program's approval or disapproval.

(d) *Corrective and/or preventative actions.* Applicants may be required to implement corrective and/or preventative actions upon completion of assessment. After implementation of corrective and/or preventative actions, the applicant may request another assessment.

§ 62.208 Publication of QSVP assessment status.

Approved programs shall be posted for public reference on the ARC Branch Web site: *http://www.ams.usda.gov/lsg/arc/audit.htm.* Such postings shall include:

(a) Program name and contact information,

(b) Products or services covered under the scope of approval,

(c) Effective dates of approval, and

(d) Control numbers of official assessments, as appropriate, and

(e) Any other information deemed necessary by the Branch Chief.

§ 62.209 Reassessment.

Approved programs are subject to periodic reassessments to ensure ongoing conformance with the LS Program QSVP procedures covered under the scope of approval. The frequency of reassessments shall be based on the LS Program QSVP procedures, or as determined by the Deputy Administrator.

§ 62.210 Denial, suspension, or cancellation of service.

(a) QSVP services may be denied if an applicant fails to meet its program requirements, or conform to LS Program QSVP procedures, such as:

(1) Adequately address any program requirement resulting in a major non-conformance or an accumulation of minor non-conformances that result in the assignment of a major non-conformance for the program.

(2) Demonstrate capability to meet any program requirement resulting in a major non-conformance.

(3) Present truthful and accurate information to any auditor or other USDA official; or

(4) Allow access to facilities and records within the scope of the program.

(b) QSVP services may be suspended if the applicant fails to meet its program requirements, or conform to LS Program QSVP procedures; such as failure to:

(1) Adequately address any program requirement resulting in a major non-conformance;

(2) Demonstrate capability to meet any program requirement resulting in a major non-conformance;

(3) Follow and maintain it's approved program or QSVP procedures;

(4) Provide corrective actions and correction as applicable in the timeframe specified;

(5) Submit significant changes to and seek approval from the Chief prior to implementation of significant changes to an approved program;

(6) Allow access to facilities and records within the scope of the approved program;

(7) Accurately represent the eligibility of agricultural products or services distributed under an approved program;

(8) Remit payment for QSVP services;

(9) Abstain from any fraudulent or deceptive practice in connection with any application or request for service under the rule; or

(10) Allow any auditor or other USDA official to perform their duties under the regulations of this Part.

(c) QSVP services maybe be cancelled, an application may be rejected, or program assessment may be terminated if the Deputy Administrator or his designee determines that a nonconformance has remained uncorrected beyond a reasonable amount of time.

§ 62.211 Appeals.

Appeals of adverse decisions under this Part, may be made in writing to the Livestock and Seed Program Deputy Administrator at STOP 0249, Room 2092—South, 1400 Independence Avenue, SW., Washington, DC 20250–0249. Appeals must be made within 30 days of receipt of adverse decision.

(a) *Procedure for Appeals.* Actions under this subparagraph concerning decision of appeals of the Deputy Administrator shall be conducted in accordance with the Rule of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes set forth at 7 CFR 1.130 through 1.151 and the Supplemental Rules of Practice in 7 CFR Part 50.

(b) [Reserved]

§ 62.212 Official assessment reports.

Official QSVP assessment reports shall be generated by the auditor at the conclusion of each assessment and a copy shall be provided to the applicant.

§ 62.213 Official identification.

The following, as shown in figure 1, constitutes official identification to show product or services produced under an approved USDA, Process Verified Program (PVP):

Figure 1

(a) Products or services produced under an approved USDA, PVP may use the ''USDA Process Verified'' statement and the ''USDA Process Verified'' shield, so long as, both the statement

and shield are used in direct association with a clear description of the process verified points that have been approved by the Branch.

(b) Use of the ''USDA Process Verified'' statement and the ''USDA Process Verified'' shield shall be approved in writing by Chief prior to use by an applicant.

Charges for Service

§ 62.300 Fees and other costs for service.

Fees and other charges will be levied based on the following provisions:

(a) *Fees for service.* Fees for QSVP services shall be based on the time required to provide service calculated to the nearest quarter hour period, including, but not limited to, official assessment time, travel time, and time required to prepare assessment reports. The hourly fee rate shall be $108 per hour.

(b) *Transportation costs.* Applicants are responsible for paying actual travel costs incurred to provide QSVP services including but not limited to: mileage charges for use of privately owned vehicles, rental vehicles and gas, parking, tolls, and public transportation costs such as airfare, train, and taxi service.

(c) *Per diem costs.* The applicant is responsible for paying per diem costs incurred to provide QSVP services away from the auditor's or USDA officials' official duty station(s). Per diem costs shall be calculated in accordance with existing travel regulations (41 CFR, subtitle F—Federal Travel Regulation System, chapter 301).

(d) *Other costs.* When costs, other than those costs specified in paragraphs (a), (b), and (c) of this section, are involved in providing the QSVP services, the applicant shall be responsible for these costs. The amount of these costs shall be determined administratively by the Chief. However, the applicant will be notified of these costs before the service is rendered.

§ 62.301 Payment of fees and other charges.

Fees and other charges for QSVP services shall be paid in accordance with the following provisions. Upon receipt of billing for fees and other charges, the applicant shall remit payment within 10 business days by check, electronic funds transfer, draft, or money order made payable to USDA, AMS, in accordance with directions on the billing. Fees and charges shall be paid in advance if required by the auditor or other authorized USDA official.

Miscellaneous

OMB Control Number

§ 62.400 OMB control number assigned pursuant to the Paperwork Reduction Act.

The information collection and recordkeeping requirements of this Part have been approved by OMB under 44 U.S.C. Chapter 35 and have been assigned OMB Control Number 0581–0124.

Subpart B—[Reserved]

Dated: April 4, 2005.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 05–6957 Filed 4–6–05; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Utilities Service

7 CFR Part 4279

RIN 0570–AA54

Business and Industry Guaranteed Loan Program

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Business-Cooperative Service (RBS) proposes to amend its regulation for the Business and Industry (B&I) Guaranteed Loans by modifying the regulations regarding personal and corporate guarantors. This action will standardize the guarantor process. The Agency will create a guarantor form which will be used to obtain the personal or corporate guarantee of anyone owning greater than 20 percent interest in the borrower. The effect of this rule is to allow the Agency to use all remedies available to pursue collection from guarantors, including offset under the Debt Collection Improvement Act.

DATES: Written or e-mail comments must be received on or before June 6, 2005, to be assured of consideration.

ADDRESSES: You may submit comments to this rule by any of the following methods:

- Agency Web site: *http://rdinit.usda.gov/regs/.* Follow instructions for submitting comments on the Web site.
- E-Mail: *comments@usda.gov.* Include RIN No. 0570–AA54 in the subject line of the message.
- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Mail: Submit written comments via the U.S. Postal Service to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, STOP 0742, 1400 Independence Avenue, SW., Washington, DC 20205–0742.
- Hand Delivery/Courier: Submit written comments via Federal Express Mail or other courier service requiring a street address to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, 300 7th Street, SW., 7th Floor, Washington, DC 20024.

All written comments will be available for public inspection during regular work hours at 300 7th Street, SW., 7th Floor, address listed above.

FOR FURTHER INFORMATION CONTACT: David Lewis, Business and Industry Loan Servicing Branch, Rural Business-Cooperative Service, U.S. Department of Agriculture, STOP 3224, 1400 Independence Avenue, SW., Washington, DC 20250–3224, telephone (202) 690–0797, or by e-mail to *david.lewis@usda.gov.*

SUPPLEMENTARY INFORMATION:

Classification

This proposed rule has been reviewed under Executive Order 12866 and determined not to be significant and has not been reviewed by the Office of Management and Budget (OMB).

Programs Affected

The Catalog of Federal Domestic Assistance number for the program impacted by this action is 10.768, Business and Industry Loans.

Intergovernmental Review

Business and Industry Guaranteed Loans are subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. RBS will conduct intergovernmental consultation in the manner delineated in and 7 CFR part 3015, subpart V, ''Intergovernmental Review of Rural Development Programs and Activities.''

Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. In accordance with this rule, (1) all State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given this rule; and (3) administrative proceedings of the National Appeals Division (7 CFR

part 11) must be exhausted before bringing suit in court challenging action taken under this rule.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, ''Environmental Program.'' RBS has determined that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321 *et seq,* this regulation is a Categorical Exclusion. Loan applications will be reviewed individually to determine compliance with NEPA.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act 1995 (UMRA) of, Pub. L. 104–4 of 1995, 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, RBS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector of $100 million or more in any 1 year. When such a statement is needed for a rule, section 205 of UMRA generally requires RBS 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) 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.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act, RBS has determined that this action would not have a significant economic impact on a substantial number of small entities, because the action will not affect a significant number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). RBS made this determination based on the fact that this regulation only impacts those who choose to participate in the program. Small entity applicants will not be impacted to a greater extent than large entity applicants.

Executive Order 13132

It has been determined that, under Executive Order 13132, Federalism, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. The provisions contained in this rule will not have a substantial direct effect on States or their political subdivisions or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, imposes requirements on USDA in the development of regulatory policies that have tribal implications or preempt tribal laws. USDA has determined that the proposed regulation does not have a substantial direct effect on one or more Indian tribe or on either the relationship or the distribution of powers and responsibilities between the Federal Government and the Indian tribes. Thus, the proposed rule is not subject to the requirements of Executive Order 13175.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the Agency will seek OMB approval of the reporting requirements contained in this regulation. These reporting and recordkeeping requirements have been previously approved under OMB control number 0570–0017. The estimate of burden is as follows:

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 30 minutes per response.

Respondents: Lenders and business owners.

Estimated Number of Respondents: 142 (based on 1 year).

Estimated Number of Responses per Respondent: 1.

Estimated Number of Responses: 142.

Estimated Total Annual Burden of Respondents: 71 hours.

Copies of this information collection can be obtained from Cheryl Thompson, Regulations and Paperwork Management Branch, Support Services Division at (202) 692–0043.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of RBS, including whether the information will have practical utility; (b) the accuracy of RBS's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (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 the 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. Comments may be sent to Cheryl Thompson, Regulations and Paperwork Management Branch, Support Services Division, U.S. Department of Agriculture, Rural Development, STOP 0742, 1400 Independence Ave., SW., Washington DC 20550. All responses to the notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Discussion

Pursuant to the Debt Collection Improvement Act of 1996 (DCIA), the Agency is required to send debt owed to the Government to the Department of the Treasury (Treasury) for collection. The DCIA covers both guaranteed and direct loans made by the Agency. Some ambiguity has existed regarding the Agency's ability to collect from guarantors of the borrower's loan. This rule will end that ambiguity by clearly making guarantors personally liable for any claims paid by the Government.

The Agency proposes to establish more uniformity in the guarantees being obtained by lenders. This should result in the program being administered more consistently and the Government recovering more of its loss claims. Currently, guaranteed lenders prepare non-uniform, personal, or corporate guarantees. When there is a loss on the guaranteed loan, the lender pursues these guarantees with mixed recovery results. By implementing this rule, the Agency will treat all guarantors consistently, collect more money on its loss claims, and rectify any ambiguities regarding its ability to refer these debts to Treasury.

List of Subjects in 7 CFR Part 4279

Loan programs—business and industry—rural development assistance, Rural areas.

Therefore, chapter XLII, title 7, Code of Federal Regulations, is amended as follows:

PART 4279—GUARANTEED LOANMAKING

1. The authority citation for part 4279 continues to read as follows:

Authority: 7 U.S.C 1989.

Subpart B—Business and Industry Loans

2. Section 4279.149 is revised to read as follows:

§ 4279.149 Personal and Corporate Guarantee.

(a) Unconditional personal and corporate guarantees are part of the collateral for the loan but are not considered in determining whether a loan is adequately secured for loanmaking purposes. Agency approved personal and corporate guarantees for the full term of the loan and at least equal to the guarantor's percent interest in the borrower, times the loan amount are required from those owning greater than a 20 percent interest in the borrower, unless the lender documents to the Agency's satisfaction that collateral, equity, cashflow, and profitability indicate an above-average ability to repay the loan. The guarantors will execute Form RD 4279–14, ''Unconditional Guarantee.'' A signature section must be created and in accordance with applicable law. The signature block must include the legal name of the individual or entity signing the Guarantee and, where applicable, the name and title of the authorized representative who will execute the document on its behalf. For instructions on how to complete an enforceable signature block that complies with applicable state law, consult with the Regional Attorney. When warranted by an Agency assessment of potential financial risk, Agency approved guarantees may also be required of parent, subsidiaries, or affiliated companies (owning less than a 20 percent interest in the borrower) and require security for any guarantee provided under this section.

(b) Exceptions to the requirement for personal guarantees must be requested by the lender and concurred by the Agency approval official on a case-by-case basis. The lender must document that collateral, equity, cashflow, and profitability indicate an above-average ability to repay the loan.

Dated: March 24, 2005.

Peter J. Thomas,

Administrator, Rural Business—Cooperative Service.

[FR Doc. 05–6869 Filed 4–6–05; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20882; Directorate Identifier 2004–NM–241–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, MD–10–30F, MD–11, and MD–11F Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain McDonnell Douglas airplanes identified above. This proposed AD would require repetitive functional tests for noisy or improper operation of the exterior emergency control handle assemblies of the mid, overwing, and aft passenger doors, and corrective actions if necessary. This proposed AD also would provide for optional terminating action for the repetitive tests. This proposed AD is prompted by a report that the exterior emergency control mechanism handles were inoperative on a McDonnell Douglas MD–11 airplane. We are proposing this AD to prevent failure of the passenger doors to operate properly in an emergency condition, which could delay an emergency evacuation and possibly result in injury to passengers and flightcrew.

DATES: We must receive comments on this proposed AD by May 23, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024).

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20882; the directorate identifier for this docket is 2004–NM–241–AD.

FOR FURTHER INFORMATION CONTACT: Ken Sujishi, Aerospace Engineer; Cabin Safety, Mechanical, and Environmental Branch; ANM–150L; FAA; Los Angeles Aircraft Certification Office; 3960 Paramount Boulevard; Lakewood, California 90712–4137; telephone (562) 627–5353; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20882; Directorate Identifier 2004–NM–241–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except

Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received a report indicating that an operator found, during a heavy maintenance visit, that the emergency control mechanism handles of the mid, overwing, and aft passenger doors were inoperative on a McDonnell Douglas MD–11 airplane. Investigation revealed that the six steel bearings in each control mechanism were corroded and had seized. This condition, if not corrected, could lead to failure of the passenger doors to operate properly in an emergency condition, which could delay an emergency evacuation and possibly result in injury to passengers and flightcrew.

Similar Models

The subject area on certain McDonnell Douglas Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, MD–10–30F, and MD–11F airplanes is almost identical to that on the affected Model MD–11 airplanes. Therefore, all of these models may be subject to the same unsafe condition.

Other Related Rulemaking

Operators should note that a notice of proposed rulemaking (NPRM), docket identifier 2001–NM–359–AD, applicable to certain McDonnell Douglas Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, MD–10–30F, MD–11 and MD–11F airplanes, was published in the **Federal Register** on November 12, 2003 (68 FR 64006). That NPRM proposed to require repetitive operation of the exterior emergency door handle of the forward passenger door to determine if binding exists in the exterior emergency control handle mechanism, and corrective actions if necessary.

Relevant Service Information

We have reviewed McDonnell Douglas Service Bulletin MD11–52–044 and Service Bulletin DC10–52–219; both Revision 1; both dated September 3, 2004. The service bulletins describe procedures for, among other things, repetitive functional tests for noisy or improper operation of the exterior emergency control handle assemblies of the mid, overwing, and aft passenger doors, and corrective actions if necessary. Corrective actions include replacing the steel bearings with bearings made from corrosion-resistant material. The service bulletins also indicate that replacing the steel bearings as described provides optional terminating action for the repetitive tests. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously.

Operators should note that this proposed AD allows operators to continue the repetitive functional tests instead of doing the terminating action. In making this determination, the FAA considers that, in the case of this AD, long-term continued operational safety is adequately assured by doing the repetitive functional tests to detect binding before it represents a hazard to the airplane, and by doing corrective actions within the specified time limits.

Clarification of Service Information

The service information also describes procedures for installing lube fittings in the emergency control handle assemblies to minimize the possibility that binding of the exterior door free fall handle mechanisms would prevent the passenger doors from free falling to the closed position. Installing the lube fittings does not help to correct the unsafe condition specified by this proposed AD and would therefore not be required by this proposed AD.

The service information is applicable to all mid, overwing, and aft passenger doors. However, some of these doors may have been fastened shut to render them inoperable according to some approved freighter configurations. Such doors would not be subject to the requirements of this proposed AD.

Costs of Compliance

There are about 633 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 218 airplanes of U.S. registry. The following table provides the estimated costs, at an average labor rate of $65 per work hour, for U.S. operators to comply with this proposed AD.

TEST AND MODIFICATION COSTS

Action	Work hours	Parts cost	Cost per airplane	Fleet cost
Functional test	1	N/A	$65 per test cycle	$14,170
Replace bearings	6	$825	1,215 per door, if required	N/A

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify that the 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. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

McDonnell Douglas: Docket No. FAA–2005–20882; Directorate Identifier 2004–NM–241–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by May 23, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the airplanes identified in Table 1 of this AD; certificated in any category.

TABLE 1.—APPLICABILITY

Airplane model	Applicable service bulletin
DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F airplanes (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, MD–10–30F airplanes.	McDonnell Douglas Service Bulletin DC10–52–219, Revision 1, dated September 3, 2004.
MD–11 and MD–11F airplanes	McDonnell Douglas Service Bulletin MD11–52–044, Revision 1, dated September 3, 2004.

Unsafe Condition

(d) This AD was prompted by a report indicating that the exterior emergency control mechanism handles of the mid, overwing and aft passenger doors were inoperative. We are issuing this AD to prevent failure of the passenger doors to operate properly in an emergency condition, which could delay an emergency evacuation and possibly result in injury to passengers and flightcrew.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Service Bulletin Reference

(f) The term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of McDonnell Douglas Service Bulletin MD11–52–044, Revision 1, and Service Bulletin DC10–52–219, Revision 1; both dated September 3, 2004; as applicable.

Functional Test

(g) Within 6,000 flight hours or 18 months after the effective date of this AD, whichever occurs later, perform a functional test of the exterior emergency control handle assemblies of the mid, overwing, and aft passenger doors; by doing all actions specified in the applicable service bulletin, except as provided by paragraph (i) of this AD.

(1) If the functional test reveals no noisy operation or binding: Repeat the functional test at intervals not to exceed 6,000 flight hours or 18 months, whichever occurs later, until the terminating action of paragraph (h) of this AD has been accomplished.

(2) If any functional test required by this AD reveals noisy operation or binding: Prior to further flight, replace the steel bearings with bearings made from corrosion-resistant material in accordance with the applicable service bulletin.

Optional Terminating Action

(h) Accomplishment of the actions required by paragraph (g)(2) of this AD constitutes terminating action for the repetitive tests required by paragraph (g)(1) of this AD only for the modified doors.

Inoperable Doors

(i) Any mid, overwing, or aft passenger door that has been fastened shut and rendered inoperable according to some approved airplane freighter configuration is not subject to the requirements of this AD.

Alternative Methods of Compliance (AMOCs)

(j) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on March 31, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6910 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19563; Directorate Identifier 2003–NM–10–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–600–2B16 (CL–604) Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Proposed rule; withdrawal.

SUMMARY: The FAA withdraws a notice of proposed rulemaking (NPRM) that proposed a new airworthiness directive (AD) for certain Bombardier Model CL–600–2B16 (CL–604) series airplanes. The proposed AD would have required replacing the side-brace fitting shafts of the main landing gear (MLG) with new, improved side-brace fitting shafts; inspecting for corrosion of the MLG side-brace fitting shafts; and replacing the nut, washer, and cotter pin of the MLG side-brace fitting shafts with new parts; as applicable. Since the proposed AD was issued, we have received new data that the actions that would have been required by the proposed AD have already been accomplished on all of the affected airplanes. Accordingly, the proposed AD is withdrawn.

ADDRESSES: You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19563; the directorate identifier for this docket is 2003–NM–10–AD.

FOR FURTHER INFORMATION CONTACT: Serge Napoleon, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, suite 410, Westbury, New York 11590; telephone (516) 228–7312; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

We proposed to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) with a notice of proposed rulemaking (NPRM) for a new AD for certain Bombardier Model CL–600–2B16 (CL–604) series airplanes. That NPRM was published in the **Federal Register** on November 9, 2004 (69 FR 64869). The NPRM would have required replacing the side-brace fitting shafts of the main landing gear (MLG) with new, improved side-brace fitting shafts; inspecting for corrosion of the MLG side-brace fitting shafts; and replacing the nut, washer, and cotter pin of the MLG side-brace fitting shafts with new parts; as applicable. The NPRM was prompted by the discovery of fractures of the MLG side-brace fitting shafts caused by corrosion on the forward side of the side-brace fitting shafts. The proposed actions were intended to prevent fracture of the MLG side-brace fitting shafts, which could result in collapse of the MLG.

Actions Since NPRM Was Issued

Since we issued the NPRM, the airplane manufacturer has informed us that all airplanes identified in the applicability section of the NPRM have already accomplished the actions specified in Bombardier Alert Service Bulletin A604–32–018, Revision 01, dated February 22, 2002, which would have been required by the proposed AD. Transport Canada Civil Aviation (TCCA), which is the airworthiness authority for Canada, has also confirmed that the proposed requirements have already been accomplished on all affected airplanes.

FAA's Conclusions

Upon further consideration, we have determined that it is unnecessary to issue the proposed AD. Accordingly, the NPRM is withdrawn.

Withdrawal of the NPRM does not preclude the FAA from issuing another related action or commit the FAA to any course of action in the future.

Regulatory Impact

Since this action only withdraws an NPRM, it is neither a proposed nor a final rule and therefore is not covered under Executive Order 12866, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Withdrawal

Accordingly, we withdraw the NPRM, Docket No. FAA–2004–19563, Directorate Identifier 2003–NM–10–AD, which was published in the **Federal Register** on November 9, 2004 (69 FR 64869).

Issued in Renton, Washington, on March 31, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6916 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20863; Directorate Identifier 2004–SW–36–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model AS350B, BA, B1, B2, B3, D, and AS355E Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes adopting a new airworthiness directive (AD) for the specified Eurocopter France (ECF) model helicopters. This proposal would require replacing the hydraulic fluid at a specified time interval when operating in cold weather. This proposal is prompted by reports of ice forming due to condensation in some parts of the hydraulic system during cold weather operation. The actions specified by this proposed AD are intended to prevent ice from forming in the hydraulic system resulting in an unintended movement of the flight controls and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before June 6, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD:

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically;
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically;
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590;
- Fax: 202–493–2251; or
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this proposed AD from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527.

You may examine the comments to this proposed AD in the AD docket on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Ed Cuevas, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Safety Management Group, Fort Worth, Texas 76193–0111, telephone (817) 222–5355, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any written data, views, or arguments regarding this proposed AD. Send your comments to the address listed under the caption **ADDRESSES.** Include the docket number ''FAA–2005–20863, Directorate Identifier 2004–SW–36–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed rulemaking. Using the search function of our docket Web site, you can find and read the comments to any of our

dockets, including the name of the individual who sent or signed the comment. You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://dms.dot.gov.*

Examining the Docket

You may examine the docket that contains the proposed AD, any comments, and other information in person at the Docket Management System (DMS) Docket Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5227) is located at the plaza level of the Department of Transportation NASSIF Building in Room PL–401 at 400 Seventh Street, S.W., Washington, DC. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

The Direction Generale de l'Aviation Civile (DGAC), the airworthiness authority for France, notified the FAA that an unsafe condition may exist on the specified ECF Model AS350 and AS355 helicopters. The DGAC advises of the formation of ice in some parts of the hydraulic system during flights in cold weather and when the hydraulic fluid is highly contaminated by water.

ECF has issued Alert Service Bulletin Nos. 05.00.43 and 05.00.45, both dated April 8, 2004, which specify provisions for replacing hydraulic fluid in cold weather. The DGAC classified these service bulletins as mandatory and issued AD Nos. F–2004–055 and F–2004–056, both dated April 28, 2004, to ensure the continued airworthiness of these helicopters in France.

These helicopter models are manufactured in France and are type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral agreement, the DGAC has kept us informed of the situation described above. We have examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of these type designs that are certificated for operation in the United States.

The previously described unsafe condition is likely to exist or develop on other helicopters of the same type designs registered in the United States. Therefore, the proposed AD would require, if the outside air temperature in an FAA weather briefing is forecast to be below negative 15 degrees Celsius (5 degrees Fahrenheit) at or below your planned flight altitude and the hydraulic fluid has not been replaced within the past 100 hours time-in-service or within the past 30 days, whichever occurred first, before further flight, replace the hydraulic fluid. The actions would be required to be accomplished following the service bulletins described previously.

We estimate that this proposed AD would affect 556 helicopters of U.S. registry, and the proposed actions would take about:

- 2 work hours to replace the hydraulic fluid per helicopter at an average labor rate of $65 per work hour; and
- $6 for hydraulic fluid each time it is changed.

Based on these figures, we estimate the total cost impact of the proposed AD to be $75,616, assuming two fluid replacements per year for 50 percent of the helicopter fleet.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. Additionally, this proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify that the 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. 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.

We prepared a draft economic evaluation of the estimated costs to comply with this proposed AD. See the DMS to examine the draft economic evaluation.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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 a new airworthiness directive to read as follows:

Eurocopter France: Docket No. FAA–2005–20863; Directorate Identifier 2004–SW–36–AD.

Applicability: Model AS350B, BA, B1, B2, B3, D and AS355E helicopters, certificated in any category.

Compliance: Required as indicated.

To prevent ice from forming in the hydraulic system resulting in an unintended movement of the flight controls and subsequent loss of control of the helicopter, do the following:

(a) If the outside air temperature in an FAA weather briefing is forecast to be below negative 15 degrees Celsius (5 degrees Fahrenheit) at or below your planned flight altitude and the hydraulic fluid has not been replaced within the past 100 hours time-in-service or within the past 30 days, whichever occurred first, before further flight, replace the hydraulic fluid. Replace the hydraulic fluid by following the Accomplishment Instructions, paragraphs 2.A. and 2.B., of Eurocopter Alert Service Bulletin Nos. 05.00.43 or 05.00.45, both dated April 8, 2004, as applicable.

(b) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Safety Management Group, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

(c) Special flight permits will not be issued.

Note: The subject of this AD is addressed in Direction Generale de l'Aviation Civile (France) AD Nos. F–2004–055 and F–2004–056, both dated April 28, 2004.

Issued in Fort Worth, Texas, on March 31, 2005.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 05–6917 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 410

Deceptive Advertising as to Sizes of Viewable Pictures Shown by Television Receiving Sets

AGENCY: Federal Trade Commission.

ACTION: Request for public comments.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') requests public comment on the overall costs, benefits, and regulatory and economic impact of its Rule concerning Deceptive Advertising as to Sizes of Viewable Pictures Shown by Television Receiving Sets (''Rule'' or ''Picture Tube Rule''), as part of the Commission's systematic review of all current Commission regulations and guides.

DATES: Written comments will be accepted until Monday, June 6, 2005.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''Picture Tube Rule Regulatory Review, Matter No. P924214'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H–159 (Annex B), 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments containing confidential material must be filed in paper form and the first page of the document must be clearly labeled ''Confidential.'' The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments filed in electronic form should be submitted by clicking on the following: *https://secure.commentworks.com/ftc-picture* and following the instructions on the Web-based form. To ensure that the Commission considers an electronic comment, you must file it on the Web-based form at *https://secure.commentworks.com/ftc-picture.*

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC Web site, to the extent practicable, at *http://www.ftc.gov.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

FOR FURTHER INFORMATION CONTACT: Neil Blickman, (202) 326–3038, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission's Picture Tube Rule, like the other trade regulation rules issued by the Commission, ''define[s] with specificity acts or practices which are unfair or deceptive acts or practices in or affecting commerce. Such rules may include requirements prescribed for the purpose of preventing such acts or practices. A violation of a rule shall constitute an unfair or deceptive act or practice in violation of section 5(a)(1) of the [Federal Trade Commission] Act, unless the Commission otherwise expressly provides in its rule.'' 16 CFR 1.8.

The Picture Tube Rule, promulgated in 1966, sets forth the appropriate means for disclosing the method by which the dimensions of television screens are measured, when this measurement is included in any advertisement or promotional material for the television set. The purpose of the Rule is to establish uniformity in measuring television screens, and advise consumers of this method, thereby aiding comparison shopping for televisions. Under the Rule, any representation of the screen size must be based on the horizontal dimension of the actual, viewable picture area. Using any other measurement is unfair and deceptive, unless the method of measurement is clearly and conspicuously disclosed in close proximity to the size designation. The Rule notes that the horizontal measurement must not take into account any curvature of the tube. Further, disclosing the method of measurement in a footnote rather than in the body of the advertisement does not constitute a disclosure in close proximity to the measurement. The Rule includes examples of both proper and improper representations of size descriptions.

In 1994, the Rule was amended to clarify some of the Rule's compliance illustrations, provide metric equivalents for the measurements stated in inches in the Rule's examples, and add a new Note 3 to the Rule to explain that the inclusion of metric figures is for information purposes only and does not impose a requirement on the industry to use metric measurements. 59 FR 54809 (Nov. 2, 1994).

Since the Rule was last subject to regulatory review and amended in 1994, broadcasting and television technology have advanced significantly, and an array of new types of televisions are available in the marketplace for consumers. The technological change with the closest nexus to the Rule is the introduction of digital television, including high definition television, and the advent of new wider screen televisions to display these enhanced digital pictures. New television display technologies available today include thin, flat panel televisions with either liquid crystal displays or plasma display panels. In addition, there have been advances in the quality and popularity of front and rear, big screen, projection televisions. Accordingly, the Commission seeks comment on the effect, if any, that advances in television technology have had on the Rule.

II. Regulatory Review Program

The Commission has determined to review all Commission rules and guides periodically. These reviews seek information about the costs and benefits of the Commission's rules and guides and their regulatory and economic impact. The information obtained assists the Commission in identifying rules and guides that warrant modification or rescission. Therefore, the Commission solicits comment on, among other things, the economic impact of its Picture Tube Rule; possible conflict between the Rule and state, local, or other federal laws; and the effect on the Rule of any technological, economic, or other industry changes.

III. Request for Comment

The Commission solicits written public comment on the following questions:

(1) Is there a continuing need for the Rule as currently promulgated?

(2) Has the television industry adopted the Rule's disclosure requirements as part of its routine business practice? If so, how, and what

effect, if any, does this have on the continuing need for the Rule?

(3) What benefits has the Rule provided to purchasers of the products or services affected by the Rule?

(4) Has the Rule imposed costs on purchasers?

(5) What changes, if any, should be made to the Rule to increase the benefits of the Rule to purchasers? How would these changes affect the costs the Rule imposes on firms subject to its requirements? How would these changes affect the benefits to purchasers?

(6) What significant burdens or costs, including costs of compliance, has the Rule imposed on businesses, whether large or small, subject to its requirements? Has the Rule provided benefits to such businesses? If so, what benefits?

(7) What changes, if any, should be made to the Rule to reduce the burdens or costs imposed on firms subject to its requirements? How would these changes affect the benefits provided by the Rule?

(8) Does the Rule overlap or conflict with other federal, state, or local laws or regulations?

(9) Since the Rule was issued, what effects, if any, have changes in relevant television technology, such as the 16:9 aspect ratio for high definition television displays, marketing methods, such as online sales, or economic conditions had on the Rule?

List of Subjects in 16 CFR Part 410

Advertising, Picture tubes, Television sets, Trade practices.

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 05–6960 Filed 4–6–05; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Part 479

[Docket No. ATF 7P; AG Order No. 2761—2005]

RIN 1140–AA23

Machine Guns, Destructive Devices, and Certain Other Firearms; Amended Definition of ''Pistol'' (2003R–33P)

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice is proposing to amend the regulations relating to machine guns, destructive devices, and certain other firearms regulated under the National Firearms Act (NFA) for the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) to clarify the definition of the term ''pistol'' and to define more clearly exceptions to the ''pistol'' definition. The added language is necessary to clarify that certain weapons, including any weapon disguised to look like an item other than a firearm or any gun that fires more than one shot without manual reloading by a single function of the trigger, are not pistols and are classified as ''any other weapon'' under the NFA.

DATES: Comments must be submitted on or before May 9, 2005.

ADDRESSES: Send written comments to: James P. Ficaretta, Program Manager; Room 5250; Bureau of Alcohol, Tobacco, Firearms, and Explosives; P.O. Box 50221; Washington, DC 20091–0221; *ATTN: ATF 7P.* Written comments must include your mailing address and be signed, and may be of any length.

Comments may also be submitted electronically to ATF at *nprm@atf.gov* or to *http://www.regulations.gov* by using the electronic comment form provided on that site. You may also view an electronic version of this proposed rule at the *http://www.regulations.gov* site. Comments submitted electronically must contain your name, mailing address and, if submitted by e-mail, your e-mail address. They must also reference this document docket number, as noted above, and be legible when printed on 8½″ x 11″ paper. ATF will treat comments submitted electronically as originals and ATF will not acknowledge receipt of comments submitted electronically. See the Public Participation section at the end of the **SUPPLEMENTARY INFORMATION** section for requirements for submitting written comments by facsimile.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives; United States Department of Justice; 650 Massachusetts Avenue, NW., Washington, DC 20226; telephone (202) 927–8203 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The regulations in title 27, Code of Federal Regulations (CFR), part 479 implement the provisions of the National Firearms Act (NFA), 26 U.S.C. 5801 *et seq.* Part 479 contains the procedural and substantive requirements relative to the importation, manufacture, making, exportation, transfer, taxing, identification and registration of, and the dealing in, machine guns, destructive devices, and certain other firearms. All NFA firearms that are not in possession or control of the United States government must be registered. Possession of an unregistered NFA firearm is a violation of Federal law and subjects the possessor to criminal prosecution and the seizure and forfeiture of the firearm.

For purposes of the NFA, the term ''firearm'' includes ''any other weapon,'' which in turn is defined in the law (26 U.S.C. 5845(e)) and its implementing regulation at 27 CFR 479.11 as follows:

> Any weapon or device capable of being concealed on the person from which a shot can be discharged through the energy of an explosive, a pistol or revolver having a barrel with a smooth bore designed or redesigned to fire a fixed shotgun shell, weapons with combination shotgun and rifle barrels 12 inches or more, less than 18 inches in length, from which only a single discharge can be made from either barrel without manual reloading, and shall include any such weapon which may be readily restored to fire. Such term shall not include a pistol or a revolver having a rifled bore, or rifled bores, or weapons designed, made, or intended to be fired from the shoulder and not capable of firing fixed ammunition.

As indicated, the definition of ''any other weapon'' specifically excludes pistols having rifled bores.

The term ''pistol'' is defined in 27 CFR 479.11 to mean:

> A weapon originally designed, made, and intended to fire a projectile (bullet) from one or more barrels when held in one hand, and having (a) a chamber(s) as an integral part(s) of, or permanently aligned with, the bore(s); and (b) a short stock designed to be gripped by one hand and at an angle to and extending below the line of the bore(s).

A weapon that meets the definition of ''pistol'' with a rifled bore falls outside the definition of ''any other weapon'' and is therefore not classified as an NFA weapon.

This notice seeks to amend the regulation that defines ''pistol'' to restore language that was inadvertently removed in 1988 and insert language that more clearly defines exceptions to the ''pistol'' definition. The language added to the regulation is necessary to clarify that certain weapons, including weapons disguised to look like items

other than firearms, are not pistols and are classified as ''any other weapon'' under the NFA and subject to that Act's requirements.

The current definition of ''pistol'' in section 479.11 dates back to amendments made in 1988, 53 FR 10480 (Mar. 31, 1988). Prior to amendment, the term was defined to read as follows:

> A weapon originally designed, made, and intended to fire a small projectile (bullet) from one or more barrels when held in one hand, and having (a) a chamber(s) as an integral part(s) of, or permanently aligned with, the bore(s); and (b) a short stock designed to be gripped by one hand and at an angle to and extending below the line of the bore(s). The term shall not include any gadget device, any gun altered or converted to resemble a pistol, any gun that fires more than one shot, without manual reloading, by a single function of the trigger, or any small portable gun such as: Nazi belt buckle pistol, glove pistol, or a one-hand stock gun designed to fire fixed shotgun ammunition.

27 CFR 179.11 (1986). As explained in the preamble to the 1988 amendments, 53 FR 10482, the definition was changed pursuant to comments received during the rulemaking process by deleting the word ''small'' before the word ''projectile.'' In addition, due to an administrative oversight, the last part of the definition was deleted. The language inadvertently deleted stated ATF's long-standing position that certain weapons are not pistols, including any gun disguised to look like an item other than a firearm, any gun altered or converted to resemble a pistol, any gun that fires more than one shot, without manual reloading, by a single function of the trigger, or any small portable gun. Such weapons were classified as ''any other weapon'' under the NFA and subject to regulation under the NFA.

Proposed Regulation

The Department believes that the NFA definition of the term ''pistol'' should be revised to more accurately reflect the Department's position concerning the weapons subject to regulation under the ''any other weapon'' category of the NFA. The term ''fixed'' has been added to paragraph (a)(2) of the regulatory definition to clarify that weapons with a short stock permanently affixed at an angle to the bore can be classified as ''pistols.''

In addition, the regulation will now include language which makes it clear that certain weapons that are particularly concealable and difficult to readily identify as firearms are regulated under the NFA. This will allow the Department to regulate certain weapons that pose significant public safety and security risks in this post 9/11 era. The types of weapons covered by this language include, but are not limited to, belt buckle guns, penguns, wallet guns, gadget devices, and devices commonly known as pager guns. These weapons are particularly hazardous, as they may easily pass through airport or other security posts or metal detectors without being recognized as firearms. Furthermore, such highly concealable weapons can be particularly appealing to prohibited persons, terrorists, or others who may misuse firearms because such weapons can be carried and even used without detection. By regulating these specific types of weapons pursuant to the NFA, the Department can more directly address these heightened security concerns and protect the public from the dangers posed by hidden weaponry.

Accordingly, the proposed definition of ''pistol'' in section 479.11 would read as follows:

> (a) A weapon originally designed, made, and intended to fire a projectile (bullet) from one or more barrels when held in one hand, and having—
>
> (1) A chamber(s) as an integral part(s) of, or permanently aligned with, the bore(s); and
>
> (2) A short fixed stock designed to be gripped by one hand and at an angle to and extending below the line of the bore(s).
>
> (b) The term shall not include any weapon disguised to look like an item other than a firearm, such as a pengun, wallet gun, belt buckle gun, pager gun or gadget device, or any gun that fires more than one shot, without manual reloading, by a single function of the trigger.

Omitted from the proposed regulation is the language: ''any gun altered or converted to resemble a pistol.'' This language mirrors the statutory provisions in 26 U.S.C. 5845(a)(2) and (4) that refer to weapons made from a shotgun or rifle. The NFA adequately reflects the Department's consistent position that a rifle or shotgun, altered to function as a smaller, pistol-like weapon, maintains its classification as a rifle or shotgun and will not be classified as a pistol. Therefore, the addition of this language into the proposed regulation is unnecessary.

Proposed omissions should not be read as an intention to regulate a narrower category of ''any other weapons'' than those previously classified by ATF under the NFA and implementing regulations.

If adopted as a final rule, the proposed amendment to the definition of ''pistol'' will be applied to previous and future classifications of firearms disguised to look like an item other than a firearm. If a firearm previously classified as a pistol is found to be an ''any other weapon'' pursuant to the proposed definition, manufacturers, current owners, and those persons who wish to purchase such a weapon would be subject to the restrictions and regulations imposed by the NFA, including background checks, registration and making/transfer tax.

Administrative Matters

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. The Attorney General has reviewed this proposed rule and, by approving it, certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The proposed rule merely restores language in the definition of the term ''pistol'' that was inadvertently removed due to an administrative oversight.

Unfunded Mandates Reform Act of 1995

This proposed rule will not 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, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Act of 1996, 5 U.S.C. 804. This proposed rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. The Department has determined that this proposed rule is a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory

Planning and Review. Accordingly, this proposed rule has been submitted to the Office of Management and Budget for review.

Executive Order 13132

This proposed rule will 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 section 6 of Executive Order 13132, the Department of Justice has determined that this proposed rule does not have sufficient federalism implications to warrant a federalism summary impact statement.

Executive Order 12988

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Paperwork Reduction Act of 1995

This proposed rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act.

Public Participation

ATF is requesting comments on the proposed regulations from all interested persons. ATF is also specifically requesting comments on the clarity of this proposed rule and how it could be made easier to understand.

Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

ATF will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material that the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting a comment is not exempt from disclosure.

A. Submitting Comments by Fax

You may submit written comments by facsimile transmission to (202) 927–0506. Facsimile comments must:

- Be legible;
- Include your mailing address;
- Reference this document number;
- Be 8½″ x 11″ in size;
- Contain a legible written signature; and
- Be not more than five pages long.

ATF will not acknowledge receipt of facsimile transmissions. ATF will treat facsimile transmissions as originals.

B. Request for Hearing

Any interested person who desires an opportunity to comment orally at a public hearing should submit his or her request, in writing, to the Director of ATF within the 30-day comment period. The Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing is necessary.

C. Disclosure

Copies of this proposed rule and the comments received will be available for public inspection by appointment during normal business hours at: ATF Reference Library, Room 6480, 650 Massachusetts Avenue, NW., Washington, DC 20226, telephone (202) 927–7890.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in the **Federal Register** in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

Drafting Information

The author of this document is James P. Ficaretta; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives.

List of Subjects in 27 CFR Part 479

Administrative practice and procedure, Arms and munitions, Authority delegations, Customs duties and inspection, Exports, Imports, Military personnel, Penalties, Reporting and recordkeeping requirements, Research, Seizures and forfeitures, and Transportation.

Authority and Issuance

Accordingly, for the reasons discussed in the preamble, 27 CFR part 479 is proposed to be amended as follows:

PART 479—MACHINE GUNS, DESTRUCTIVE DEVICES, AND CERTAIN OTHER FIREARMS

1. The authority citation for 27 CFR part 479 continues to read as follows:

Authority: 26 U.S.C. 7805.

2. Section 479.11 is amended by revising the definition of the term ''Pistol'' to read as follows:

§ 479.11 Meaning of terms.

* * * * *

Pistol. (a) A weapon originally designed, made, and intended to fire a projectile (bullet) from one or more barrels when held in one hand, and having—

(1) A chamber(s) as an integral part(s) of, or permanently aligned with, the bore(s); and

(2) A short fixed stock designed to be gripped by one hand and at an angle to and extending below the line of the bore(s).

(b) The term shall not include any weapon disguised to look like an item other than a firearm, such as a pengun, wallet gun, belt buckle gun, pager gun or gadget device, or any gun that fires more than one shot, without manual reloading, by a single function of the trigger.

* * * * *

Dated: March 8, 2005.

Alberto R. Gonzales,

Attorney General.

[FR Doc. 05–6932 Filed 4–6–05; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701 and 774

RIN 1029–AC49

Transfer, Assignment, or Sale of Permit Rights

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; extension of comment period.

SUMMARY: In response to a request, we are extending the comment period for the proposed rule published in the **Federal Register** on January 26, 2005, concerning the transfer, assignment, or sale of permit rights under the provisions of the Surface Mining Control and Reclamation Act of 1977.

DATES: *Written comments:* We will accept written comments on the proposed rule until 4:30 p.m. eastern time, on April 15, 2005.

ADDRESSES: You may submit comments, identified by docket number 1029–AC49, by any of the following methods:

- E-mail: *osmregs@osmre.gov.* Include docket number 1029–AC49 in the subject line of the message.

• Mail/Hand Delivery/Courier: Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 252, 1951 Constitution Avenue, NW., Washington, DC 20240.

• Federal eRulemaking Portal: *http://www.regulations.gov*. Following the instructions for submitting comments.

• Docket: You may review the docket (administrative record) for this rulemaking including comments received in response to this proposed rule at the Office of Surface Mining Reclamation and Enforcement, Administrative Record, located in Room 101, 1951 Constitution Avenue, NW., Washington, DC 20240. The Administrative Record office is opened Monday through Friday, excluding holidays from 8 a.m. to 4 p.m. The telephone number is 202–208–2847.

If you wish to comment on the information collection aspects of this proposed rule, submit your comments to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Interior Desk Officer, via electronic mail, to *OIRA_DOCKET@omb.eop.gov* or via telefacsimile at 202–395–6566.

FOR FURTHER INFORMATION CONTACT: Earl D. Bandy, Jr., Office of Surface Mining Reclamation and Enforcement, Appalachian Region, Applicant/Violator System Office, 2679 Regency Road, Lexington, Kentucky 40503. Telephone: 859–260–8424 or 800–643–9748. E-mail: *ebandy@osmre.gov.*

SUPPLEMENTARY INFORMATION: On January 26, 2005 (70 FR 3840), we published a proposed rule that would revise our regulations for, and related to, the transfer, assignment, or sale of permit rights. The proposed rule effectuates a settlement agreement we entered into with the National Mining Association (NMA) in connection with NMA's judicial challenge to certain provisions of our December 19, 2000, final ownership and control rule (2000 ownership and control rule or 2000 rule). In the proposed rule, we propose to: (1) Revise the regulatory definitions of *transfer, assignment, or sale of permit rights* and *successor in interest;* (2) revise the regulatory provisions relating to transfer, assignment, or sale of permit rights; and (3) create separate rules for successors in interest. The primary purpose of the proposed rule is to distinguish clearly the circumstances that will constitute a transfer, assignment, or sale of permit rights (requiring a regulatory authority's approval and, at a minimum, a permit revision) or result in a successor in interest (requiring the issuance of a new permit) from those that will only require a permittee to provide information updates. The proposed rule also affords us an opportunity to ensure our rules are consistent with recent legal developments. The proposed rule does not suspend or withdraw any of the provisions of our 2000 ownership and control rule, nor does it affect any of our proposed revisions to the 2000 rule published on December 29, 2003. This proposed rule is authorized under the Surface Mining Control and Reclamation Act of 1977, as amended. For a full explanation of the proposed rule, please refer to the rule text and preamble.

The comment period on the proposed rule was originally scheduled to close on March 29, 2005. In response to a telephone request for an extension, we are extending the comment period until April 15, 2005. Written or electronic comments may be submitted in accordance with the instructions provided in **DATES** and **ADDRESSES** above and in Part III of the preamble to the January 26, 2005, proposed rule.

Dated: April 1, 2005.

Jeffrey D. Jarrett,

Director, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 05–6858 Filed 4–6–05; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09–05–005]

RIN 1625–AA00

Safety Zone; Cleveland Triathlon, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish an annual safety zone for the Cleveland Triathlon located in the Captain of the Port Cleveland Zone. This safety zone will manage vessel traffic in order to provide for the safety of life and property on navigable waters during the event. Entry of vessels or persons into this zone would be prohibited unless specifically authorized by the Coast Guard Captain of the Port or their on-scene representative.

DATES: Comments and related material must reach the Coast Guard on or before May 9, 2005.

ADDRESSES: You may mail comments and related material to Coast Guard Marine Safety Office Cleveland (CGD09–05–005), 1055 East 9th Street, Cleveland, OH 44114. Marine Safety Office Cleveland maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at MSO Cleveland between 8 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Allen Turner, U.S. Coast Guard Marine Safety Office Cleveland at 216–937–0128.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD09–05–005), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know your submission reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Coast Guard Marine Safety Office Cleveland at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

This safety zone is necessary to protect the participants in the Cleveland Triathlon, held annually on the third Sunday of July, from hazards associated with swimming in close proximity to recreational watercraft in Cleveland Harbor off of Voinovich Park in Cleveland, OH. The Captain of the Port has determined that this event poses a threat to the participants as well as spectator vessels due to the hazards associated with these events. The Captain of the Port has determined that

swimming in close proximity to watercraft poses a risk to safety and property.

The combination of large numbers of inexperienced recreational boaters, congested waterways, and the use of commercially transited waterways could easily result in serious injuries or fatalities.

Establishing a safety zone by notice and comment rulemaking gives the public an opportunity to comment on the proposed zone and provides better notice than promulgating temporary final rules each year.

Discussion of Proposed Rule

The Coast Guard is proposing a safety zone in Cleveland Harbor, Cleveland, Ohio. The Safety would be enforced from 5 a.m. until 11 a.m. each year on the third Sunday in July. The safety zone would encompass all waters in Cleveland Harbor, to include the North Coast Harbor, originating at a line drawn from Pier 32, at position 41°30′36″ N, 081°42′56″ W, extending to position 41°30′43″ N, 081°42′03″ W, thence to Buoy 11 (LLNR 4135) at position 41°30′49″ N, 081°41′53″ W in Cleveland Harbor, thence to the Northeast corner of Municipal Pier at position 41°30′43″ N, 081°41′47″ W. These coordinates are based upon North American Datum 1983 (NAD 83).

The Coast Guard would notify the public in advance by way of Ninth Coast Guard District Local Notice to Mariners, marine information broadcasts, and for those who request it from Marine Safety Office Cleveland, by facsimile.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

This determination is based upon the size and location of the safety zone within the waterway. Commercial vessels will not be hindered by the safety zone, as only a portion of the East Basin channel is restricted. Recreational vessels may transit through the safety zone with permission from the COTP Cleveland or his designated on-scene patrol commander.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the East Basin of Cleveland Harbor.

This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons: Although the safety zone restricts the movement of vessels through a navigable channel, commercial vessels will be able to transit along the northern edge of the zone and all other recreational vessels will be able to transit the zone with the permission of the COTP Cleveland or his designated on-scene Patrol Commander. Before the effective period, the Coast Guard will issue maritime advisories to users who may be impacted through notification in the **Federal Register**, the Ninth District Coast Guard District Local Notice to Mariners, and through Marine Information Broadcasts and when requested by facsimile.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Lieutenant Allen Turner, U.S. Coast Guard Marine Safety Office Cleveland, 1055 East 9th Street, Cleveland, OH 44114.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

The Coast Guard has analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive

Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. We invite your comments on how this proposed rule might impact tribal government, even if that impact may not constitute a ''tribal implication'' under that Order.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, we believe that this rule should be categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

Event participants swimming in the water pose no inherent risk to the surrounding environment, and a safety zone is needed to protect the participants. Under figure 2–1, paragraph (34)(g), of the Instruction, an ''Environmental Analysis Check List'' is not required for this rule. Comments on this section will be considered before we make the final decision on whether to categorically exclude this rule from further environmental review.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.922 to read as follows:

165.922 Safety Zone; Cleveland Triathlon Swimming Event in the Captain of the Port Cleveland Zone.

(a) *Location.* The following area is a safety zone:

(1) All waters in Cleveland Harbor, to include the North Coast Harbor, originating at a line drawn from Pier 32, at position 41°30′36″ N, 081°42′56″ W, extending to position 41°30′43″ N, 081°42′03″ W, thence to Buoy 11 (LLNR 4135) at position 41°30′49″ N, 081°41′53″ W in Cleveland Harbor, thence to the Northeast corner of Municipal Pier at position 41°30′43″ N, 081°41′47″ W. These coordinates are based upon North American Datum 1983 (NAD 83).

(b) *Enforcement Period.* This safety zone will be enforced from 5 a.m. (local) until 11 a.m., annually on the third Sunday of July.

(c) *Regulations.* No vessel shall enter the safety zone. Permission to deviate from the above rules must be obtained from the Captain of the Port or the on-scene Coast Guard Patrol Commander via VHF/FM radio, Channel 16 or by telephone at 216–937–0111.

Dated: March 28, 2005.

Lorne W. Thomas,

Commander, U.S. Coast Guard, Captain of the Port Cleveland.

[FR Doc. 05–6952 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1, 3, and 10

[Docket No.: 2005–P–053]

RIN 0651–AB85

Provisions for Persons Granted Limited Recognition To Prosecute Patent Applications and Other Miscellaneous Matters

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (Office) is proposing changes to the rules of practice concerning persons acting with limited recognition in a patent matter, the filing of the English translation of foreign-language provisional applications, and the submission of evidence ownership when an assignee takes action in a patent matter. The Office is proposing changes to the rules of practice to allow a person acting with limited recognition to be given a power of attorney and authorized to sign amendments and other correspondence respecting patent applications, reexamination proceedings, and other proceedings. A person granted limited recognition is not a registered patent attorney or agent. The Office is also proposing changes to the rules of practice to require that a copy of the English translation of a foreign-language provisional application be filed in the provisional application (rather than in either the provisional application or the nonprovisional application) if a non-provisional application claims the benefit of the provisional application. In addition, the Office is proposing changes to require that a copy of documentary evidence of ownership be recorded in the Office's assignment records when an assignee takes action in a patent matter, and that separate copies of a document be submitted to the Office for recording in the Office's assignment records, each accompanied by a cover sheet, if the document to be recorded includes an interest in, or a transaction involving, both patents and trademarks.

DATES: To be ensured of consideration, written comments must be received on or before June 6, 2005. No public hearing will be held.

ADDRESSES: Comments should be sent by electronic mail over the Internet addressed to: *AB85.comments@uspto.gov.* Comments may also be submitted by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450; or by facsimile to (703) 273–7744, marked to the attention of Karin Ferriter. Although comments may be submitted by mail or facsimile, the Office prefers to receive comments via the Internet. If comments are submitted by mail, the Office would prefer that the comments be submitted on a DOS formatted 3 ½-inch disk accompanied by a paper copy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking

Portal Web site *(http://www.regulations.gov)* for additional instructions on providing comments via the Federal eRulemaking Portal.

The comments will be available for public inspection at the Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, currently located at Room 7D74 of Madison West, 600 Dulany Street, Alexandria, Virginia, and will be available through anonymous file transfer protocol (ftp) via the Internet (address: *http://www.uspto.gov).* Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter ((571) 272–7744), Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy; Harry I. Moatz ((571) 272–4097), Director of the Office of Enrollment and Discipline (OED Director); or Robert J. Spar ((571) 272–7700) Director of the Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, directly by phone, or by facsimile to (571) 273–7744, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450.

SUPPLEMENTARY INFORMATION: This notice proposes changes in the rules of practice in title 37 of the Code of Federal Regulations (CFR) pertaining to the availability of patent application files, persons acting with limited recognition in a patent matter, the filing of the English translation of foreign-language provisional applications, and the submission of evidence ownership when an assignee takes action in a patent matter and for recording in the Office's assignment records. The proposed changes concerning the availability of patent application files relate to § 1.11. The proposed changes concerning persons acting with limited recognition in a patent matter relate to §§ 1.4, 1.17, 1.31, 1.32, 1.33, 1.34, and 1.36. The proposed changes concerning the filing of the English translation of foreign-language provisional applications relate to § 1.78. The proposed changes concerning the submission of evidence ownership when an assignee takes action in a patent matter and for recording in the Office's assignment records relate to §§ 3.28, 3.31, 3.73, and 10.112.

Discussion of Specific Rules

Section 1.4: The title is proposed to be revised to read: ''Nature of correspondence and Signature Requirements.'' Section 1.4(d)(2) is proposed to be revised to delete ''with a signature in permanent dark ink or its equivalent,'' because dark ink applies to handwritten signatures, not S-signatures. Section 1.4(d)(2)(ii) is proposed to be revised to change ''registered practitioner'' to ''patent practitioner (§ 1.32(a)(1))'' and to insert ''or limited recognition number'' after ''registration number'' in two places so that a person acting with limited recognition can use an S-signature. The term ''patent practitioner'' is defined in § 1.32(a).

Section 1.11: Section 1.11(a) is proposed to be revised for clarity and to reflect the policy regarding availability to the public of papers in the files of applications that have been published. For example, § 1.11(a) is proposed to be revised to remove ''abandoned'' before ''published application.'' Published applications are not physically available to the public if the file was maintained in a paper file wrapper, but any electronic file relating to a published application is made available through the Patent Application Information Retrieval (PAIR) system pursuant to § 1.14(a)(1)(iii) and 1.14(b). Since most pending applications are now available through PAIR, the reference to only abandoned published applications in § 1.11 may have been misleading. In addition, § 1.11(a) is proposed to be revised to include: ''If an application was published in redacted form pursuant to § 1.217, the complete file wrapper and contents of the patent application will not be available if: The requirements of paragraphs (d)(1), (d)(2), and (d)(3) of § 1.217 have been met in the application; and the application is still pending.''

Section 1.17: Section 1.17(f) is proposed to be revised to add ''§ 1.36(a)—for revocation of a power of attorney by fewer than all of the applicants.'' See the discussion of the proposed change to § 1.36(a). This proposed change would correct § 1.17 by including § 1.36(a) in the list of petitions for which a fee set forth in § 1.17 can be charged, and also groups the fee for a petition under § 1.36(a) with similar petitions (under § 1.182 and § 1.183).

Section 1.31: Section 1.31 is proposed to be revised to change the title to ''Applicants may be represented by one or more patent practitioners or joint inventors'' in order to make the title of the rule more descriptive of the proposed revised rule. A definition for ''patent practitioner'' is proposed to be added to § 1.32(a), as discussed below, and the term ''patent practitioner'' is proposed to be used in place of ''registered patent attorney or agent'' in § 1.31, and in other rules. Further, § 1.31 is proposed to be revised to indicate that one or more patent practitioners or joint inventors may be given a power of attorney, to thereby recognize that there may be a single person appointed or an appointment of more than one practitioner or joint inventor to represent the applicant. Section 1.32(c)(1) permits one or more joint inventors to be given power of attorney to represent the other joint inventor or inventors; accordingly, the revision to § 1.31 is necessary for consistency with § 1.32(c)(1). Furthermore, § 1.31 is proposed to be amended to delete the cross references to §§ 11.6 and 11.9, which would no longer be useful in view of the definition of patent practitioner proposed to be added to § 1.32(a).

Section 1.32: Section 1.32(a)(1) is proposed to be revised to set forth the definition of ''patent practitioner'' and to renumber sections (a)(1) to (a)(4) as (a)(2) through (a)(5), respectively.

Proposed new § 1.32(a)(1) defines the term ''patent practitioner'' as ''a registered patent attorney or registered patent agent under § 11.6, or individual granted limited recognition to file or prosecute a patent application, or other patent proceeding, before the United States Patent and Trademark Office under § 11.9(a) or § 11.9(b).'' This definition is consistent with the definition of ''practitioner'' in § 11.1 as ''(1) An attorney or agent registered to practice before the Office in patent matters* * *or (3) An individual authorized to practice before the Office in a patent case or matters under § 11.9(a) or (b).'' A person with limited recognition pursuant to § 11.9(a) and § 11.9(b) is not a registered patent practitioner, but is someone who has been given limited recognition to prosecute a patent application. Individuals granted limited recognition pursuant to § 11.9(a) are given such recognition for one or more specified patent applications or other patent proceedings. For example, a parent or spouse may be given limited recognition to represent the inventor where the inventor is competent and 35 U.S.C. 117 and § 1.43 do not apply. Limited recognition pursuant to § 11.9(b) is granted to individuals who have passed the patent examination and are U.S. residents, but are neither citizens of the U.S. nor permanent residents and thus are not eligible to become registered.

Because these individuals have a visa to work in the U.S., they are accorded limited recognition consistent with the visa. The term ''patent practitioner'' is limited to those that are registered or authorized by the Office to act in patent matters.

Section 1.32(a)(1) is proposed to be renumbered as § 1.32(a)(2) and further revised to change ''registered patent attorneys or registered patent agents'' to ''one or more patent practitioners or joint inventors'' to reflect that one, or more than one, patent practitioner may be appointed in a power of attorney. Section 1.32(c) permits a power of attorney to be to one or more patent practitioners or joint inventors, and this change is consistent therewith.

Section 1.32(a)(2) is proposed to be renumbered as § 1.32(a)(3) and further revised to add ''or, in a reexamination proceeding, the assignee of the entirety of ownership of a patent'' to reflect that the assignee of the entire interest in a patent may authorize a patent practitioner to represent the assignee in reexamination proceedings, for example, in addition to patent applications. In addition, § 1.32(a)(3) is proposed to be revised to change ''registered patent attorney or registered patent agent'' to ''patent practitioners'' and ''joint inventor'' to ''joint inventors.'' As explained above, use of the term ''patent practitioner'' expands the rule to also apply to individuals granted limited recognition to file (present) or prosecute a patent application or other patent proceeding before the United States Patent and Trademark Office, as well as registered patent attorneys and registered patent agents.

Section 1.32(a)(3) is proposed to be renumbered as § 1.32(a)(4), and further proposed to be revised to change ''registered patent attorney or registered patent agent'' to ''patent practitioner or joint inventor.''

Section 1.32(a)(4) is proposed to be renumbered as § 1.32(a)(5), and the resulting new paragraph § 1.32(a)(5)(i) is proposed to be revised to change ''patent application or patent'' to ''patent application, patent or other patent proceeding'' and the resulting new paragraph 1.32(a)(5)(iii) is proposed to be revised to delete ''registered.''

Section 1.32(c)(3) is proposed to be revised such that the first sentence reads: ''Ten or fewer patent practitioners, stating the name and registration number or limited recognition number of each patent practitioner.'' The Office needs the registration number of the patent practitioner to make the practitioner of record. Because the former rules did not require a registration number, registration numbers were sometimes omitted, leading to delays in Office processing of powers of attorney. Accordingly, § 1.32(c)(3) is proposed to be amended to add a requirement for the registration number or limited recognition number of the patent practitioner to assist the Office in making the practitioner of record. Limited recognition numbers recently began to be assigned by the Office of Enrollment and Discipline.

Section § 1.33: Section 1.33(a) is proposed to be revised to use the generic term ''patent practitioner'' instead of ''registered patent attorney or patent agent'' so as to also include those acting with limited recognition. Specifically, § 1.33(a) is proposed to be amended to change ''registered patent attorney or patent agent'' to ''patent practitioner'' in two places. In addition, § 1.33(a)(1) is proposed to be amended to change ''If the application was filed by a registered attorney or agent, any other registered practitioner named in the transmittal papers may also change the correspondence address'' to ''If the application was filed by a patent practitioner, any other patent practitioner named in the transmittal papers may also change the correspondence address.''

Section 1.33(b)(1) and § 1.33(b)(2) are proposed to be amended to change registered patent attorney or patent agent'' to ''patent practitioner.''

Section 1.33 is also proposed to be revised to add new paragraph (e) to remind patent practitioners that the attorney roster must be updated separately from individual patent applications. Section 1.33 is proposed to be revised to state: ''(e) A change of address filed in a patent application or patent does not change the address for a patent practitioner in the roster of patent attorneys and agents. See § 11.11 of this part.''

Section 1.34: Section 1.34 is proposed to be revised to change ''registered patent attorney or patent agent'' to ''patent practitioner'' in two places, and change ''must specify his or her registration number and name with his or her signature'' to ''must set forth his or her registration number, or limited recognition number, and his or her name and signature'' in order to provide support for someone accorded limited recognition to act in a representative capacity.

Section 1.36: Section 1.36(a) is proposed to be revised to change § 1.17(h) to § 1.17(f). The fee for a petition to allow a split power of attorney should be the same regardless of whether the split power of attorney results from revocation by fewer than all of the inventors, as provided in § 1.36(a), or from a petition under § 1.183 to waive the provisions of § 1.32(b)(4) requiring that a power of attorney be signed by the applicant for patent (§ 1.41(b)) or the assignee of the entire interest of the applicant. Furthermore, ''registered patent attorney or patent agent'' is proposed to be changed to ''patent practitioner.''

Section 1.78: Section 1.78(a)(2)(i) is proposed to be revised to add '', or international application designating the United States of America,'' to require international applications to contain a specific reference to the earlier nonprovisional application.

Section 1.78(a)(5)(iv) is proposed to be revised to require the English translation of a provisional application to be filed in a provisional application, instead of also permitting the translation to be filed in each nonprovisional application that claims the benefit of the filing date of the provisional application. Section 1.78(a)(5)(iv) is also proposed to be revised to provide that applicant must file, in a nonprovisional application, confirmation of the filing of the translation and statement, when a notice is mailed in the nonprovisional application requiring the translation and statement. Currently, § 1.78(a)(5)(iv) provides that when, pursuant to 35 U.S.C. 119(e), benefit is being claimed to a provisional application which was filed in a language other than English, an English language translation of the provisional application, accompanied by a statement that the translation is accurate, must be filed in either: (a) the provisional application or (b) each nonprovisional application that claims the benefit of the provisional application. Thus, if the translation and statement are not filed in the provisional application, they may be filed in each application that claims the benefit of the filing date of the provisional application (to satisfy the requirement of the rule). A provisional application is open to the public if the benefit of the provisional application is claimed in an application that has either been published or patented. Where the translation and statement are not filed in the provisional application because they are filed in each nonprovisional application(s) claiming the benefit of the provisional application, there is a burden on the public in finding the translation and statement, and to the Office in storing possibly duplicate copies of the documents. Further, when a translation of the provisional application is filed in the nonprovisional application, the Office

has sometimes confused the translation of the provisional with the specification papers to be used for the application. Since the option is available to file the translation and statement in the nonprovisional application, applicant's counsel may inadvertently choose that option in situations where there are many nonprovisional applications claiming the benefit of a single provisional application, and incur substantial expense for having to file a copy in each nonprovisional application. Having only one copy of the translation (and statement) ''centrally'' filed in the provisional application, regardless of how many nonprovisional applications claim benefit of that provisional application, would be beneficial for applicants, the public, and the Office. Accordingly, § 1.78(a)(5)(iv) is proposed to be revised to delete from the first sentence ''or the later-filed nonprovisional application'' to thereby eliminate the option to file the translation and statement in the nonprovisional application. Furthermore, § 1.78(a)(5)(iv) is further proposed to be revised to add '', in the provisional application,'' after ''a period of time within which to file.'' Lastly, the last sentence of § 1.78(a)(5)(iv) is further proposed to be revised to read ''If the notice is mailed in a pending nonprovisional application, a timely reply to such a notice must include the filing of a confirmation in the nonprovisional application that the translation and statement were filed in the provisional application or the nonprovisional application will be abandoned.''

Section 3.28: Section 3.28 currently directs that ''[o]nly one set of documents and cover sheets to be recorded should be filed'' which discourages assignees from submitting one set of documents including a patent cover sheet and the document to be recorded, and another set of documents including a trademark cover sheet and another copy of the document to be recorded. While the Office can process a set of documents that includes a patent cover sheet, trademark cover sheet, and only one copy of the document to be recorded, submitting only one copy of the document can lead to the misconception that a document submitted for recordation has been omitted, or the document submitted only belongs to the second cover sheet, particularly when the documents are submitted by facsimile and there is a break in the transmission. For example, if a submission includes: a trademark sheet on pages 1 and 2, a patent cover sheet on page 3, and a document for recording on pages 4–7, then, if pages 1 and 2 are separated from the remainder of the set of documents, it may not be clear that the trademark cover sheet is missing since the patent cover sheet and the document to be recorded would have themselves made a complete set of documents. To reduce confusion, it is proposed to revise § 3.28 to require that a separate copy of the document to be recorded be submitted with each cover sheet. Note that even if the term ''copy of the document to be recorded'' is not used in this discussion, the document submitted for recordation must be a copy, and not the original document, and the term ''document to be recorded'' has been used to emphasize that the document is to be recorded, not to suggest that an original may be submitted.

Section 3.28 is proposed to be revised to state that each document to be recorded must be accompanied by a single cover sheet (and not multiple cover sheets), to put parenthesis around ''as specified in § 3.31,'' and to delete the statement that at least one cover sheet must be included with each document submitted for recording. Section 3.28 is also proposed to be revised to delete the sentence that states that only one set of documents and cover sheets to be recorded should be filed, and to make it clear that if an assignment includes interests in, or transactions involving, both patents and trademarks, then two copies of each document (each document with its own cover sheet) would have to be submitted. Thus, a patent cover sheet and a copy of the document, and a trademark cover sheet and a copy of the document, would be submitted.

Section 3.31: Section 3.31(a)(7) is proposed to be amended to delete ''submission'' before ''(*e.g.*/Thomas O'Malley III/)'' to correct an obvious error.

Section 3.73: Section 3.73(b)(1)(i) is proposed to be revised to require, for patent matters, that the document(s) submitted to establish ownership under § 3.73(b) be recorded pursuant to § 3.11 in the assignment records.

In order to take action in a patent application or a patent, a party must comply with § 3.73 to establish ownership of the rights to a patent application or a patent (*i.e.*, a patent property) by submitting to the Office a signed statement identifying the assignee. The signed statement must be accompanied by either: (i) Documentary evidence of a chain of title from the original owner to the assignment, or (ii) a statement specifying where such documentary evidence is recorded in the Office's assignment records. Where option (i) is chosen, there is no requirement that the document(s) submitted to establish ownership also be recorded pursuant to § 3.11 in the assignment records, unless the Office explicitly requires such recordation on a case-by-case basis. Such a requirement is made only in the rare situation where a question arises as to ownership of the property. It is desirable, however, that the Office's patent assignment records should, as a rule, reflect the assignment of any assignee seeking to take action in a patent application or patent. The current system which permits an assignee to take action by submitting a copy of the assignment in a patent application or patent, but not requiring the assignment to be recorded in the Office's patent assignment records, makes a search of the Office's patent assignment records unreliable. Permitting an assignee to take action in an application or patent without also recording the assignment (in the Office's assignment records) can also serve to discourage an assignee from recording its assignment document(s), and thus lose the right to rely upon recordation pursuant to 35 U.S.C. 261 (''An assignment, grant or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage.'')

Section 3.73(b)(1)(i) is proposed to be revised to require that the submission of the documentary evidence to establish ownership must be accompanied by a statement affirming that the documentary evidence of the chain of title from the original owner to the assignee was submitted for recordation pursuant to § 3.11. Thus, when filing a § 3.73(b) statement to establish ownership an applicant or patent owner must also submit the assignment document(s) to the Office for recordation, if such a submission has not been previously made. If the § 3.73(b) statement is not accompanied by a statement affirming that the documentary evidence was submitted for recordation pursuant to § 3.11, then the § 3.73(b) statement will not be accepted, and the assignee(s) will not have established the right to take action in the patent application or the patent for which the § 3.73(b) statement was submitted. For trademark matters, there would continue to be no requirement that the submission of the documentary evidence be accompanied by a statement affirming that the documentary evidence was submitted

for recordation. Rather, paragraph (b)(1)(i) would continue to set forth that the Office may require (as deemed appropriate in any individual case) the documents submitted to establish ownership to be recorded pursuant to § 3.11 in the assignment records of the Office as a condition to permitting the assignee to take action in a matter pending before the Office.

Section 10.112: Section 10.112 is proposed to be revised to correct the cross reference, changing ''10.6(c)'' to ''11.6(c).''

Rule Making Considerations

Administrative Procedure Act: The changes proposed in this notice (except for the petition fee change for a split power of attorney resulting from revocation of the power of attorney by fewer than all of the applicants or assignees of the applicants) relate solely to the procedures to be followed during the prosecution of a patent application. Specifically, the changes proposed in this notice concern: (1) Providing the proper S-signature by someone acting with limited recognition pursuant to § 11.9(a) and § 11.9(b); (2) providing for a power of attorney to a person acting with limited recognition pursuant to § 11.9(a) and § 11.9(b); (3) providing that the petition fee for a split power of attorney resulting from revocation of the power of attorney by fewer than all of the applicants or assignees of the applicants be the same as the petition fee to waive the rules to appoint a split power of attorney initially; (4) requiring that the translation of a non-English language provisional application and statement that the translation is accurate be filed in a provisional application, rather than either the nonprovisional application claiming the benefit of the provisional application or the provisional application; and (5) requiring that the evidentiary evidence of ownership be recorded under 37 CFR part 3 when an assignee takes action in a patent application. Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure under 5 U.S.C. 553(b)(A). *See Bachow Communications Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are ''rules of agency organization, procedure, or practice'' and are exempt from the Administrative Procedure Act's notice and comment requirement); *see also Merck & Co., Inc.* v. *Kessler,* 80 F.3d 1543, 1549–50, 38 USPQ2d 1347, 1351 (Fed. Cir. 1996) (the rules of practice promulgated under the authority of former 35 U.S.C. 6(a) (now in 35 U.S.C. 2(b)(2)) are not substantive rules to which the notice and comment requirements of the Administrative Procedure Act apply), and *Fressola* v. *Manbeck,* 36 USPQ2d 1211, 1215 (D.D.C. 1995) (''it is doubtful whether any of the rules formulated to govern patent and trade-mark practice are other than 'interpretative rules, general statements of policy, * * * procedure, or practice.'''') (quoting C.W. Ooms, *The United States Patent Office and the Administrative Procedure Act,* 38 Trademark Rep. 149, 153 (1948)).

Regulatory Flexibility Act: Prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553 (or any other law) for the procedural changes proposed in this notice. Therefore, an initial regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is not required for those changes proposed in this notice (with the sole exception of the change to the petition fee for revocation of a power of attorney by fewer than all of the applicants). *See* 5 U.S.C. 603.

With respect to the petition fee change, the proposed rule will increase the petition fee for revocation of a power of attorney by fewer than all of the applicants. This notice proposes to change the petition fee (from the $130.00 fee specified in § 1.17(h) to the $400.00 fee specified in § 1.17(f)) in situations where a split power of attorney results from revocation of the power of attorney by fewer than all of the applicants or assignees of the applicants. The proposed rule will bring the fees in line with the actual cost of treating such petitions (in view of the special handling required for the split power of attorney resulting from revocation of the power of attorney). This petition fee is established pursuant to the Office's authority under 35 U.S.C. 41(d) to establish fees for all processing, services, or materials relating to patents not otherwise specified in 35 U.S.C. 41 to recover the estimated average cost to the Office of such processing, services, or materials.

The Office received over 376,000 nonprovisional patent applications and over 102,000 provisional patent applications in fiscal year 2004. The Office receives fewer than five petitions for revocation of the power of attorney by fewer than all of the applicants or assignees of the applicants each year. On this basis alone, the fee change will not have an impact on a substantial number of small businesses. While the Office does not track the entity status of such petitions, the small entity patent application filing rate has not been greater than 31.0% during the last five fiscal years. Thus, this proposed change (even if all of the affected patents were by a small entity) would impact no more than two small entities in any calendar year.

Accordingly, for the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes proposed in this notice will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

Executive Order 13132: This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866: This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Paperwork Reduction Act: This notice involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this notice has been reviewed and previously approved by OMB under OMB control number 0651–0012, 0651–0027, 0651–0031, 0651–0032, and 0651–0035. The United States Patent and Trademark Office is not resubmitting any information collection package to OMB for its review and approval because the changes in this notice do not affect the information collection requirements associated with the information collection under these OMB control numbers. The principal impacts of the changes proposed in this notice are: (1) Providing for the proper S-signature by someone acting with limited recognition pursuant to § 11.9(a) and § 11.9(b); (2) providing for power of attorney to a person acting with limited recognition pursuant to § 11.9(a) and § 11.9(b); (3) providing that the fee for a split power of attorney resulting from revocation of the power of attorney by fewer than all of the applicants or assignees of the applicants be the same as the fee to waive the rules to appoint a split power of attorney initially; (4) requiring that the translation of a non-English language provisional application and statement that the translation is accurate be filed in a provisional application, rather than either the nonprovisional application claiming the benefit of the provisional application or the provisional application; and (5) requiring that the evidentiary evidence of ownership be recorded under 37 CFR part 3 when an

assignee takes action in a patent application.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Robert J. Spar, Director, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, P.O. Box 1450, Alexandria, VA 22313–1450, or to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Patent and Trademark Office.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person 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 currently valid OMB control number.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small businesses.

37 CFR Part 3

Administrative practice and procedure, Inventions and patents, Reporting and record keeping requirements.

37 CFR Part 10

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and record keeping requirements.

For the reasons set forth in the preamble, 37 CFR parts 1, 3, and 10 are proposed to be amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

2. Section 1.4 is amended by revising paragraph (d)(2) introductory text, and paragraph (d)(2)(ii) to read as follows:

§ 1.4 Nature of correspondence and Signature Requirements.

* * * * *

(d) * * *

(2) *S-signature.* An S-signature is a signature inserted between forward slash marks, but not a handwritten signature as defined by § 1.4(d)(1). An S-signature includes any signature made by electronic or mechanical means, and any other mode of making or applying a signature not covered by either a handwritten signature of § 1.4(d)(1) or an Office Electronic Filing System (EFS) character coded signature of § 1.4(d)(3). Correspondence being filed in the Office in paper, by facsimile transmission as provided in § 1.6(d), or via the Office Electronic Filing System as an EFS Tag(ged) Image File Format (TIFF) attachment, for a patent application, patent, or a reexamination proceeding may be S-signature signed instead of being personally signed (*i.e.*, with a handwritten signature) as provided for in paragraph (d)(1) of this section. The requirements for an S-signature under this paragraph (d)(2) are as follows.

* * * * *

(ii) A patent practitioner (§ 1.32(a)(1)), signing pursuant to §§ 1.33(b)(1) or 1.33(b)(2), must supply his/her registration number or limited recognition number either as part of the S-signature, or immediately below or adjacent to the S-signature. The number (#) character may only be used as part of the S-signature when appearing before a practitioner's registration number or limited recognition number; otherwise the number character may not be used in an S-signature.

* * * * *

3. Section 1.11 is amended by revising paragraph (a) to read as follows:

§ 1.11 Files open to the public.

(a) The specification, drawings, and all papers relating to the file of: a published application; a patent; or a statutory invention registration are open to inspection by the public, and copies may be obtained upon the payment of the fee set forth in § 1.19(b)(2). If an application was published in redacted form pursuant to § 1.217, the complete file wrapper and contents of the patent application will not be available if: the requirements of paragraphs (d)(1), (d)(2), and (d)(3) of § 1.217 have been met in the application; and the application is still pending. See § 2.27 for trademark files.

* * * * *

4. Section 1.17 is amended by revising paragraph (f) to read as follows:

§ 1.17 Patent application and reexamination processing fees.

* * * * *

(f) For filing a petition under one of the following sections which refers to this paragraph: $400.00.

§ 1.36(a)—for revocation of a power of attorney by fewer than all of the applicants.

§ 1.53(e)—to accord a filing date.

§ 1.57(a)—to accord a filing date.

§ 1.182—for decision on a question not specifically provided for.

§ 1.183—to suspend the rules.

§ 1.378(e)—for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.

§ 1.741(b)—to accord a filing date to an application under § 1.740 for extension of a patent term.

* * * * *

5. Section 1.31 is revised to read as follows:

§ 1.31 Applicants may be represented by one or more patent practitioners or joint inventors.

An applicant for patent may file and prosecute his or her own case, or he or she may give a power of attorney so as to be represented by one or more patent practitioners or joint inventors. The United States Patent and Trademark Office cannot aid in the selection of a patent practitioner.

6. Section 1.32 is amended by revising paragraphs (a) and (c)(3) to read as follows:

§ 1.32 Power of attorney.

(a) *Definitions*—(1) *Patent practitioner* means a registered patent attorney or registered patent agent under § 11.6 of this chapter, or an individual granted limited recognition to file or prosecute a patent application, or other patent proceeding, before the United States Patent and Trademark Office under § 11.9(a) or § 11.9(b).

(2) *Power of attorney* means a written document by which a principal authorizes one or more patent practitioners or joint inventors to act on his or her behalf.

(3) *Principal* means either an applicant for patent (§ 1.41(b)) or an assignee of entire interest of the applicant for patent or in a reexamination proceeding, the assignee of the entirety of ownership of a patent. The principal executes a power of attorney designating one or more patent practitioners or joint inventors to act on his or her behalf.

(4) *Revocation* means the cancellation by the principal of the authority previously given to a patent practitioner or joint inventor to act on his or her behalf.

(5) *Customer Number* means a number that may be used to:

(i) Designate the correspondence address of a patent application or patent such that the correspondence address for the patent application, patent or other patent proceeding would be the address associated with the Customer Number;

(ii) Designate the fee address (§ 1.363) of a patent such that the fee address for the patent would be the address associated with the Customer Number; and

(iii) Submit a list of patent practitioners such that those patent practitioners associated with the Customer Number would have power of attorney.

* * * * *

(c) * * *

(3) Ten or fewer patent practitioners, stating the name and registration number or limited recognition number of each patent practitioner. Except as provided in paragraph (c)(1) or (c)(2) of this section, the Office will not recognize more than ten patent practitioners as being of record in an application or patent. If a power of attorney names more than ten patent practitioners, such power of attorney must be accompanied by a separate paper indicating which ten patent practitioners named in the power of attorney are to be recognized by the Office as being of record in the application or patent to which the power of attorney is directed.

7. Section 1.33 is amended by revising paragraphs (a) introductory text, (a)(1), (b)(1) and (b)(2) and by adding paragraph (e) to read as follows:

§ 1.33 Correspondence respecting patent applications, reexamination proceedings, and other proceedings.

(a) *Correspondence address and daytime telephone number.* When filing an application, a correspondence address must be set forth in either an application data sheet (§ 1.76), or elsewhere, in a clearly identifiable manner, in any paper submitted with an application filing. If no correspondence address is specified, the Office may treat the mailing address of the first named inventor (if provided, see §§ 1.76(b)(1) and 1.63(c)(2)) as the correspondence address. The Office will direct all notices, official letters, and other communications relating to the application to the correspondence address. The Office will not engage in double correspondence with an applicant and a patent practitioner, or with more than one patent practitioner except as deemed necessary by the Director. If more than one correspondence address is specified in a single document, the Office will establish one as the correspondence address and will use the address associated with a Customer Number, if given, over a typed correspondence address. For the party to whom correspondence is to be addressed, a daytime telephone number should be supplied in a clearly identifiable manner and may be changed by any party who may change the correspondence address. The correspondence address may be changed as follows:

(1) *Prior to filing of § 1.63 oath or declaration by any of the inventors.* If a § 1.63 oath or declaration has not been filed by any of the inventors, the correspondence address may be changed by the party who filed the application. If the application was filed by a patent practitioner, any other patent practitioner named in the transmittal papers may also change the correspondence address. Thus, the inventor(s), any patent practitioner named in the transmittal papers accompanying the original application, or a party that will be the assignee who filed the application, may change the correspondence address in that application under this paragraph.

* * * * *

(b) * * *

(1) A patent practitioner of record appointed in compliance with § 1.32(b);

(2) A patent practitioner not of record who acts in a representative capacity under the provisions of § 1.34;

* * * * *

(e) A change of address filed in a patent application or patent does not change the address for a patent practitioner in the roster of patent attorneys and agents. See § 11.11 of this chapter.

8. Section 1.34 is revised to read as follows:

§ 1.34 Acting in a representative capacity.

When a patent practitioner acting in a representative capacity appears in person or signs a paper in practice before the United States Patent and Trademark Office in a patent case, his or her personal appearance or signature shall constitute a representation to the United States Patent and Trademark Office that under the provisions of this subchapter and the law, he or she is authorized to represent the particular party in whose behalf he or she acts. In filing such a paper, the patent practitioner must set forth his or her registration number, or limited recognition number, and his or her name and signature. Further proof of authority to act in a representative capacity may be required.

9. Section 1.36 is amended by revising paragraph (a) to read as follows:

§ 1.36 Revocation of power of attorney; withdrawal of patent attorney or agent.

(a) A power of attorney, pursuant to § 1.32(b), may be revoked at any stage in the proceedings of a case by an applicant for patent (§ 1.41(b)) or an assignee of the entire interest of the applicant, or the owner of the entire interest of a patent. A power of attorney to the patent practitioners associated with a Customer Number will be treated as a request to revoke any powers of attorney previously given. Fewer than all of the applicants (or fewer than all of the assignees of the entire interest of the applicant or, in a reexamination proceeding, fewer than all the owners of the entire interest of a patent) may only revoke the power of attorney upon a showing of sufficient cause, and payment of the petition fee set forth in § 1.17(f). A patent practitioner will be notified of the revocation of the power of attorney. Where power of attorney is given to the patent practitioners associated with a Customer Number (§ 1.32(c)(2)), the practitioners so appointed will also be notified of the revocation of the power of attorney when the power of attorney to all of the practitioners associated with the Customer Number is revoked. The notice of revocation will be mailed to the correspondence address for the application (§ 1.33) in effect before the revocation. An assignment will not of itself operate as a revocation of a power previously given, but the assignee of the entire interest of the applicant may revoke previous powers of attorney and give another power of attorney of the assignee's own selection as provided in § 1.32(b).

* * * * *

10. Section 1.78 is amended by revising paragraphs (a)(2)(i) and (a)(5)(iv) to read as follows:

§ 1.78 Claiming benefit of earlier filing date and cross-references to other applications.

(a) * * *

(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application, or international application designating the United States of America, claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14).

* * * * *

(5) * * *

(iv) If the prior-filed provisional application was filed in a language other than English and both an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application, applicant will be notified and given a period of time within which to file, in the provisional application, an English-language translation of the non-English-language prior-filed provisional application and a statement that the translation is accurate. If the notice is mailed in a pending nonprovisional application, a timely reply to such a notice must include the filing of a confirmation in the nonprovisional application that the translation and statement were filed in the provisional application or the nonprovisional application will be abandoned.

* * * * *

PART 3—ASSIGNMENT, RECORDING AND RIGHTS OF ASSIGNEE

11. The authority citation for 37 CFR part 3 continues to read as follows:

Authority: 15 U.S.C. 1123; 35 U.S.C. 2(b)(2).

12. Section 3.28 is revised to read as follows:

§ 3.28 Requests for recording.

Each document submitted to the Office for recording must include a single cover sheet (as specified in § 3.31) referring either to those patent applications and patents, or to those trademark applications and registrations, against which the document is to be recorded. If a document to be recorded includes interests in, or transactions involving, both patents and trademarks, then separate patent and trademark cover sheets, each accompanied by a copy of the document to be recorded, should be submitted. If a document to be recorded is not accompanied by a completed cover sheet, the document and the incomplete cover sheet will be returned pursuant to § 3.51 for proper completion, in which case the document and a completed cover sheet should be resubmitted.

13. Section 3.31 is amended by revising paragraph (a)(7)(i) to read as follows:

§ 3.31 Cover sheet content.

(a) * * *

(7) * * *

(i) Place a symbol comprised of letters, numbers, and/or punctuation marks between forward slash marks (*e.g.* /Thomas O'Malley III/) in the signature block on the electronic submission; or

* * * * *

14. Section 3.73 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 3.73 Establishing right of assignee to take action.

* * * * *

(b)(1) * * *

(i) Documentary evidence of a chain of title from the original owner to the assignee (*e.g.*, copy of an executed assignment). For trademark matters only, the documents submitted to establish ownership may be required to be recorded pursuant to § 3.11 in the assignment records of the Office as a condition to permitting the assignee to take action in a matter pending before the Office. For patent matters only, the submission of the documentary evidence must be accompanied by a statement affirming that the documentary evidence of the chain of title from the original owner to the assignee was submitted for recordation pursuant to § 3.11; or

* * * * *

PART 10—REPRESENTATION OF OTHERS BEFORE THE PATENT AND TRADEMARK OFFICE

15. The authority citation for 37 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 500; 15 U.S.C. 1123; 35 U.S.C. 2, 6, 32, 41.

16. Section 10.112 is amended by revising paragraph (a) to read as follows:

§ 10.112 Preserving identity of funds and property of client.

(a) All funds of clients paid to a practitioner or a practitioner's firm, other than advances for costs and expenses, shall be deposited in one or more identifiable bank accounts maintained in the United States or, in the case of a practitioner having an office in a foreign country or registered under § 11.6(c), in the United States or the foreign country.

* * * * *

Dated: April 1, 2005.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 05–6931 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 2 and 7

[Docket No. 2005–T–056]

RIN 0651–AB88

Requirements To Receive a Reduced Fee for Filing an Application Through the Trademark Electronic Application System

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rule making.

SUMMARY: The United States Patent and Trademark Office (Office) proposes to amend its rules to permit an applicant using the Trademark Electronic Application System (TEAS) to file a trademark or service mark application for registration on the Principal Register under section 1 and/or 44 of the Act to pay a reduced fee under certain circumstances. The Office proposes to offer a reduced fee to TEAS applicants if the application meets certain filing requirements beyond those required to receive a filing date. The applicant must also respond to Office actions within two months of the mailing date, file communications regarding the application through TEAS, and agree to receive communications concerning the application by electronic mail (e-mail). TEAS applications that qualify for the reduced fee option will be referred to as ''TEAS Plus'' applications. The reduced fee option will not apply to applications filed pursuant to section 66(a) of the Act because they cannot be filed through TEAS.

DATES: Comments must be received by May 9, 2005 to ensure consideration.

ADDRESSES: Submit comments by e-mail to: *TEASPLUS.comments@uspto.gov*.

Written comments may be submitted by mail to: Commissioner for Trademarks, P.O. Box 1451, Alexandria, Virginia 22313–1451, attention Cheryl L. Black; or by hand delivery to: Trademark Assistance Center, Concourse Level, James Madison Building-East Wing, 600 Dulany Street, Alexandria, Virginia, attention Cheryl L. Black.

FOR FURTHER INFORMATION CONTACT: Cheryl L. Black, Office of the Commissioner for Trademarks, by telephone at (571) 272–9565, by e-mail to *cheryl.black@uspto.gov*, or by facsimile at (571) 273–9565.

SUPPLEMENTARY INFORMATION: The Office proposes to offer a reduced fee to TEAS applicants using the Office's

Trademark/Servicemark Application, Principal Register form if: (1) The application meets certain additional filing requirements; (2) the applicant responds to Office actions within two months of the mailing date; (3) the applicant files certain communications regarding the application through TEAS; and (4) the applicant agrees to accept communications concerning the application by e-mail. The application will be referred to as a TEAS Plus application. The applicant must pay an additional fee set forth in proposed § 2.6(a)(1)(iv) if, at any time during examination of the TEAS Plus application, the Office determines that: (1) The application does not meet the filing requirements of proposed § 2.22(a); (2) the applicant did not file a complete response to an Office action; (3) the applicant's response to an Office action was not filed within two months of the mailing date; (4) the applicant filed one of the communications listed in proposed § 2.23(a) on paper; or (5) the applicant refused to receive correspondence from the Office by e-mail.

References in this notice to ''the Act,'' ''the Trademark Act,'' or ''the statute'' refer to the Trademark Act of 1946, 15 U.S.C. 1051 *et seq.*, as amended.

Background

This proposed rule is in accordance with the Consolidated Appropriations Act, 2005, Public Law 108–447 (Appropriations Act), enacted on December 8, 2004. The Appropriations Act amends the Trademark Act of 1946 to require that:

[D]uring fiscal years 2005 and 2006, under such conditions as may be prescribed by the Director, the fee under § 31(a) of the Trademark Act for (1) the filing of a paper application for trademark registration shall be $375; (2) the filing of an electronic application shall be $325; and (3) the filing of an electronic application meeting certain additional requirements prescribed by the Director shall be $275.

Effective January 31, 2005, application filing fees were amended in accordance with the provisions of 15 U.S.C. 1113(a) as amended by the Appropriations Act. A notice of final rule making was published at 70 FR 2952 (January 19, 2005). The filing fee for paper applications filed under section 1 or 44 of the Trademark Act is now $375.00 per class, and the filing fee for TEAS applications filed pursuant to section 1 or 44 of the Trademark Act is now $325.00 per class.

Requirements for a TEAS Plus Trademark Application

This proposed rule sets forth additional requirements for TEAS applications to be eligible for a reduced fee of $275.00 per class. The rule only applies to TEAS applications filed on the Office's Trademark/Servicemark Application, Principal Register form. Under proposed § 2.22, to obtain a reduced filing fee an application must include the following:

(1) The applicant's name and address;

(2) The applicant's legal entity;

(3) The citizenship of an individual applicant, or the state or country of incorporation or organization of a juristic applicant;

(4) If applicant is a partnership, the names and citizenship of applicant's general partners;

(5) A name and address for correspondence;

(6) An e-mail address for correspondence and an authorization for the Office to send correspondence concerning the application to the applicant or applicant's attorney by e-mail;

(7) One or more basis or bases for filing under sections 1 and/or 44 of the Act that satisfy all the requirements of § 2.34;

(8) Correctly classified goods and/or services, with an identification of goods and/or services from the Office's Acceptable Identification of Goods and Services Manual (Goods and Services Manual). In an application based on section 44 of the Act, the scope of goods and/or services covered by the section 44 basis may not exceed the scope of goods and/or services in the foreign application or registration;

(9) If the application contains goods and/or services in more than one class, compliance with § 2.86;

(10) A filing fee for each class of goods and/or services as required by § 2.6(a)(iii);

(11) A verified statement that meets the requirements of § 2.33, dated and signed by a person properly authorized to sign on behalf of the applicant pursuant to § 2.33(a);

(12) A drawing of the mark that meets the requirements of §§ 2.51 and 2.52;

(13) If the mark is in standard characters, a mark comprised of only characters in the USPTO standard character set available at: *http://www.uspto.gov/teas/standardCharacterSet.html*;

(14) If the mark is not in standard characters, a description of the mark;

(15) If the mark includes non-English wording, an English translation of that wording;

(16) If the mark includes non-Latin characters, a transliteration of those characters;

(17) If the mark includes an individual's name or portrait, either (1) a statement that identifies the living individual whose name and likeness the mark comprises and written consent of the individual, or (2) a statement that the name or portrait does not identify a living individual (*see* section 2(c) of the Act);

(18) If the applicant owns one or more registrations for the same mark, a claim of ownership of the registration(s) identified by the U.S. registration number(s), pursuant to § 2.36; and

(19) If the application is a concurrent use application, compliance with § 2.42.

In addition to the TEAS Plus filing requirements in proposed § 2.22, an applicant filing a TEAS Plus application must comply with the examination requirements set forth in proposed § 2.23: (1) File response(s) to Office action(s), request(s) to change the correspondence address, appointment, revocation or withdrawal of power of attorney, appointment or revocation of domestic representative, and preliminary amendment(s) through TEAS; (2) respond completely to Office actions within two months of the mailing date (except that a notice of appeal from a final action under section 20 of the Act may be filed within six months of the mailing date of the Office action); (3) agree to receive communications from the Office by e-mail; and (4) for applications with a section 1(b) basis, file any amendment to allege use, statement of use, request for extension of time to file a statement of use, or request to delete the section 1(b) basis through TEAS.

Discussion of Specific Rules

The Office proposes to add § 2.22, and to amend §§ 2.6, 2.23, 2.53, 2.62 and 7.25.

The Office proposes to revise § 2.6(a)(1) to more clearly enumerate the application filing fee options and to add new subsections (iii) and (iv). Proposed § 2.6(a)(1)(iii) adds a new fee for filing a TEAS Plus application under proposed § 2.22.

Proposed § 2.6(a)(1)(iv) adds a new fee in the amount of $50.00 per class for processing a TEAS Plus application filed under proposed § 2.22 that does not meet the requirements of proposed §§ 2.22 and 2.23. The additional fee is the difference between the filing fee for a TEAS application and the reduced fee for a TEAS Plus application.

The Office proposes to add a new § 2.22. Proposed § 2.22(a) sets forth the requirements for filing a TEAS Plus

application. To file a TEAS Plus application, an applicant must use the electronic Trademark/Servicemark Application, Principal Register form, accessed from *http://teas.uspto.gov,* and choose the reduced fee option presented as the TEAS Plus form on the initial screen.

For most of the filing requirements in proposed § 2.22(a), an applicant must enter the information in the appropriate data fields on the TEAS Plus form. To enter the identification of goods and/or services, an applicant will be instructed to enter search terms appropriate for the desired goods and/or services within the identified field on the TEAS Plus form. The system will then retrieve relevant entries from the Goods and Services Manual, and the applicant must select one or more of the entries to add to the TEAS Plus form. The Goods and Services Manual currently available on the Office's Web site at: *http://www.uspto.gov,* contains more than 20,000 listings of acceptable identifications of goods and services.

Proposed § 2.22(b) provides that if a TEAS Plus application does not meet the filing requirements of paragraph (a), the applicant must pay the fee required by proposed § 2.6(a)(1)(iv). The application will retain its original filing date if the initial application met the minimum application filing requirements of § 2.21. Proposed § 2.22(b) applies where an application is initially designated as a TEAS Plus application, but upon examination, the Office determines that the application did not meet the TEAS Plus filing requirements.

Proposed § 2.22(c) lists the types of TEAS applications that are not eligible for the reduced fee option under paragraph (a). Applications for certification marks, collective marks, collective membership marks and applications for registration on the Supplemental Register cannot be filed as TEAS Plus applications because the Office does not have TEAS Plus forms for these types of applications.

The Office proposes to revise current § 2.23. This section discusses the Office practice of assigning a serial number to applications and informing the applicant of the serial number and filing date. The Office will continue this practice but will delete this administrative information from the rules of practice. Such administrative practices are generally set forth in the Office's Trademark Manual of Examining Procedure.

The Office proposes to add new subsections §§ 2.23(a) and 2.23(b). Proposed § 2.23(a) sets forth additional examination requirements for a TEAS Plus application. Proposed § 2.23(b) requires payment of the additional fee set forth in proposed § 2.6(a)(1)(iv), if a TEAS Plus applicant fails to meet any of the requirements in proposed § 2.23(a) during the pendency of the application.

The Office proposes to redesignate § 2.53(a) as § 2.53(a)(2), and to amend the rule to state that the requirement applies to standard character drawings filed with all TEAS submissions except TEAS Plus applications. The Office proposes to add new paragraph § 2.53(a)(1) to set forth the requirements for standard character drawings filed with TEAS Plus applications. Proposed § 2.53(a)(1) provides that a mark in standard characters in a TEAS Plus application must be entered in the appropriate field on the TEAS Plus form. A TEAS Plus applicant will not have the option of attaching a digitized image of a mark in standard characters. The applicant must enter a mark comprised of only standard characters from the Office's standard character set, currently available at: *http://www.uspto.gov/teas/standardCharacterSet.html,* and the Office will generate a digitized image of the mark in .jpg format and attach the image to the TEAS Plus form.

The Office proposes to amend § 2.62 by rewording the current language to simplify the rule and by redesignating it as § 2.62(a). The Office also proposes to add § 2.62(b), stating that to maintain a TEAS Plus application, an applicant's response must: (1) address all issues raised in the Office action; and (2) be filed within two months of the mailing date of the Office action. If the applicant does not file a complete response to an Office action within two months of the mailing date, the application will lose its TEAS Plus status and the applicant must pay the additional fee required by proposed § 2.6(a)(1)(iv). This is consistent with proposed § 2.23, discussed above. The applicant must respond to the Office action within six months of the mailing date to avoid abandonment. 37 CFR 2.65.

When issuing an Office action in a TEAS Plus application, the examining attorney will require that the applicant respond to all issues within two months of the mailing date through TEAS or respond within six months and include the additional $50.00 per class fee with the response.

The Office proposes to amend § 7.25(a) to add proposed §§ 2.22 and 2.23 to the list of rules in part 2 of this chapter that do not apply to requests for extension of protection of international registrations to the United States. A request for extension of protection to the United States is not eligible for examination as a TEAS Plus application because it cannot be filed directly through TEAS.

Rule Making Requirements

Executive Order 13132: This rule making does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866: This rule making has been determined not to be significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Regulatory Flexibility Act: The Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule changes will not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)).

The current filing fees for trademark applications are $375.00 per class for applications filed on paper and $325.00 per class for trademark applications filed electronically through the Trademark Electronic Application System (TEAS). The sole purpose of the proposed rules is to provide applicants that electronically file trademark applications through TEAS with the added option of filing the application for a reduced fee of $275.00 per class. Applications filed under the reduced fee option will be referred to as TEAS Plus applications.

In fiscal year 2004, the agency received approximately 245,000 trademark applications. Of that total, the Office estimates that 179,000 trademark applications were filed through TEAS and that 66,000 of the TEAS filers were small entities. The Office projects that it will receive approximately 264,000 trademark applications in fiscal year 2005, that an estimated 211,000 will be filed through TEAS, and that approximately 42,000 TEAS filers will take advantage of the reduced fee option. The Office estimates that of the projected 42,000 TEAS Plus applications filed during fiscal year 2005, approximately 15,500 will be filed by small entities.

Because the proposed rule merely provides all trademark applicants, including small businesses, with additional benefits at a reduced cost, the agency certifies that any economic impact on small entities affected by the proposed rule will not be significant.

Paperwork Reduction Act: The proposed rules are in conformity with the requirements of the Paperwork

Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*).

Notwithstanding any other provision of law, no person is required to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

This proposed rule involves collections of information requirements subject to the PRA. The collections of information involved in this rule have been reviewed and previously approved by OMB under the following control numbers: 0651–0009 and 0651–0050. This rule includes provisions that affect the fee structures for approved information collection activities under 0651–0009 Trademark Processing. Changes to the fee structures, as set forth in this rule, will be submitted to the Office of Management and Budget for review and approval at the time of renewal of 0651–0009.

Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency, (2) the accuracy of the agency's estimate of the burden, (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 to respondents.

Send comments regarding any other aspect of this data collection, including suggestions for reducing the burden, to the Commissioner for Trademarks, P.O. Box 1451, Alexandria, VA 22313–1451 (Attn: Ari Leifman), and to the Office of Information and Regulatory Affairs, OMB, 725 17th Street, NW., Washington, DC 20230 (Attn: PTO Desk Officer).

List of Subjects

37 CFR Part 2

Administrative practice and procedure, Trademarks.

37 CFR Part 7

Administrative practice and procedure, Trademarks.

For the reasons given in the preamble and under the authority contained in 35 U.S.C. 2 and 15 U.S.C. 1123, as amended, the Office proposes to amend part 2 and part 7 of title 37 as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

1. The authority citation for 37 CFR part 2 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

2. Amend § 2.6 to revise paragraph (a)(1) to read as follows:

§ 2.6 Trademark fees

* * * * *

(a) * * *

(1) Application filing fees.

(i) For filing an application on paper, per class—$375.00

(ii) For filing an application through TEAS, per class—$325.00

(iii) For filing a TEAS Plus application under § 2.22, per class—$275.00

(iv) Additional processing fee under §§ 2.22(b) and 2.23(b), per class—$50.00

* * * * *

3. Add § 2.22, to read as follows:

§ 2.22 Filing requirements for a TEAS Plus application.

(a) A trademark/service mark application for registration on the Principal Register under section 1 and/or section 44 of the Act will be entitled to a reduced filing fee under § 2.6(a)(1)(iii) if it is filed through TEAS and includes:

(1) The applicant's name and address;

(2) The applicant's legal entity;

(3) The citizenship of an individual applicant, or the state or country of incorporation or organization of a juristic applicant;

(4) If the applicant is a partnership, the names and citizenship of the applicant's general partners;

(5) A name and address for correspondence;

(6) An e-mail address for correspondence, and an authorization for the Office to send correspondence concerning the application to the applicant or applicant's attorney by e-mail;

(7) One or more bases for filing that satisfy all the requirements of § 2.34;

(8) Correctly classified goods and/or services, with an identification of goods and/or services from the Office's *Acceptable Identification of Goods and Services Manual,* available through the TEAS form and at *http://www.uspto.gov.* In an application based on section 44 of the Act, the scope of the goods and/or services covered by the section 44 basis may not exceed the scope of the goods and/or services in the foreign application or registration;

(9) If the application contains goods and/or services in more than one class, compliance with § 2.86;

(10) A filing fee for each class of goods and/or services, as required by § 2.6(a)(1)(iii);

(11) A verified statement that meets the requirements of § 2.33, dated and signed by a person properly authorized to sign on behalf of the applicant pursuant to § 2.33(a);

(12) A drawing of the mark that meets the requirements of §§ 2.51 and 2.52;

(13) If the mark is in standard characters, a mark comprised of only characters in the USPTO standard character set available at: *http://www.uspto.gov/teas/standardCharacterSet.html;*

(14) If the mark is not in standard characters, a description of the mark;

(15) If the mark includes non-English wording, an English translation of that wording;

(16) If the mark includes non-Latin characters, a transliteration of those characters;

(17) If the mark includes an individual's name or portrait, either a statement that identifies the living individual whose name or likeness the mark comprises and written consent of the individual, or a statement that the name or portrait does not identify a living individual (see section 2(c) of the Act);

(18) If the applicant owns one or more registrations for the same mark, a claim of ownership of the registration(s) identified by the U.S. registration number(s), pursuant to § 2.36; and

(19) If the application is a concurrent use application, compliance with § 2.42.

(b) If an application does not meet the requirements of paragraph (a) of this section at the time of filing, the applicant must pay the fee required by § 2.6(a)(1)(iv). If the application as filed meets the filing date requirements of § 2.21, the application will retain its original filing date.

(c) The following types of applications cannot be filed as TEAS Plus applications under paragraph (a) of this section:

(1) Applications for certification marks (*see* § 2.45);

(2) Applications for collective marks (*see* § 2.44);

(3) Applications for collective membership marks (*see* § 2.44); and

(4) Applications for registration on the Supplemental Register (*see* § 2.47).

4. Revise § 2.23 to read as follows:

§ 2.23 Additional requirements for TEAS Plus application.

(a) In addition to the filing requirements under § 2.22(a), the applicant must:

(1) File the following communications through TEAS:

(i) Responses to Office actions;

(ii) Requests to change the correspondence address and owner's address;

(iii) Appointment and revocation of power of attorney;

(iv) Withdrawal of attorney;

(v) Appointment and revocation of domestic representative; and

(vi) Preliminary amendments;

(2) Respond to Office actions, including requests for reconsideration of a final Office action, within two months of the mailing date, except that a notice of appeal under section 20 of the Act may be filed within six months of the mailing date. Responses must address all issues raised in the Office action;

(3) Receive communications from the Office by electronic mail; and

(4) File the following additional communications through TEAS *if the application has a section 1(b) basis:*

(i) Amendment to allege use under section 1(c) of the Act or statement of use under section 1(d) of the Act;

(ii) Request(s) for extensions of time to file a statement of use under section 1(d) of the Act; and

(iii) Request to delete section 1(b) basis.

(b) If an application does not meet the requirements of paragraph (a) of this section, the applicant must pay the fee required by § 2.6(a)(1)(iv).

5. Amend § 2.53 to revise paragraph (a) to read as follows:

§ 2.53 Requirements for drawings filed through the TEAS.

* * * * *

(a)(1) *Standard character drawings in TEAS Plus applications filed under § 2.22:* If an applicant is filing a standard character drawing, the applicant must enter the mark in the appropriate field.

(2) *Standard character drawings in all other TEAS submissions:* If an applicant is filing a standard character drawing, the applicant must enter the mark in the appropriate field or attach a digitized image of the mark to the TEAS submission that meets the requirements of paragraph (c) of this section.

* * * * *

6. Revise § 2.62 to read as follows:

§ 2.62 Period for response.

(a) To avoid abandonment, an applicant has six months from the date of mailing to respond to an Office action (*see* § 2.65).

(b) In a TEAS Plus application filed under § 2.22, an applicant must file a response that addresses all issues raised in an Office action within two months of the mailing date (except that a notice of appeal under section 20 of the Act may be filed within six months of the mailing date). If a response is incomplete or is not received within two months of the mailing date of the Office action, the applicant must pay the fee required by § 2.6(a)(1)(iv).

PART 7—RULES OF PRACTICE IN FILINGS PURSUANT TO THE PROTOCOL RELATING TO THE MADRID AGREEMENT CONCERNING THE INTERNATIONAL REGISTRATION OF MARK

7. The authority citation for 37 CFR part 7 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

8. Amend § 7.25 to revise paragraph (a) to read as follows:

§ 7.25 Sections of part 2 applicable to extension of protection.

(a) Except for §§ 2.22–2.23, 2.130–2.131, 2,160–2.166, 2.168, 2.173, 2.175, 2.181–2.186 and 2.197, all sections in part 2 and all sections in part 10 of this chapter shall apply to an extension of protection of an international registration to the United States, including sections related to proceedings before the Trademark Trial and Appeal Board, unless otherwise stated.

* * * * *

Dated: April 1, 2005.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 05–6947 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R06–OAR–2004–TX–0014; FRL–7896–3]

Approval and Promulgation of Air Quality Implementation Plans; Texas; Rules for the Control of Highly Reactive Volatile Organic Compounds in the Houston/Galveston (HGA) Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: We are proposing to approve rules adopted by the Texas Commission on Environmental Quality (TCEQ) for the control of highly reactive Volatile Organic Compounds (HRVOCs) in the Houston/Galveston ozone nonattainment area. These rules for the control of HRVOCs supplement Texas' existing rules for controlling volatile organic compounds (VOC) by providing more extensive requirements for certain equipment in HRVOC service. These additional controls of HRVOC emissions will help to attain and maintain the national ambient air quality standards (NAAQS) for ozone in HGA. Inhaling even low levels of ozone can trigger a variety of health problems including chest pains, coughing, nausea, throat irritation, and congestion. It can also worsen bronchitis, asthma and reduce lung capacity.

DATES: Comments must be received on or before May 9, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID No. R06–OAR–2004–TX–0014, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- Agency Web site: *http://docket.epa.gov/rmepub/* Regional Material in EDocket (RME), EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.
- U.S. EPA Region 6 ''Contact Us'' Web site: *http://epa.gov/region6/r6coment.htm*. Please click on ''6PD'' (Multimedia) and select ''Air'' before submitting comments.
- E-mail: Mr. Thomas Diggs at *diggs.thomas@epa.gov*. Please also cc the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.
- Fax: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), at fax number 214–665–7263.
- Mail: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.
- Hand or Courier Delivery: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Regional Material in EDocket (RME) ID No. R06–OAR–2004–TX–0014. EPA's policy is that all comments received will be included in the public file without change, and may be made available online at *http://docket.epa.gov/rmepub/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information

the disclosure of which is restricted by statute. Do not submit information through Regional Material in EDocket (RME), regulations.gov, or e-mail if you believe that it is CBI or otherwise protected from disclosure. The EPA RME website and the Federal regulations.gov are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public file and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. Guidance on preparing comments is given in the **SUPPLEMENTARY INFORMATION** section of this document under the General Information heading.

Docket: All documents in the electronic docket are listed in the Regional Material in EDocket (RME) index at *http://docket.epa.gov/rmepub/*. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in the official file which is available at the Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at (214) 665–7253 to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cent per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

The State submittal is also available for public inspection at the State Air Agency listed below during official business hours by appointment:

Texas Commission on Environmental Quailty, Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: Guy R. Donaldson, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7242; fax number 214–665–7263; e-mail address *donaldson.guy@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

What Action Are We Taking?

We are proposing to approve portions of revisions to the SIP submitted by the State of Texas in letters dated January 23, 2003, November 7, 2003, March 26, 2004, and December 17, 2004. We are approving the portions of these revisions that pertain to the control of HRVOCs. These rules, which are codified at 30 TAC Chapter 115, Subchapter H, apply to facilities in the Houston/Galveston ozone nonattainment area. We are also proposing to approve the associated revisions to the definitions section of 30 Texas Administrative Code (TAC) 115.10. We are not proposing any action, at this time, regarding the other revisions that were submitted in these letters. We are approving these additional rules pursuant to sections 110, 116 and part D of the Federal Clean Air Act (the Act).

What General Requirements Do the Rules Establish?

The rules establish improved monitoring requirements for flares, cooling towers, process vents and pressure relief valves. For sources in Harris county, the source monitoring provides the information necessary for sources to demonstrate compliance with annual and short term caps on emissions of HRVOCs from cooling tower, process vents, pressure relief devices and flares. The annual cap for each facility will be established based on processes outlined in 30 TAC chapter 101. The short term cap is 1200 lbs/hr.

Because of the difficulty in their quantification, fugitive emissions are not included in the long and short term cap. Instead, the current work practice rules have been made more comprehensive and more stringent to achieve additional reduction in HRVOCs.

Why Are We Approving These Rules?

The addition of these rules for the control of HRVOCs will supplement Texas' existing rules controlling volatile organic compounds (VOC) and provide improvements to the Texas SIP's VOC Reasonably Available Control Technology (RACT) rules. These additional controls of HRVOC emissions will help to attain and maintain the national ambient air quality standards (NAAQS) for ozone in HGA. Today's proposal, when finally approved, will make the revised regulations Federally enforceable.

What Are Highly Reactive VOCs?

First, Volatile Organic Compounds are a class of compounds that react in the atmosphere with oxides of nitrogen and oxygen in the presence of sunlight to form ozone. HRVOC is a term used to refer to chemicals that because of their very high propensity to form ozone have been targeted for additional control beyond the level of control that has been established for controlling VOCs in general. These HRVOCs have been found to contribute a disproportionate amount to the formation of ozone in the HGA. Further, ambient measurements from both airplanes and ground based monitors have shown that current emissions estimates for HRVOCs are substantially underestimated. Therefore, there is a need to improve the emissions estimates of HRVOCs through better source monitoring.

HRVOCs have been defined in chapter 115.10 as:

In Harris County, one or more of the following volatile organic compounds (VOCs): 1,3-butadiene; all isomers of butene (*e.g.*, isobutene (2-methylpropene or isobutylene), alpha-butylene (ethylethylene), and beta-butylene (dimethylethylene, including both cis- and trans-isomers)); ethylene; and propylene.

In Brazoria, Chambers, Fort Bend, Galveston, Liberty, Montgomery and Waller Counties, one or more of the following VOCs: ethylene and propylene.

What Processes Will Be Impacted by These Rules?

TCEQ has targeted the following emission sources with these rules: Flares, process vents, cooling tower heat exchange systems and fugitive emissions. These sources are believed to generate the greatest amount of HRVOC emissions. Also, flares, cooling towers and fugitive emissions are believed to

suffer the greatest error in reported emissions. The improved source monitoring requirements included in the rules will greatly enhance the accuracy of the source emissions estimates.

What Are the Requirements for Flares?

Flares are used in a wide variety of applications both for the control of continuous vent emissions and for the control of intermittent emissions during start up, shutdowns and malfunctions. The ability of flares to safely handle a wide range of flow rates and chemicals makes them a popular choice for vent gas disposal. Because flares are not enclosed combustion devices, it is extremely difficult to measure the exhaust emissions from flares. EPA has established requirements for the proper operation of flares for its New Source Performance Standards at 40 Code of Federal Regulations (CFR) 60.18. Texas has adopted, by reference, these performance requirements for flares in HRVOC service. The requirements establish limits for the minimum heating value for the inlet gas to a flare and for maximum gas velocity at the flare tip.

In addition, the Texas rules establish flow and composition monitoring requirements for flares that facilities will use to show compliance with the flare operation requirements of 40 CFR 60.18. Also, using the flow data and an assumed destruction efficiency for a properly operated flare, a company can estimate the HRVOC emission rate to be used for determining compliance with the short and long term caps. Flares in compliance with 40 CFR 60.18 are allowed to assume a 98% destruction efficiency for most VOCs and a 99% destruction efficiency for ethylene and propylene. Flares not operated in compliance with 40 CFR 60.18 are required to assume a destruction efficiency of 93%. Texas has based these assumed destruction efficiencies on EPA studies of flare destruction efficiencies.

For flares that are used as a continuous control device, the monitoring requirements call for continuous flow and hydrocarbon monitoring of the streams being sent to the flare. For flares that are used more intermittently such as flares for control of loading operations, emergency flares or flares used only for control during start up/shutdown and maintenance, the Texas rules allow various alternative practices that are described in the rule. We have reviewed the monitoring requirements for flares and believe they will be adequate to establish compliance with the requirements of 40 CFR 60.18, the annual cap and the short term cap. For a more complete description of the requirements, see the technical support document for this action available in the RME.

What Are the Monitoring Requirements for Cooling Towers?

Facilities are required to continuously monitor the flow and concentration of VOCs to cooling towers. The samples must be collected before the water comes in contact with the atmosphere and must be taken in a location that insures the rate all of the HRVOCs going into the cooling tower is measured. Streams containing only non-highly reactive VOCs are not required to be sampled. If the concentration in the stream exceeds 50ppb total VOCs, the company is required to collect an additional sample to determine speciated and total HRVOC. These additional samples must be taken each day until the concentration of strippable VOC is reduced below 50 ppb. Cooling towers with capacities less than 8000 gallons/minute are required to monitor flow continuously, but only have to take samples at least twice per week with an interval of at least 48 hours between samples.

EPA has reviewed the monitoring requirements for cooling tower heat exchange systems and believes them sufficient to demonstrate compliance with the annual and short term cap. For a more complete description of the cooling tower requirements, see the technical support document for this action available in the RME.

What Are the Monitoring Requirements for Process Vents?

For process vents, facilities are required to establish a maximum potential emission rate using a performance test. During the performance test, a process parameter or parameters is to be identified that is affected by the emission rate from the process vent. The performance test must establish an operational limit for the process parameter(s). For every hour the process parameter(s) remains within it its operational limit, a facility would report the maximum potential emission rate for determining compliance with the annual and short term cap. Instead of assuming the maximum potential emission rate, sources have the option of installing continuous emission monitors and flow monitors to directly determine emissions. During time periods when the process parameter is outside the operational limit, companies must use engineering estimates and process information to determine emissions for compliance with the annual and short term caps. Texas has made clear that time periods outside the operational limits are violations of the rule. We have reviewed the monitoring requirements for vents and believe that they will provide sufficient information to determine compliance with the annual and short term caps. For a more complete description of the process vent requirements, see the technical support document for this action available in the RME.

What Is the Short Term Cap?

As mentioned previously, these rules establish a limit of 1200 lbs/hr of HRVOCs in Harris County. This limit has been established because recent modeling information indicates that releases of this magnitude in the right place at the right time can impact peak ozone levels 1–2 parts per billion.

What Are the Monitoring Requirements for Fugitive Emissions?

TCEQ, for a number of years, has implemented a leak detection and repair program as part of its program to control volatile organic compounds. When TCEQ determined that additional reductions of HRVOCs were needed, they established a number of new requirements for their leak detection and repair. These include among other things:

- Inclusion of connectors in the program.
- Inclusion of other non-traditional potential leak sources such as heat exchanger heads and man way covers.
- Elimination of allowances for skipping leak detection periods for valves.
- Requirement for third party audits to help insure that effective leak survey and repairs are conducted.
- Requirement that ''extra-ordinary'' efforts be used to repair valves before putting them on the delay of repair list.

EPA has reviewed the additional requirements for control of HRVOC fugitive emissions and determined these measures will result in additional emission reductions of HRVOCs.

Final Action: EPA is proposing to approve for inclusion in the federally enforceable State Implementation Plan the rules contained in 30 TAC Chapter 115, Subchapter H for the control of HRVOCs, first submitted in a letter dated January 23, 2003 and revised in letters dated November 7, 2003, March 26, 2004 and December 17, 2004. We are also approving revisions to the definition section in the State Rules 30 TAC 115.10 as the definitions are necessary for the implementation of the rules. We are proposing to approve these rules because they strengthen the

State Implementation Plan by improving monitoring requirements and reducing emissions of HRVOCs in the Houston area. EPA is proposing to approve these revisions to the HGA SIP under part D of the Act because they supplement and improve the existing SIP-approved VOC rules and they are consistent with the RACT requirements and guidance for ozone nonattainment areas. Reductions achieved by these rules will contribute to attainment of the ozone standard.

Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: March 24, 2005.

Lawrence Starfield,

Acting Regional Administrator, Region 6.

[FR Doc. 05–6944 Filed 4–6–05; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 70, No. 66

Thursday, April 7, 2005

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

Submission for OMB Review; Comment Request

April 4, 2005.

AGENCY: The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the 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 burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Housing Service

Title: RD 3550–28, ''Authorization Agreement for Preauthorization Payments''; RD 1951–65, ''Customer Initiated Payments (CIP)'' and RD 1951–66, ''Fedwire Worksheet''.

OMB Control Number: 0575–0184.

Summary of Collection: Rural Development (RD) uses electronic methods for receiving and processing loan payments and collections. These electronic collection methods are approved by Treasury and include Preauthorized Debits (PAD), Customer Initiated Payments (CIP), and FedWire. These electronic collection methods provide the borrower the ability to submit their loan payments the day prior to, or the day of their installment due date. To administer these electronic payment methods, RD will use approved agency forms for collecting financial institution routing information. Form RD 3550–28, Authorization Agreement for Preauthorized Payments, is prepared by the borrower to authorized RD to electronically collect regular loan payments from a borrower's account at a financial institution (FI) as preauthorized debits. Form RD 1951–65, is prepared by the borrower to enroll in CIP. CIP is an electronic collection method that enables borrowers to input payment data to a contract bank via telephone (touch tone and voice) or computer terminal. Form RD 1951–66, FedWire Worksheet, is completed by the borrower to establish an electronic FedWire format with their FI.

Need and Use of the Information: RD will request that borrowers make payments electronically via PAD, CIP, or FedWire. The information is collected only once unless the FI routing information changes. If the information were not collected, RD would be unable to collect loan payments electronically.

Description of Respondents: Not-for-profit institutions; business or other for-profit; State, local or tribal government.

Number of Respondents: 22,263.

Frequency of Responses: Reporting: on occasion.

Total Burden Hours: 11,132.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–6933 Filed 4–6–05; 8:45 am]

BILLING CODE 3410–XT–M

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 05–008N]

Codex Alimentarius Commission: Proposals for New Work and Priorities for the Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology

AGENCY: Office of the Under Secretary for Food Safety.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Office of the Under Secretary for Food Safety, United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA), United States Department of Health and Human Services, are sponsoring a public meeting on April 7, 2005, to provide information and receive public comments on the draft U.S. responses to Codex Circular Letter CL 2005/2–FBT: Proposals for new work to be undertaken by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Following approval at the 27th Session of the Codex Alimentarius Commission (from June 28 to July 3, 2004) to establish the Task Force, under the chairmanship of Japan, Codex agreed to solicit comments on the work that the Task Force ought to undertake and on the priorities for this new work.

DATES: The public meeting is scheduled for Thursday, April 7, 2005, from 1 p.m. to 4 p.m.

ADDRESSES: The public meeting will be held in Room 107–A of the Jamie L. Whitten Federal Building, USDA, 1400 Independence Avenue, SW., Washington, DC.

The Food Safety and Inspection Service (FSIS) invites interested persons to submit comments on this notice. Comments may be submitted by any of the following methods:

- Mail, including floppy disks or CD–ROMs, and hand- or courier-delivered items: Send to the FSIS Docket Clerk,

U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102, Cotton Annex, Washington, DC 20730. All comments received must include the Agency name and docket number 05–008N.

All comments submitted in response to this notice will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations/2005 Notices Index/index.asp.*

For Further Information About the Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology, Contact: Bernice Slutsky, Ph.D., Special Assistant to the Secretary for Biotechnology, Office of the Secretary, USDA, 1400 Independence Avenue, SW., Washington, DC 20250; telephone: (202) 690–0735; electronic mail: *bernice.slutsky@usda.gov.*

For Further Information About the Public Meeting Contact: Paulo Almeida, U.S. Codex Office, FSIS, Room 4861, South Building, 1400 Independence Avenue SW., Washington, DC 20250–3700; telephone: (202) 690–4042; facsimile: (202) 720–3157.

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius Commission (Codex) was established in 1962 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the major international standard-setting organization for protecting the health and economic interests of consumers and encouraging fair international trade in food. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to ensure that the world's food supply is sound, wholesome, free from adulteration, and correctly labeled. In the United States, USDA, FDA, and the Environmental Protection Agency (EPA) manage and carry out U.S. Codex activities.

The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology develops standards, guidelines, and recommendations for foods derived from modern biotechnology or for traits introduced into foods by modern biotechnology. The standards, guidelines, and recommendations are developed on the basis of scientific evidence and risk analysis, having regard, where appropriate, for other legitimate factors relevant to the health of consumers and the promotion of fair practices in the food trade.

Public Meeting

At the April 7, 2005, public meeting, attendees will have an opportunity to pose questions and offer comments on draft U.S. responses to Codex Circular Letter CL 2005/2–FBT: proposals for new work to be undertaken by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Written comments may be offered at the meeting or sent to Dr. Bernice Slutsky (*see* addresses). Written comments should state that they relate to activities of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Members of the public may access Circular Letter CL 2005/2–FBT at *http://www.fsis.usda.gov/PDF/Codex_cl05_02e.pdf.*

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and, in particular, minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2005_Notices_Index/index.asp.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to constituents and stakeholders. The update is communicated via Listserv, a free electronic mail subscription service for industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have asked to be included. The update is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an electronic mail subscription service that provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options in eight categories. Options range from recalls to export information to regulations, directives, and notices.

Customers can add or delete subscriptions themselves and have the option to protect their accounts with passwords.

Done at Washington, DC, on April 4, 2005.

F. Edward Scarbrough,

U.S. Manager for Codex Alimentarius.

[FR Doc. 05–7012 Filed 4–5–05; 11:36 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Action Affecting Export Privileges; Ghashim Group, Inc. d.b.a. KZ Results; Mazen Ghashim; MNC Group International, Inc. d.b.a. Wearform, d.b.a. Sports Zone, d.b.a. Soccer Zone

In the Matter of: Ghashim Group, Inc., d.b.a. KZ Results, 3334 Walnut Bend Lane, Houston, Texas 77042 and Mazen Ghashim, 10734 Overbrook Lane, Houston, Texas 77042, Respondents, and, MNC Group International, Inc., d.b.a. Wearform, d.b.a. Sports Zone, d.b.a. Soccer Zone, 3334 Walnut Bend Lane, Houston, Texas 77042; Related Person.

Order Temporarily Denying Export Privileges

Pursuant to Section 766.24 of the Export Administration Regulations (''EAR''),[1] the Bureau of Industry and Security (''BIS''), U.S. Department of Commerce, through its Office of Export Enforcement (''OEE''), has requested that I issue an Order temporarily denying the export privileges under the EAR of: Ghashim Group, Inc. doing business as (''d.b.a.'') KZ Results, 3334 Walnut Bend Lane, Houston, Texas 77042 (''Ghashim Group'') and Mazen Ghashim, 10734 Overbrook Lane, Houston, Texas 77042 (hereinafter collectively referred to as the ''Respondents''); and related person

[1] The EAR, which are currently codified at 15 CFR Parts 730–774 (2004), are issued under the Export Administration Act of 1979, as amended (50 U.S.C. app. 2401–2420) (2000) (the ''Act''). From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12,924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 CFR, 2000 Comp. 397 (2001)), continued the EAR in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701–1707 (2000)) (''IEEPA''). On November 13, 2000, the Act was reauthorized and remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13,222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), as extended by the Notice of August 6, 2004, (69 FR 48763 (August 10, 2004)), continued the Regulations in effect under the IEEPA.

MNC Group International, Inc. d.b.a. Wearform, d.b.a. Sports Zone, and d.b.a. Soccer Zone, 3334 Walnut Bend Lane, Houston, Texas 77042 (''MNC'').

In its request, BIS has presented evidence that shows that the Respondents conspired to cause items subject to the EAR to be illegally exported to Syria directly and via transshipments through the United Arab Emirates (''UAE'') with knowledge that violations of the EAR would occur, and that they took actions intended to evade the EAR.

Specifically, the evidence shows that, from January 2003 through May 2004 and in November 2004, Respondents conspired to export computers, items that are included on the Commerce Control List and controlled for national security and anti-terrorism purposes, from the United States to Syria without the required BIS export licenses. The evidence shows that, after learning of the EAR requirements governing the export of computers to Syria, Respondents developed and implemented a scheme to avoid the requirements of the EAR by causing these computers to be exported through the UAE to Syria. More specifically, between on or about February 26, 2003 and on or about December 13, 2003, Ghashim Group exported personal computers in fourteen shipments from the United States to Syria without the required BIS export licenses. The President of Ghashim Group is Mazen Ghashim.

After learning in December 2004 that shipments of computers to Syria require BIS export licenses, the Respondents began arranging shipments to Syria through the UAE. Between on or about January 7, 2004 and on or about May 21, 2004, Ghashim Group exported computers in eleven shipments from the United States to the UAE without BIS export licenses, knowing that they were destined for Syria. On or about June 16, 2004 and on or about June 22, 2004, Ghashim Group attempted to make two additional shipments through the UAE to Syria without the required BIS export licenses, but these shipments were detained by the U.S. Government.

Thereafter, the evidence shows that, in November 2004, after the May 14, 2004 implementation of the Syria Accountability and Lebanese Sovereignty Restoration Act,[2] Mazen Ghashim and MNC conspired to export garment samples, items that are subject to the EAR, from the United States to Syria without the required BIS export licenses. After May 14, 2004, export of all products of the United States except food and medicine to Syria was prohibited.[3]

MNC is a Related Person pursuant to 15 CFR § 766.23 because it is owned and operated by Mazen Ghashim, who is the President of Ghashim Group. It is also operated out of the same facilities as Ghashim Group, and is therefore affiliated with Mazen Ghashim and Ghashim Group.

I find the evidence presented by BIS demonstrates that the Respondents have conspired to commit acts that violate the EAR, that such violations have been deliberate and covert, and that there is a strong likelihood of future violations, particularly given the nature of the transactions and the elaborate steps that have been taken by Respondents to avoid detection by the U.S. Government while knowing that their actions were in violation of the EAR. As such, a Temporary Denial Order (''TDO'') is needed to give notice to persons and companies in the United States and abroad and that they should cease dealing with the Respondents in export transactions involving items subject to the EAR. Such a TDO is consistent with the public interest to preclude future violations of the EAR.

Accordingly, I find that a TDO naming Ghashim Group and Mazen Ghashim as Respondents, and MNC as a Related Person is necessary, in the public interest, to prevent an imminent violation of the EAR. This Order is issued on an ex parte basis without a hearing based upon BIS's showing of an imminent violation.

It is therefore ordered:

First, that the Respondents, Ghashim Group, Inc. d.b.a. KZ Results, 3334 Walnut Bend Lane, Houston, Texas 77042, its successors or assigns, and when acting for or on behalf of Ghashim Group, Inc., its officers, representatives, agents, or employees; Mazen Ghashim, 10734 Overbrook Lane, Houston, Texas 77042, and, when acting for or on behalf of Mazen Ghashim, his representatives, agents, assigns or employees; and Related Person MNC Group International, Inc. d.b.a. Wearform, d.b.a. Sports Zone, and d.b.a. Soccer Zone, 3334 Walnut Bend Lane, Houston, Texas 77042, its successors or assigns, and when acting for or on behalf of MNC Group International, Inc., its officers, representatives, agents, or employees (collectively, the ''Denied Persons''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Export Administration Regulations (''EAR''), or in any other activity subject to the EAR, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR.

Second, that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Persons any item subject to the EAR;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Persons of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Persons acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Persons of any item subject to the EAR that has been exported from the United States;

D. Obtain from the Denied Persons in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Persons, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Persons if such service involves the use of any item subject to the EAR that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, that, after notice and opportunity for comment as provided in

[2] Pub. L. No. 108–175 (2003); Exec. Order 13,338 of May 11, 2004, 69 FR 26,751 (May 13, 2004); 15 CFR Supplement No. 1 to Part 736, General Order No. 2(a).

[3] *Id.*

section 766.23 of the EAR, any other person, firm, corporation, or business organization related to any of the Respondents by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be made subject to the provisions of this Order.

Fourth, that this Order does not prohibit any export, reexport, or other transaction subject to the EAR where the only items involved that are subject to the EAR are the foreign-produced direct product of U.S.-origin technology.

In accordance with the provisions of Section 766.24(e) and Section 766.23(c) of the EAR, the Respondents and the Related Person, respectively, may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of Section 766.24(d) and Section 766.23(c) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. The Respondents and the Related Person may oppose a request to renew this Order by filing a written submission with the Assistant Secretary for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be served on the Respondents and the Related Person, and shall be published in the **Federal Register**.

This Order is effective upon date of publication in the **Federal Register** and shall remain in effect for 180 days.

Entered this 1st day of April, 2005.

Wendy L. Wysong,

Acting Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 05–6940 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–OT–M

DEPARTMENT OF COMMERCE

International Trade Administration

[C–351–504, A–351–503, A–122–503, A–570–502, A–821–801, A–823–801, A–570–001]

Iron Construction Castings From Brazil, Canada, and China; Solid Urea From Russia and Ukraine, and Potassium Permanganate From China: Extension of Time Limit for the Final Results of Sunset Reviews of Antidumping and Countervailing Duty Orders

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Martha Douthit at 202–482–5050, or Hilary Sadler, Esq. at 202–482–4340, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, DC 20230.

Background

On October 1, 2004, the Department initiated sunset reviews of the antidumping orders on Iron Construction Castings from Brazil, Canada, and China; Solid Urea from Russia and Ukraine, and Potassium Permanganate from China, and the countervailing duty order on Iron Construction Casting from Brazil. Based on adequate responses from the domestic interested parties and inadequate responses from respondent interested parties, the Department of Commerce (''the Department'') is conducting expedited sunset reviews of the antidumping duty orders on Iron Construction Castings from Brazil, Canada, and China, Solid Urea from Russia and Ukraine, and Potassium Permanganate from China, and the countervailing duty on Iron Construction Castings from Brazil. The Department's final results of these sunset reviews were originally scheduled for January 31, 2005. On December 17, 2004, the Department extended the final results of these reviews until March 31, 2005.

Extension of Time Limit for Final Results of Reviews

In accordance with section 751(c)(5)(B) of the Tariff Act of 1930, as amended (''the Act''), the U.S. Department of Commerce (''the Department'') may extend the period of time for making its final determination in a sunset review by not more than 90 days if it determines that the review is extraordinarily complicated. As set forth in 751(c)(5)(C)(v) of the Act, the Department may treat a sunset review as extraordinarily complicated if it is a review of a transition order, as is the case in these proceedings. The Department has determined, pursuant to section 751(c)(5)(C)(v) of the Act, that the sunset reviews of the antidumping duty orders on Iron Construction Casting from Brazil, Canada, and China, Solid Urea from Russia and Ukraine, Potassium Permanganate from China, and the countervailing duty order on Iron Construction Castings from Brazil, are extraordinarily complicated and require additional time for the Department to complete its analysis. Therefore, the Department will extend the deadlines in these proceedings and, as a result, intends to issue the final results of the sunset reviews on Iron Constructions Casting from Brazil, Canada, and China, Solid Urea from Russia, and Ukraine, and Potassium Permanganate from China, on or about Monday, May 2, 2005, 90 days from the original scheduled date of final results of review. This notice is issued and published in accordance with sections 751(c)(5)(B) and 751(c)(5)(C)(v) of the Act.

Dated: March 31, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–1610 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–602, A–588–602, A–570–814, A–583–605, A–549–807, A–475–703, A–588–707]

Carbon Steel Butt-Weld Pipe Fittings From Brazil, Japan, the People's Republic of China, Taiwan, and Thailand, and Granular Polytetrafluoroethylene Resin From Italy and Japan: Extension of Time Limit for the Final Results of Sunset Reviews of Antidumping Duty Orders

AGENCY: Import Administration, International Trade Administration, U.S. Department of Commerce.

DATES: *Effective Date:* April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Martha Douthit at 202–482–5050, or Hilary Sadler, Esq. at 202–482–4340, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, DC 20230.

Background

On December 1, 2004, the Department initiated sunset reviews of the

antidumping duty orders on Carbon Steel Butt-Weld Pipe Fittings from Brazil, Japan, the People's Republic of China, Taiwan, and Thailand, and Granular Polytetrafluoroethylene Resin from Italy and Japan. Based on adequate responses from the domestic interested parties and inadequate responses from respondent interested parties, the Department of Commerce (''the Department'') is conducting expedited sunset reviews of the antidumping duty orders on Carbon Steel Butt-Weld Pipe Fittings from Brazil, Japan, the People's Republic of China, Taiwan, and Thailand, and Granular Polytetrafluoroethylene Resin from Italy and Japan. The Department's final results of these sunset reviews are currently scheduled for March 31, 2005.

Extension of Time Limit for Final Results of Reviews

In accordance with section 751(c)(5)(B) of the Tariff Act of 1930, as amended (''the Act''), the U.S. Department of Commerce (''the Department'') may extend the period of time for making its final determination in a sunset review by not more than 90 days, if it determined that the review is extraordinarily complicated. As set forth in 751(c)(5)(C)(v) of the Act, the Department may treat a sunset review as extraordinarily complicated if it is a review of a transition order, as is the case in these proceedings. The Department has determined, pursuant to section 751(c)(5)(C)(v) of the Act, that the sunset reviews of the antidumping duty orders on Carbon Steel Butt-Weld Pipe Fittings from Brazil, Japan, the People's Republic of China, Taiwan, Thailand, and Granular Polytetrafluoroethylene Resin from Italy and Japan, are extraordinarily complicated and require additional time for the Department to complete its analysis. Therefore, the Department will extend the deadlines in these proceedings and, as a result, intends to issue the final results of the sunset reviews on Carbon Steel Weld-Pipe Fittings from Brazil, Japan, the People's Republic of China, Taiwan, and Thailand, and Granular Polytetrafluoroethylene Resin from Italy and Japan, on or about June 29, 2005, 90 days from the original scheduled date of final results of review.

This notice is issued and published in accordance with sections 751(c)(5)(B) and 751(c)(5)(C)(v) of the Act.

Dated: March 31, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–1609 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–822]

Notice of Rescission, in Part, of Antidumping Duty Administrative Review: Corrosion-Resistant Carbon Steel Flat Products From Canada

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Candice Kenney Weck or Sean Carey at (202) 482–0938 and (202) 482–3964, respectively; AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

The Department received timely requests for an administrative review of the antidumping duty order on corrosion-resistant carbon steel flat products from Canada, with respect to Dofasco Inc. (Dofasco), Impact Steel Canada, Ltd. (Impact Steel), and Stelco Inc. (Stelco). On September 22, 2004, the Department published the initiation of an administrative review of Dofasco, Impact Steel, and Stelco, covering the period August 1, 2003, through July 31, 2004. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part* (69 FR 56745). On November 12, 2004, Impact Steel timely withdrew its request for an administrative review. The request was the only request for an administrative review of Impact Steel.

Rescission, in Part, of the Administrative Review

Pursuant to the Department's regulations, the Department will rescind an administrative review ''if a party that requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review.'' *See* 19 CFR 351.213(d)(1). Since Impact Steel submitted a timely withdrawal of its request for review, and since this was the only request for a review of Impact Steel, the Department is rescinding its antidumping administrative review of Impact Steel in accordance with 19 CFR 351.213(d)(1). Based on this rescission, the administrative review of the antidumping duty order on corrosion-resistant carbon steel flat products from Canada covering the period August 1, 2003, through July 31, 2004, now covers the following companies: Dofasco and Stelco.

We are issuing and publishing this determination and notice in accordance with section 777(i) of the Act and 19 CFR 351.213(d)(4).

Dated: April 1, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–1615 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–816]

Corrosion Resistant Carbon Steel Flat Products From Korea: Extension of Time Limits for the Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Lyman Armstrong or Victoria Cho at (202) 482–3601 or (202) 482–5075 respectively, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave, NW., Washington, DC 20230.

Background

On September 22, 2004, the U.S. Department of Commerce (''Department'') published a notice of initiation of the administrative review of the antidumping duty order on corrosion resistant carbon steel flat products from Korea, covering the period August 1, 2003 to July 31, 2004 (69 FR 56745). The preliminary results of this review are currently due no later than May 3, 2005.

Extension of Time Limit of Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to make a preliminary determination within 245 days after the last day of the anniversary month of an order or finding for which

a review is requested. Section 751(a)(3)(A) of the Act further states that if it is not practicable to complete the review within the time period specified, the administering authority may extend the 245-day period to issue its preliminary results by up to 120 days.

We determine that completion of the preliminary results of this review within the 245-day period is not practicable for the following reasons. This review covers six companies, and to conduct the sales and cost analyses for each requires the Department to gather and analyze a significant amount of information pertaining to each company's sales practices, manufacturing costs and corporate relationships. In addition, the Department is analyzing issues related to scope exclusions of certain products. Given the number and complexity of issues in this case, and in accordance with section 751(a)(3)(A) of the Act, we are extending the time period for issuing the preliminary results of review to 365 days. Therefore, the preliminary results are now due no later than August 31, 2005. The final results continued to be due 120 days after publication of the preliminary results.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–1608 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–836]

Glycine From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request from Baoding Mantong Fine Chemistry Co., Ltd. (''Baoding Mantong''), the Department of Commerce (''the Department'') is conducting an administrative review of the antidumping duty order on glycine from the People's Republic of China (''PRC''). This review covers Baoding Mantong. The period of review (''POR'') is March 1, 2003 through February 29, 2004. We preliminarily find that sales have been made below normal value (''NV''). The preliminary results are listed below in the section titled ''Preliminary Results of Review.'' If these preliminary results are adopted in our final results, we will instruct U.S. Customs and Border Protection (''CBP'') to assess the *ad valorem* margins against the entered value of each entry of the subject merchandise during the POR. We invite interested parties to comment on these preliminary results. Parties that submit comments are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument(s).

EFFECTIVE DATE: April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Matthew Renkey, Catherine Bertrand, or Shannon Fraser, at (202) 482–2313, (202) 482–3207, or (202) 482–0165, respectively; AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On March 29, 1995, the Department published in the **Federal Register** an antidumping duty order on glycine from the PRC. *See Antidumping Duty Order: Glycine from the People's Republic of China,* 60 FR 16116, (March 29, 1995). On March 1, 2004, the Department published a *Notice of Opportunity to Request an Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation,* 69 FR 9584 (March 1, 2004). On March 16, 2004, Baoding Mantong requested that the Department conduct an administrative review of its company's sales of subject merchandise to the United States during the POR, in accordance with section 351.213(b) of the Department's regulations. On April 28, 2004, the Department initiated the review for Baoding Mantong. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews in Part,* 69 FR 23170 (April 28, 2004). On May 26, 2004, the Department issued an antidumping duty questionnaire to Baoding Mantong. On November 9, 2004, we invited interested parties to comment on the Department's surrogate country selection and/or significant production in the other potential surrogate countries and to submit publicly available information to value the factors of production. On February 14, 2005, the Department received comments from Baoding Mantong on surrogate information with which to value the factors of production in this proceeding. With regard to Baoding Mantong, the Department received timely filed original and supplemental questionnaire responses.

Scope of the Order

The product covered by the order is glycine, which is a free-flowing crystalline material, like salt or sugar. Glycine is produced at varying levels of purity and is used as a sweetener/taste enhancer, a buffering agent, reabsorbable amino acid, chemical intermediate, and a metal complexing agent. This review covers glycine of all purity levels. Glycine is currently classified under subheading 2922.49.4020 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and Customs purposes, the written description of the merchandise under the order is dispositive.

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (''the Act'') and 19 CFR 351.307, we conducted verification of the questionnaire responses of Baoding Mantong. We used standard verification procedures, including on-site inspection of the production and sales facilities, and an examination of relevant sales and financial records. Our verification results are outlined in the *Administrative Review of Glycine from the People's Republic of China: Sales and Factors Verification Report for Baoding Mantong Fine Chemistry Co., Ltd.,* dated March 31, 2005 (''*Baoding Mantong Verification Report*''). A public version of this report is on file in the Central Records Unit located in room B–099 of the Main Commerce Building.

Separate Rates

In proceedings involving non-market economy (''NME'') countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty rate unless an exporter can affirmatively demonstrate an absence of government control, both in law (*de jure*) and in fact (*de facto*), with respect to its export activities. *See Notice of Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991) (''*Sparklers*''). In this review, Baoding Mantong requested a separate company-specific rate. Accordingly, we have considered whether the company is independent from government control, and therefore eligible for a separate rate. The Department's separate rate test to determine whether the exporter is independent from government control does not consider, in general,

macroeconomic/border-type controls, *e.g.*, export licenses, quotas, and minimum export prices, particularly if these controls are imposed to prevent dumping. The test focuses, rather, on controls over the investment, pricing, and output decision-making process at the individual firm level. *See Certain Cut-to-Length Carbon Steel Plate from the Ukraine: Final Determination of Sales at Less than Fair Value,* 62 FR 61754, 61757 (November 19, 1997), and *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 62 FR 61276, 61279 (November 17, 1997).

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise under a test arising from *Sparklers,* as amplified by *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*''). In accordance with the separate rates criteria, the Department assigns separate rates in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

Baoding Mantong provided complete separate-rate information in its responses to our original and supplemental questionnaires. Accordingly, we performed a separate rates analysis to determine whether it is independent of government control.

Absence of *De Jure* Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies. *See Sparklers,* 56 FR at 20589. Our analysis shows that the evidence on the record supports a preliminary finding of *de jure* absence of government control for Baoding Mantong based on each of these factors. Baoding Mantong has placed on the record a number of documents to demonstrate absence of *de jure* control, including the ''Foreign Trade Law of the People's Republic of China.'' *See* Attachment A–1 of Baoding Mantong's July 14, 2004 submission. The Foreign Trade Law allows the company full autonomy from the central authority in governing its business operations. We have reviewed Article 11 of Chapter II of the Foreign Trade Law, which states ''foreign trade dealers shall enjoy full autonomy in their business operation and be responsible for their own profits and losses in accordance with the law.'' During verification, Baoding Mantong also provided its ''Articles of Association,'' ''Certificate of Approval for Enterprises with Foreign Trade Rights in the People's Republic of China,'' and ''Foreign Trade Entity Registration Form.'' *See Baoding Mantong Verification Report,* Exhibit 1. As in prior cases, we have analyzed such PRC laws and approvals and found that they establish an absence of *de jure* control. *See, e.g., Pure Magnesium from the People's Republic of China: Final Results of New Shipper Review,* 63 FR 3085, 3086 (January 21, 1998) and *Preliminary Results of New Shipper Review: Certain Preserved Mushrooms From the People's Republic of China,* 66 FR 30695, 30696 (June 7, 2001). Baoding Mantong also submitted a copy of its business licence in Attachment A–2 of its July 14, 2004 submission. This license was issued by the Agency of Registration, Mancheng County, Industry and Commerce Administrative Bureau. Baoding Mantong indicates that its business operations are limited to the scope of the licence, and that the licence may be revoked if the company acts outside of its business scope, fails to pay taxes, or violates criminal laws. At verification, we reviewed Baoding Mantong's business license and found that it was granted in accordance with the relevant PRC laws. Moreover, the results of verification support the information provided regarding the PRC laws. Therefore, we preliminarily determine that there is an absence of *de jure* control over the export activities of Baoding Mantong.

Absence of *De Facto* Control

Typically, the Department considers four factors in evaluating whether a respondent is subject to *de facto* government control of its export functions: (1) Whether the export prices are set by, or subject to, the approval of a government authority; (2) whether the respondent has authority to negotiate and sign contracts, and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of its management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. *See Silicon Carbide,* 59 FR at 22587.

As stated in previous cases, there is some evidence that certain enactments of the PRC central government have not been implemented uniformly among different sectors and/or jurisdictions in the PRC. *See Silicon Carbide,* 59 FR at 22586–22587. Therefore, the Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates.

Baoding Mantong has asserted the following: (1) It is a privately owned limited liability company; (2) there is no government participation in its setting of export prices; (3) its general manager has the authority to bind sales contracts; (4) it does not have to notify any government authorities of its management selection; (5) there are no restrictions on the use of its export revenue; and (6) its management is selected by its board of directors and it does not have to notify any government authorities of its management selection (*See* July 14, 2004 submission). We have examined the documentation provided and note that it does not suggest that pricing is coordinated among exporters of glycine from the PRC. Furthermore, our analysis of the responses during verification reveals no other information indicating the existence of government control. *See Baoding Mantong Verification Report.*

Consequently, because evidence on the record indicates an absence of government control, both in law and in fact, over Baoding Mantong's export activities, we preliminarily determine that the company has met the criteria for the application of a separate rate.

Normal Value Comparisons

To determine whether Baoding Mantong's sale of the subject merchandise to the United States was made at a price below NV, we compared its United States price to a normal value, as described in the ''United States Price'' and ''Normal Value'' section of this notice.

United States Price

For Baoding Mantong, we based United States price on export price (''EP'') in accordance with section 772(a) of the Act, because the first sale to an unaffiliated purchaser was made prior to importation, and constructed export price was not otherwise warranted by the facts on the record. We calculated EP based on the packed price from the exporter to the first unaffiliated

customer in the United States. Although Baoding Mantong reported that its sale was made on an FOB basis, at verification the Department found that Baoding Mantong arranged and paid for the ocean freight from China to the U.S. port and then was reimbursed by the U.S. customer for the amount of freight expense. Accordingly, we have added the amount of freight revenue to the U.S. sales price and deducted the freight cost from the U.S. price. Because the Department verified that Baoding Mantong paid for the freight expense in renminbi, we valued the ocean freight using a surrogate value.

Where foreign inland freight, foreign brokerage and handling, or ocean freight were provided by PRC service providers or paid for in renminbi, we valued these services using Indian surrogate values or a U.S. surrogate value, as appropriate. (*see* ''Factors of Production'' section below for further discussion). For those expenses that were provided by a market-economy supplier and paid for in market-economy currency, we used the reported expense.

Normal Value

Non-Market-Economy Status

In every case conducted by the Department involving the PRC, the PRC has been treated as an NME country. Pursuant to section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Preliminary Results 2001–2002 Administrative Review and Partial Rescission of Review,* 68 FR 7500 (February 14, 2003). None of the parties to this review have contested such treatment. Accordingly, we calculated NV in accordance with section 773(c) of the Act, which applies to NME countries.

Surrogate Country

Section 773(c)(4) of the Act requires the Department to value an NME producer's factors of production, to the extent possible, in one or more market-economy countries that (1) are at a level of economic development comparable to that of the NME country, and (2) are significant producers of comparable merchandise. India is among the countries comparable to the PRC in terms of overall economic development, as identified in the October 15, 2004, Memorandum from the Office of Policy to Alex Villaneuva. *See* Attachment 1, Memorandum to the File from Shannon Fraser through James Doyle, ''*Selection of a Surrogate Country,*'' dated March 31, 2005 (''*Surrogate Country Selection Memorandum*''). In addition, based on publicly available information placed on the record (*e.g.*, U.S. import data), India is a significant producer of the subject merchandise. Specifically, the United States imported 600,206 kilograms of glycine from India during the POR, making India the largest exporter of glycine to the United States. Accordingly, we considered India the surrogate country for purposes of valuing the factors of production because it meets the Department's criteria for surrogate-country selection. *See Surrogate Country Selection Memorandum.*

Factors of Production

Section 773(c)(1) of the Act provides that the Department shall determine NV using a factors-of-production methodology if (1) the merchandise is exported from an NME country, and (2) available information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. Factors of production include the following elements: (1) Hours of labor required, (2) quantities of raw materials employed, (3) amounts of energy and other utilities consumed, and (4) representative capital costs. We valued all the input factors using publicly available information.

In accordance with section 351.301(c)(3)(ii) of the Department's regulations, for the final results of an administrative review, interested parties may submit publicly available information to value the factors of production no later than twenty days following the date of publication of these preliminary results.

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on the factors of production which included, but were not limited to: (1) Hours of labor required; (2) quantities of raw materials employed; (3) amounts of energy and other utilities consumed; and (4) representative capital costs, including depreciation. We used factors of production reported by the producer or exporter for materials, energy, labor, and packing. To calculate NV, we multiplied the reported unit factor quantities by publicly available Indian or U.S. values.

In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data, in accordance with our practice. When we used publicly available import data from the Ministry of Commerce of India (''*Indian Import Statistics*'') for March 2003 through February 2004 to value inputs sourced domestically by PRC suppliers, we added to the Indian surrogate values a surrogate freight cost calculated using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory. This adjustment is in accordance with the Court of Appeals for the Federal Circuit's decision in *Sigma Corp.* v. *United States,* 117 F. 3d 1401, 1408 (Fed. Cir. 1997). In instances where we relied on Indian import data to value inputs, in accordance with the Department's practice, we excluded imports from both NME countries and countries deemed to maintain broadly available, non-industry-specific subsidies which may benefit all exporters to all export markets (*i.e.*, Indonesia, South Korea, and Thailand) from our surrogate value calculations. *See, e.g., Final Determination of Sales at Less Than Fair Value: Certain Automotive Replacement Glass Windshields from the People's Republic of China,* 67 FR 6482 (February 12, 2002) and accompanying Issues and Decision Memorandum at Comment 1. *See, also, Notice of Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Affirmative Preliminary Determination of Critical Circumstances: Certain Color Television Receivers From the People's Republic of China,* 68 FR 66800, 66808 (November 28, 2003), unchanged in the Department's final results at 69 FR 20594 (April 16, 2004).

Where we could not obtain publicly available information contemporaneous with the POR to value factors, we adjusted the surrogate values using the Indian Wholesale Price Index (''WPI'') as published in the *International Financial Statistics* (''IFS'') of the International Monetary Fund (''IMF''), for those surrogate values in Indian rupees. We made currency conversions, where necessary, pursuant to section 351.415 of the Department's regulations, to U.S. dollars using the applicable average exchange rate for the POR. We based the average exchange rates on exchange rate data from the Import Administration Web site at *http://ia.ita.doc.gov/exchange/index.html. See Surrogate Values Used for the Preliminary Results of the 3/1/03–2/29/04 Administrative Review of Glycine from the People's Republic of China ''Factor Valuation Memo''.*

We valued the factors of production as follows:

Material and Packing Inputs

To value the inputs of acetic acid, sulfur, liquid ammonia, formaldehyde, methyl alcohol, paper bags, and plastic liners, we used the weighted-average unit import value derived from Indian import statistics, as published in the *World Trade Atlas* for the period March 1, 2003 through February 29, 2004. To value the input of liquid chlorine, we relied upon the average of two liquid chlorine prices, as obtained from the April 1, 2002 through March 31, 2003 financial statements of two Indian chemical companies, Bihar Caustic & Chemicals Limited and Kanoria Chemicals & Industries Limited.

Energy

We valued electricity using the reported price for electricity in India in dollars per kilowatt hour for the year 2000 as reported by the International Energy Agency (IEA) in *Key World Energy Statistics (2003),* and we inflated the value for the POR by using the WPI for India. To value water, we relied upon public information from the Municipal Corporation of Greater Mumbai's Web site. *See http://www.mcgm.gov.inStat%20&%20Fig/Revenue.htm.* The Web site notes that the Municipal Corporation of Greater Mumbai's data is for 2000 through 2001. Because this data is not contemporaneous with the POR, an adjustment has been made for inflation using the WPI for India. To value coal, we used the weighted-average unit import value derived from Indian import statistics in the *World Trade Atlas* for the period March 1, 2003 through February 29, 2004.

By-Products

Baoding Mantong reported that it produced two by-products in its production of subject merchandise: Hydrochloric acid and ammonium chloride. At verification, we confirmed that Baoding Mantong made sales of these by-products. Accordingly, we adjusted the material cost downward to reflect a by-product offset to the material cost included in the normal value. We valued ammonium chloride by using the weighted-average unit import values derived from Indian import statistics in the *World Trade Atlas* for the period March 1, 2003 through February 29, 2004. We valued hydrochloric acid by using price information obtained from *Chemical Weekly* from March 1, 2003 through February 29, 2004.

Labor

For labor, we used the PRC regression-based wage rate at the Import Administration's home page, *Import Library, Expected Wages of Selected NME Countries,* updated on November 15, 2004. *See http://ia.ita.doc.gov/wages/02wages/ 02wages.html.* Because of the variability of wage rates in countries with similar per capita gross domestic products, section 351.408(c)(3) of the Department's regulations requires the use of a regression-based wage rate. The source of these wage rate data on the Import Administration's web site is the *Yearbook of Labour Statistics 2002,* International Labour Office (Geneva: 2002), Chapter 5B: Wages in Manufacturing.

Factory Overhead, Selling, General, and Administrative (''SG&A'') Expenses, and Profit

To value factory overhead, SG&A, and profit, we used the financial information obtained from the 2003–2004 financial statement of an Indian pharmaceutical producer, Torrent Pharmaceuticals Limited (''Torrent''). The factory overhead ratio was calculated as a percentage of total manufacturing costs (which includes materials, labor, and energy). The SG&A ratio was calculated as a percentage of total factory overhead and total manufacturing costs. The profit ratio was calculated as a percentage of factory overhead, SG&A, and total manufacturing costs.

Transportation Expenses

To value inland truck freight costs, we used freight prices published in the April 26, 2002 edition of the *Iron & Steel Newsletter,* which cites *http://www.INFreight.com,* which is an Indian logistics Web site that tracks freight rates for all of India. The Department averaged the rates from three points of origin (Mumbai, Dehli, and Calcutta) to all destinations for which distances were published by *http://www.mapsofindia.com.* Since the rate was not contemporaneous with the POR, we adjusted the rate for inflation using the WPI for India. To value ocean freight cost, we used information obtained from a U.S. international shipping company for a delivery from Baoding Mantong's reported port of export to the reported U.S. port of importation. *See* Memorandum to the File, *''Selection of Ocean Freight Cost,''* dated March 31, 2005.

Preliminary Results of Review

We preliminary determine that the following dumping margin exists:

Manufacturer/export	Time period	Margin
Baoding Mantong Fine Chemistry Co., Ltd	3/1/03–2/29/04	76.72%

Assessment Rates

Upon completion of this administrative review, the Department shall determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b)(1), for assessment purposes, we will calculate importer-specific assessment rates for glycine from the PRC. We divide the total dumping margin for the reviewed sales by the total entered value of the reviewed sales for each importer during the POR. Upon completion of this review, we will direct CBP to assess antidumping duties based on a percentage of entered value equivalent to the company-specific dumping margin established in this review for each entry of subject merchandise made by Baoding Mantong during the POR. The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of the final results of this administrative review.

Cash-Deposit Requirements

The following cash-deposit rates will be effective upon publication of the final results of this review for all shipments of glycine from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(c) of the Act: (1) For subject merchandise exported by Baoding Mantong, the cash deposit rate will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, de minimis within the meaning of the 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not listed above that have

separate rates, the cash-deposit rate will continue to be the company-specific rate published for the most recent period; (3) the cash-deposit rate for all other PRC exporters will be the PRC-wide rate which is currently 155.89 percent; and (4) the cash-deposit rate for all other non-PRC exporters will be the rate applicable to the PRC exporter that supplied that exporter. These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

Schedule for Final Results of Review

The Department will disclose calculations performed in connection with the preliminary results of this review within five days of the date of publication of this notice in accordance with section 351.224(b) of the Department's regulations. Any interested party may request a hearing within 30 days of publication of this notice in accordance with section 351.310(c) of the Department's regulations. Any hearing would normally be held 37 days after the publication of this notice, or the first workday thereafter, at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Individuals who wish to request a hearing must submit a written request within 30 days of the publication of this notice in the **Federal Register** to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room 1870, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Requests for a public hearing should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) to the extent practicable, an identification of the arguments to be raised at the hearing.

Unless otherwise notified by the Department, interested parties may submit case briefs within 30 days of the date of publication of this notice in accordance with section 351.309(c)(ii) of the Department's regulations. As part of the case brief, parties are encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited. Rebuttal briefs, which must be limited to issues raised in the case briefs, must be filed within five days after the case brief is filed. If a hearing is held, an interested party may make an affirmative presentation only on arguments included in that party's case brief and may make a rebuttal presentation only on arguments included in that party's rebuttal brief. Parties should confirm by telephone the time, date, and place of the hearing no later than 48 hours before the scheduled time. The Department will issue the final results of this review, which will include the results of its analysis of issues raised in the briefs, not later than 120 days after the date of publication of this notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under section 351.402(f) of the Department's regulations to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during these review periods. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and this notice are published in accordance with sections 751(a)(2)(B) and 777(i)(1) of the Act.

Dated: March 31, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. E5–1612 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–507–501]

Certain In-shell Pistachios From the Islamic Republic of Iran: Preliminary Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the countervailing duty (CVD) order on certain in-shell (raw) pistachios from the Islamic Republic of Iran (Iran) for the period January 1, 2003, through December 31, 2003. For information on the net subsidy rate for the reviewed company, please see the ''Preliminary Results of Review'' section of this notice. Interested parties are invited to comment on these preliminary results. (*See* the ''Public Comment'' section of this notice).

DATES: *Effective Date:* April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Darla Brown, AD/CVD Operations, Office 3, Import Administration, U.S. Department of Commerce, Room 4014, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On March 11, 1986, the Department published in the **Federal Register** the countervailing duty order on certain in-shell (raw) pistachios from Iran. *See Final Affirmative Countervailing Duty Determination and Countervailing Duty Order: In-shell Pistachios from Iran,* 51 FR 8344 (March 11, 1986) (*In-shell Pistachios*). On March 1, 2004, the Department published a notice of opportunity to request an administrative review of this CVD order. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 69 FR 9584 (March 1, 2004). On March 19, 2004, we received a timely request for an administrative review from Tehran Negah Nima Trading Company, Inc., trading as Nima Trading Company (Nima), the respondent company in this proceeding. On April 28, 2004, we initiated an administrative review of the CVD order on in-shell (raw) pistachios from Iran covering the period of review (POR) January 1, 2003, through December 31, 2003. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 69 FR 23170 (April 28, 2004).

On May 11, 2004, we issued our initial questionnaire to the Government of Iran (GOI) and Nima. On June 14, 2004, petitioners [1] filed an entry of appearance, request for verification, and request for a duty absorption determination. On June 24, 2004, in a letter to petitioners, we declined to conduct a duty absorption determination in this CVD administrative review.

On July 6, 2004, and July 8, 2004, the GOI and Nima, respectively, submitted questionnaire responses.

On July 23, 2004, petitioners submitted a request for extension to file new subsidy allegations. On July 28, 2004, we granted petitioners a two-week extension to file new subsidy allegations in this administrative review. On August 11, 2004, petitioners submitted new subsidy allegations.

On August 18, 2004, we issued supplemental questionnaires to the GOI and Nima. On September 1, 2004, and September 15, 2004, the GOI and Nima, respectively, submitted supplemental questionnaire responses.

[1] Petitioners are comprised of members of the California Pistachio Commission (CPC).

On October 18, 2004, we extended the period for the completion of the *Preliminary Results* pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act). *See Certain In-shell Pistachios from the Islamic Republic of Iran: Extension of Time Limit for Preliminary\ Results of Countervailing Duty Administrative Review,* 69 FR 61341 (October 18, 2004).

On October 27, 2004, we initiated investigations of three of petitioners' new subsidy allegations. For additional information, *see* the October 27, 2004, New Subsidy Allegations memorandum to Melissa G. Skinner, Director, AD/CVD Operations, Office 3, from the Team (New Subsidies Memo), on file in the Central Records Unit, Room B–099 of the Main Commerce Building (CRU).

On November 4, 2004, we issued a second supplemental questionnaire to Nima, and on November 15, 2004, we issued a second supplemental questionnaire to the GOI. On November 29, 2004, we received a response from Nima to our second supplemental questionnaire. On December 13, 2004, we received a response from the GOI to our second supplemental questionnaire. On January 31, 2005, we issued a third supplemental questionnaire to the GOI. On February 28, 2005, we received a response from the GOI to our third supplemental questionnaire.

In accordance with 19 CFR 351.213(b), this administrative review covers only those producers or exporters for which a review was specifically requested. Accordingly, this administrative review covers Nima and ten programs.

Scope of Order

The product covered by this order is in-shell (raw) pistachio nuts from which the hulls have been removed, leaving the inner hard shells and edible meat, as currently classifiable in the Harmonized Tariff Schedules of the United States (HTSUS) under item number 0802.50.20.00. The HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of this proceeding is dispositive.

Analysis of Programs

I. Programs Preliminarily Determined To Be Not Used

Based on the information supplied by Nima on behalf of itself and its grower, Razi Domghan Agricultural and Animal Husbandry Company (Razi), we preliminarily determine that the programs listed below were not used during the POR. For further discussion of the Iranian Export Guarantee Fund, GOI Grants and Loans to Pistachio Farmers, and Crop Insurance for Pistachios programs, *see* the October 27, 2004, New Subsidies Memo.

A. *Provision of Fertilizer and Machinery.*

B. *Provision of Credit.*

C. *Tax Exemptions.*

D. *Provision of Water and Irrigation Equipment.*

E. *Technical Support.*

F. *Duty Refunds on Imported Raw or Intermediate Materials Used in the Production of Export Goods.*

G. *Program to Improve Quality of Exports of Dried Fruit.*

H. *Iranian Export Guarantee Fund.*

I. *GOI Grants and Loans to Pistachio Farmers.*

J. *Crop Insurance for Pistachios.*

Preliminary Results of Review

In accordance with 19 CFR 351.221(b)(4)(i), we have calculated an individual subsidy rate for Nima, the only producer/exporter subject to this administrative review, for the POR, *i.e.*, calendar year 2003. We preliminarily determine that the total estimated net countervailable subsidy rate is 0.00 percent *ad valorem.*

As Nima is the exporter but not the producer of subject merchandise, the Department's final results of review will apply to subject merchandise exported by Nima and produced by Nima's supplier of pistachios, Razi. *See* 19 CFR 351.107(b). Therefore, we intend to issue the following cash deposit requirements, effective upon publication of the notice of final results of review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication: (1) For merchandise exported by Nima and produced by Razi, the cash deposit rate will be the *ad valorem* rate calculated in the final results of the instant administrative review; (2) for merchandise exported by Nima and produced by Maghsoudi Farms, the cash deposit rate will be 23.18 percent, the rate calculated for Nima and Maghsoudi Farms in the new shipper reviews (*see Certain In-Shell Pistachios (C–507–501) and Certain Roasted In-Shell Pistachios (C–507–601) from the Islamic Republic of Iran: Final Results of New Shipper Countervailing Duty Reviews,* 68 FR 4997 (January 31, 2003) (*New Shipper Reviews*); (3) for merchandise exported by Nima but not produced by Razi or Maghsoudi Farms, the cash deposit rate will be the ''all others'' rate established in the original CVD investigation (*see* 51 FR 8344 (March 11, 1986)); (4) if the exporter is not a firm covered in this review, a prior review, or the original CVD investigation, but the producer is, the cash deposit rate will be the rate established for the most recent period for the producer of the merchandise; and (5) if neither the exporter nor producer is a firm covered in this review or the original investigation, the cash deposit rate for all other producers or exporters of the subject merchandise will continue to be 99.52 percent *ad valorem.* This rate is the ''all others'' rate from the final determination in the original investigation.

If the final results of this review remain the same as these preliminary results, the Department intends to instruct U.S. Customs and Border Protection (CBP), within 15 days of publication of the final results of this review, to liquidate without regard to countervailing duties all shipments of subject merchandise exported by Nima and produced by Razi, entered, or withdrawn from warehouse, for consumption during the POR. Should the final results of this review remain the same as these preliminary results, the Department also will instruct CBP not to collect cash deposits of estimated countervailing duties on all shipments of the subject merchandise exported by Nima and produced by Razi, entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

Because the Uruguay Round Agreements Act (URAA) replaced the general rule in favor of a country-wide rate with a general rule in favor of individual rates for investigated and reviewed companies, the procedures for establishing countervailing duty rates, including those for non-reviewed companies, are now essentially the same as those in antidumping cases, except as provided for in section 777A(e)(2)(B) of the Act. The requested review will normally cover only those companies specifically named. *See* 19 CFR 351.213(b). Pursuant to 19 CFR 351.212(c), for all companies for which a review was not requested, duties must be assessed and cash deposits must continue to be collected, at the cash deposit rate previously ordered. As such, the countervailing duty cash deposit rate applicable to a company can no longer change, except pursuant to a request for a review of that company. *See Federal-Mogul Corporation and The Torrington Company* v. *United States,* 822 F. Supp. 782 (CIT 1993), and *Floral Trade Council* v. *United States,* 822 F. Supp. 766 (CIT 1993) (interpreting 19 CFR 353.22(e), the old antidumping regulation on automatic assessment, which is identical to the current

regulation, 19 CFR 351.212(c)(1)(ii)). Therefore, the cash deposit rates for all companies except those covered by this review will be unchanged by the results of this review.

We will instruct CBP to continue to collect cash deposits for non-reviewed companies at the most recent company-specific or country-wide rate applicable to the company. Accordingly, the cash deposit rates that will be applied to non-reviewed companies covered by this order will be the rate for that company established in the most recently completed administrative proceeding. *See Certain In-Shell Pistachios from the Islamic Republic of Iran: Final Results of Countervailing Duty Administrative Review,* 68 FR 41310 (July 11, 2003). These cash deposit rates shall apply to all non-reviewed companies until a review of a company assigned these rates is requested.

Verification

In accordance with section 782(i)(3) of the Act, we intend to verify the information submitted by respondents prior to making our final determination.

Public Comment

Pursuant to 19 CFR 351.224(b), the Department will disclose to parties to the proceeding any calculations performed in connection with these preliminary results within five days after the date of the public announcement of this notice. Pursuant to 19 CFR 351.309, interested parties may submit written comments in response to these preliminary results. Unless otherwise indicated by the Department, case briefs must be submitted within 30 days after the publication of these preliminary results. Rebuttal briefs, which are limited to arguments raised in case briefs, must be submitted no later than five days after the time limit for filing case briefs, unless otherwise specified by the Department. Parties who submit argument in this proceeding are requested to submit with the argument: (1) A statement of the issue, and (2) a brief summary of the argument. Parties submitting case and/or rebuttal briefs are requested to provide the Department copies of the public version on disk. Case and rebuttal briefs must be served on interested parties in accordance with 19 CFR 351.303(f). Also, pursuant to 19 CFR 351.310, within 30 days of the date of publication of this notice, interested parties may request a public hearing on arguments to be raised in the case and rebuttal briefs. Unless the Secretary specifies otherwise, the hearing, if requested, will be held two days after the date for submission of rebuttal briefs.

Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under 19 CFR 351.309(c)(ii), are due. The Department will publish the final results of this administrative review, including the results of its analysis of issues raised in any case or rebuttal brief or at a hearing.

This administrative review and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: March 31, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. E5–1614 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–507–502]

Notice of Rescission of Antidumping Duty Administrative Review: Certain In-Shell Raw Pistachios From Iran

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from Tehran Negah Nima Trading Company, Inc., trading as Nima Trading Company, Inc. (Nima), an exporter of subject merchandise, California Pistachio Commission (petitioner), and Cal Pure Pistachios, Inc. (Cal Pure), an interested party to this proceeding, the U.S. Department of Commerce (the Department) initiated an administrative review of the antidumping duty order on certain in-shell raw pistachios (pistachios) from Iran. No other interested party requested a review of Nima. The period of review (POR) is July 1, 2003, through June 30, 2004. For the reasons discussed below, the Department is rescinding this administrative review.

EFFECTIVE DATE: April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Angelica Mendoza at (202) 482–3019 or Abdelali Elouaradia at (202) 482–1374, respectively; AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2004, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on pistachios from Iran, 69 FR 39903. On July 9, 2004, and July 27, 2004, we received requests from petitioner and Cal Pure, respectively, to conduct an administrative review of Nima's sales of pistachios to the United States during the POR. On July 30, 2004, Nima, an exporter of subject merchandise during the POR, requested that the Department conduct an administrative review of its sales of pistachios to the United States. On August 30, 2004, the Department initiated an administrative review of the antidumping duty order on pistachios from Iran for the period July 1, 2003, through June 30, 2004, in order to determine whether merchandise imported into the United States was sold at less than fair value by Nima. *See* Initiation of Antidumping and Countervailing Duty Administrative Review and Requests for Revocations in Part, 69 FR 52857.

On March 14, 2005, Nima filed a letter in which it requested that the Department rescind the instant administrative review. On March 15, 2005, Department officials contacted Nima's representative in order to clarify the intent of Nima's March 14, 2005, filing. During this conversation, Nima clarified that it had intended to withdraw its request for the current administrative review pursuant to section 351.213(d)(1) of the Department's regulations. *See* Memorandum to the File through Abdelali Elouaradia, Program Manager, Office 7, Telephone Conversation with Respondent's Representative, dated March 15, 2005. On March 24, 2005, both petitioner and Cal Pure also withdrew their requests for the instant review.

Rescission of Review

If a party that requested a review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review, the Secretary will rescind the review pursuant to 19 CFR 351.213(d)(1) of the Department's regulations. However, the Secretary may extend this time limit if the Secretary decides that it is reasonable to do so. The Department finds that it is reasonable to extend the time limit by which a party may withdraw its request for review in the instant proceeding. Given that all

parties have withdrawn from, and thereby are no longer participating in, the instant review, we find it reasonable to accept the parties' withdrawals of their requests for review. The Department has not yet devoted considerable time and resources to this review, and the Department concludes that the withdrawals do not constitute an abuse of our procedures by the involved parties. Therefore, the Department is rescinding this administrative review of the antidumping duty order on pistachios from Iran.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's assumption that reimbursement of antidumping duties occurred and subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3) of the Department's regulations. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4) of the Department's regulations.

Dated: April 1, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–1613 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–829]

Stainless Steel Bar From Italy: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Rescission of Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce is conducting an administrative review of the antidumping duty order on stainless steel bar from Italy. The period of review is March 1, 2003, through February 29, 2004. This review covers imports of stainless steel bar from one producer/exporter. We have preliminarily found that the respondent in this review did not make shipments of subject merchandise to the United States during the period of review and, therefore, we are preliminarily rescinding this administrative review. In addition, the Department of Commerce has received information sufficient to warrant a successor-in-interest analysis. Based on this information, we preliminarily find that UGITECH S.A. is the successor-in-interest to Ugine-Savoie Imphy S.A. for purposes of determining antidumping duty liability. We invite interested parties to comment on these preliminary results. We will issue the final results not later than 120 days from the date of publication of this notice.

DATES: *Effective Date:* April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Scott Holland, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1279.

SUPPLEMENTARY INFORMATION:

Background

On March 7, 2002, the Department of Commerce (''the Department'') published an antidumping duty order on stainless steel bar (''SSB'') from Italy. *See Notice of Antidumping Duty Order: Stainless Steel Bar from Italy*, 67 FR 10384 (March 7, 2002). On October 10, 2003, the Department published an amended antidumping duty order on SSB from Italy. *See Notice of Amended Antidumping Duty Orders: Stainless Steel Bar from France, Germany, Italy, Korea, and the United Kingdom*, 68 FR 58660 (October 10, 2003).

On March 1, 2004, the Department published in the **Federal Register** a notice of the opportunity for interested parties to request an administrative review of the antidumping duty order on SSB from Italy. *See Notice of Opportunity to Request Administrative Review of Antidumping or Countervailing Duty Order, Finding or Suspended Investigation,* 69 FR 9584 (March 1, 2004). On March 31, 2004, Carpenter Technology Corp., Crucible Specialty Metals, Electralloy Corp., Empire Specialty Steel Inc., Slater Steels Corp., and the United Steelworkers of America, AFL–CIO/CLC (collectively, ''the petitioners''), requested an administrative review of imports of the subject merchandise produced by UGITECH S.A. (''UGITECH'') (formerly known as Ugine Savoie-Imphy S.A.), an Italian exporter/producer of the subject merchandise.

In accordance with 19 CFR 351.221(b)(1), we published a notice of initiation of this antidumping duty administrative review on May 27, 2004. *See Notice of Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 69 FR 30282 (May 27, 2004). The period of review (''POR'') is March 1, 2003, through February 29, 2004.

On May 21, 2004, UGITECH informed the Department that it made no entries of subject merchandise during the POR and requested that the Department rescind the instant review with respect to UGITECH, in accordance with 19 CFR 351.213(d)(3). In June 2004, the petitioners submitted comments on UGITECH's May 21, 2004, submission and requested that the Department investigate further UGITECH's rescission request. In June 2004, UGITECH responded to the petitioner's comments.

For our successor-in-interest analysis, on June 25, 2004, the Department requested additional information concerning the nature of the name change of Ugine Savoie-Imphy S.A. to UGITECH. We received UGITECH's response on July 23, 2004. On September 1, 2004, the petitioners submitted comments on UGITECH's July 23, 2004, response. We issued a supplemental questionnaire on October 12, 2004, requesting additional information with regard to UGITECH's no shipment claim and received UGITECH's response on October 28, 2004.

In November 2004, the Department conducted a verification of UGITECH's questionnaire responses, in accordance with 19 CFR 351.307. The verification report was issued on January 13, 2005. *See* Memorandum to the File, ''Verification of UGITECH's S.A.'s No-Shipment Claim,'' (''UGITECH's VR'') dated January 13, 2005.

On November 17, 2004, we extended the time limit for the preliminary results in this review until February 1, 2005. *See Stainless Steel Bar from Italy: Notice of Extension of Time Limit for the Preliminary Results of the Antidumping Duty Administrative Review*, 69 FR 67309 (November 17, 2004). On January 14, 2005, we extended the time limit for the preliminary results in this review until March 31, 2005. *See Stainless Steel Bar from Italy: Notice of Extension of Time*

Limit for the Preliminary Results of the Antidumping Duty Administrative Review, 70 FR 2612 (January 14, 2005). On February 10, 2005, and March 14, 2005, the petitioners submitted comments for purposes of the preliminary results. On March 18, 2005, UGITECH responded to the petitioner's comments.

Scope of the Order

For purposes of this order, the term ''stainless steel bar'' includes articles of stainless steel in straight lengths that have been either hot-rolled, forged, turned, cold-drawn, cold-rolled or otherwise cold-finished, or ground, having a uniform solid cross section along their whole length in the shape of circles, segments of circles, ovals, rectangles (including squares), triangles, hexagons, octagons, or other convex polygons. Stainless steel bar includes cold-finished stainless steel bars that are turned or ground in straight lengths, whether produced from hot-rolled bar or from straightened and cut rod or wire, and reinforcing bars that have indentations, ribs, grooves, or other deformations produced during the rolling process.

Except as specified above, the term does not include stainless steel semi-finished products, cut length flat-rolled products (*i.e.*, cut length rolled products which if less than 4.75 mm in thickness have a width measuring at least 10 times the thickness, or if 4.75 mm or more in thickness having a width which exceeds 150 mm and measures at least twice the thickness), products that have been cut from stainless steel sheet, strip or plate, wire (*i.e.*, cold-formed products in coils, of any uniform solid cross section along their whole length, which do not conform to the definition of flat-rolled products), and angles, shapes and sections.

The stainless steel bar subject to this order is currently classifiable under subheadings 7222.11.00.05, 7222.11.00.50, 7222.19.00.05, 7222.19.00.50, 7222.20.00.05, 7222.20.00.45, 7222.20.00.75, and 7222.30.00.00 of the *Harmonized Tariff Schedule of the United States* (''HTSUS''). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Successor-In-Interest Analysis

In its July 23, 2004, response to the Department's request for additional information, UGITECH reported that on November 28, 2003, the shareholders of Ugine-Savoie Imphy S.A. voted to change the company's name to UGITECH S.A. UGITECH claimed that Ugine-Savoie Imphy S.A. and UGITECH remained the same legal entity and there was no change in ownership associated with the change in name. According to UGITECH, prior to the name change Ugine-Savoie Imphy S.A. dissolved one of its wholly-owned French subsidiaries (*i.e.*, Ugine-Savoie France S.A.) and integrated that company's operations as an internal department within Ugine-Savoie Imphy S.A. Similarly, shortly after the name change, UGITECH dissolved another wholly-owned French subsidiary (*i.e.*, Sprint Metal S.A.) and integrated its operations as a internal department within UGITECH. Also at that time, the former chief executive officer of Sprint Metal was made vice president of sales at UGITECH. Other than the name change and the incorporation of the two former subsidiaries into the company, UGITECH operations and facilities remain essentially unchanged.

Thus, in accordance with section 751(b) of the Act, the Department is conducting a successor-in-interest analysis to determine whether UGITECH is the successor-in-interest to Ugine-Savoie Imphy S.A. for purposes of determining antidumping liability with respect to the subject merchandise. In making such a successor-in-interest determination, the Department examines several factors including, but not limited to, changes in: (1) Management; (2) production facilities; (3) supplier relationships; and (4) customer base. *See, e.g., Polychloroprene Rubber from Japan: Final Results of Changed Circumstances Review,* 67 FR 58 (January 2, 2002) (''*Polychloroprene Rubber from Japan*''); and *Brass Sheet and Strip from Canada: Final Results of Antidumping Duty Administrative Review,* 57 FR 20460 (May 13, 1992) (''*Canadian Brass*''). While no single factor or combination of factors will necessarily provide a dispositive indication, the Department will generally consider the new company to be the successor to the previous company if its resulting operation is not materially dissimilar to that of its predecessor. *See, e.g., Polychloroprene Rubber from Japan; Industrial Phosphoric Acid from Israel: Final Results of Changed Circumstances Review,* 59 FR 6944 (February 14, 1994); *Canadian Brass*; and *Fresh and Chilled Atlantic Salmon from Norway: Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review,* 63 FR 50880 (September 23, 1998). Thus, if the evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the former company, the Department will accord the new company the same antidumping duty treatment as its predecessor.

We preliminarily find that UGITECH is the successor-in-interest to Ugine-Savoie Imphy S.A. UGITECH submitted documentation supporting its claims that its name change resulted in no significant changes in either production facilities, supplier relationships, customer base, or management. This documentation consisted of: (1) A copy of the board meeting minutes for the name change; (2) a copy of the article of incorporation for UGITECH; and (3) copies of the official registration of Ugine-Savoie Imphy S.A. (before the name change) and UGITECH (after the name change); and (4) copies of the statements of dissolution for Ugine-Savoie France S.A. and Sprint Metal S.A. These documents, which the Department examined thoroughly at verification, demonstrate that UGITECH operates as the same business entity as Ugine-Savoie Imphy S.A. Because UGITECH has presented evidence to establish a *prima facie* case of its successorship status, we preliminarily find that UGITECH should receive the same antidumping duty treatment with respect to SSB as the former Ugine-Savoie Imphy S.A.

Preliminary Rescission of Administrative Review

In accordance with 19 CFR 351.213(d)(3), we are preliminarily rescinding this review with respect to UGITECH, which reported that it made no shipments of subject merchandise during the POR. We examined shipment data furnished by U.S. Customs and Border Protection (''CBP'') and analyzed UGITECH's quantity and value of sales at verification. *See UGITECH's VR.* Based on this, we are satisfied that there were no U.S. shipments of subject merchandise from UGITECH during the POR.

Public Comment

Any interested party may request a hearing within 30 days of publication of this notice. A hearing, if requested, will be held 37 days after the publication of this notice, or the first business day thereafter. Interested parties may submit case briefs within 30 days of the date of publication of this notice. Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 35 days after the date of publication of this notice. The Department will issue the final results of this administrative review, which

will include the results of its analysis of issues raised in any such comments, within 120 days of publication of the preliminary results.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(I)(1) of the Act.

Dated: March 31, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. E5–1607 Filed 4–7–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–831]

Notice of Correction to the Amended Final Determination in Accordance With Court Decision in the Antidumping Duty Investigation of Stainless Steel Sheet and Strip in Coils From Taiwan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date*: April 7, 2005.

FOR FURTHER INFORMATION CONTACT: Robert Bolling, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–3434.

SUMMARY: On November 17, 2004, the Department of Commerce (''Department'') published an *Amended Final Determination in Accordance with Court Decision of the Antidumping Duty Investigation of Stainless Steel Sheet and Strip in Coils From Taiwan*, 69 FR 67311 (November 17, 2004) (''*Amended Final Determination*''). In the *Amended Final Determination*, the Department announced the incorrect effective date of the exclusion from the antidumping duty order on stainless steel sheet and strip in coils from Taiwan with respect to entries from Tung Mung Development Corporation (''Tung Mung'').

SUPPLEMENTARY INFORMATION:

Background

On June 8, 1999, the Department published the *Final Determination of Sales at Less than Fair Value: Stainless Steel Sheet and Strip in Coils From Taiwan*, 64 FR 30592 (June 8, 1999) (''*Final Determination*''), covering the period of investigation (''POI'') of April 1, 1997, through March 31, 1998. This investigation involved three Taiwanese producers/exporters, Tung Mung, Yieh United Steel Corporation (''YUSCO''), Chang Mien Industries Co., Ltd. (''Chang Mien''), and a Taiwanese middleman, Ta Chen Stainless Pipe Company Ltd. (''Ta Chen''). Tung Mung and YUSCO contested various aspects of the *Final Determination*. On July 3, 2001, the Court of International Trade (''CIT'') issued slip opinion 01–83 in *Tung Mung Development Co., Ltd.* v. *United States*, Consol. Court No. 99–06–00457 (CIT July 3, 2001) (''*Tung Mung I*'') and remanded the *Final Determination* to the Department. In the March 21, 2001, remand determination, the Department found, among other issues, that the merchandise produced and exported by Tung Mung had not been sold at less than fair value during the POI. On August 22, 2002, the CIT found that the Department's remand determination was in accordance with the law. *See Tung Mung Development Co., Ltd.* v. *U.S.*, 219 F.Supp.2d 1333 (CIT August 22, 2002) (''*Tung Mung II*'').

Domestic producers appealed this decision. On January 15, 2004, the Court of Appeals for the Federal Circuit ruled that the Department's decision to calculate middleman antidumping rates using combination rates was not arbitrary and capricious and affirmed the CIT's affirmance of the Department's redetermination. *See Tung Mung Development Co., Ltd.* v. *U.S.*, 354 F.3d 1371 (Fed.Cir. January 15, 2004) (''*Tung Mung III*''), *Tung Mung II*, and the Department's *Final Results of Redetermination Pursuant to Court Remand* in response to *Tung Mung I*.

On November 17, 2004, the Department published the *Amended Final Determination* in which it stated that it will instruct U.S. Customs and Border Protection (''CBP'') to liquidate entries from Tung Mung without regard to antidumping duties because Tung Mung is excluded from the antidumping duty order effective October 16, 2002, the date on which the Department published a notice of the Court decision (see *Stainless Steel Sheet and Strip in Coils from Taiwan: Notice of Court Decision*, 67 FR 63887 (October 16, 2002)). The above instructions should have read that the Department will instruct CBP to liquidate entries from Tung Mung without regard to antidumping duties effective June 8, 1999, the date on which the Department published its *Final Determination*, because liquidation of entries from Tung Mung was first suspended on that date and remained covered by an injunction during the pendency of the litigation. Thus, we will instruct CBP to liquidate entries from Tung Mung without any regard to antidumping duties effective June 8, 1999.

This notice is issued and published in accordance with section 735(d) of Tariff Act of 1930, as amended.

Dated: March 30, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. E5–1611 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040105C]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Extension of the Gulf of Mexico Charter Vessel/Headboat Permit Moratorium

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent; request for comments.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) and NMFS intend to prepare a draft supplemental environmental impact statement (DSEIS) in support of a proposed Amendment to Extend the Charter Vessel/Headboat Permit Moratorium (Moratorium Amendment). The DSEIS will evaluate alternatives for allowing the permit moratorium to expire, extending the moratorium for a finite time period, or establishing a permanent limited access program. The purpose of this notice of intent is to solicit public comments on the range of alternatives and scope of issues to be addressed in the DSEIS.

DATES: Written comments on the scope of the DSEIS must be received by 5 p.m. May 9, 2005.

ADDRESSES: You may submit comments on the scope of the DSEIS by any of the following methods:

• E-mail: *0648–AS70.NOI@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: Charter Headboat Permit Moratorium.

• Mail: Andy Strelcheck, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

• Fax: 727–824–5308; Attention: Andy Strelcheck. Requests for the scoping document may be directed to the Gulf of Mexico Fishery Management Council, The Commons at Rivergate, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619; telephone: 813–228–2815; fax: 813–225–7015. Scoping documents are also available to download at *http://www.gulfcouncil.org*.

FOR FURTHER INFORMATION CONTACT: Stu Kennedy (phone: 813–228–2815; fax: 813–225–7015; e-mail: Stu.Kennedy@gulfcouncil.org); or Andy Strelcheck (phone: 727–824–5305; fax: 727–824–5308; e-mail: *Andy.Strelcheck@noaa.gov*).

SUPPLEMENTARY INFORMATION: The Council and NMFS intend to prepare a DSEIS in support of the proposed Moratorium Amendment. For-hire vessel permits were initially required in the coastal migratory pelagic (CMP) fishery starting in 1987 and in the reef fish fishery in 1997. Amendments establishing the charter vessel/headboat permit moratorium for the CMP fishery (Amendment 14) and the Reef Fish fishery (Amendment 20) were approved by NMFS on May 6, 2003, and implemented on June 16, 2003 (68 FR 26280). The intended effect of these amendments was to cap the number of for-hire vessels operating in these two fisheries at the current level (as of March 29, 2001) while the Council evaluated whether limited access programs were needed to constrain effort. In this proposed Moratorium Amendment, the Council is considering alternatives that would: allow the moratorium on for-hire reef fish and CMP permits to expire; extend the moratorium for a finite period of time (5 or 10 years); or establish a permanent limited access program. In any case, except for allowing the moratorium to expire, there would be no new permits issued. The DSEIS will evaluate the impacts of these alternatives. Alternatives which have been under consideration are described in detail in *The Scoping Document for Extending the Charter Vessel/Headboat Permit Moratorium by Amending the FMPs for: Reef Fish (Amendment 25) and Coastal Migratory Pelagics (Amendment 17)*, which is available from the Council (see **ADDRESSES**). The Council is soliciting public comment on the range of alternatives and scope of issues that should be considered in this DSEIS.

In accordance with NOAA's Administrative Order NAO 216–6, Section 502(c)4, the Council previously held nine scoping hearings during June 2004 to solicit input from interested parties on proposed actions and alternatives identified in the above-mentioned scoping document. These hearings were held in the following locations: Port Isabel, Port Aransas, and Galveston, TX; Kenner, LA; Biloxi, MS; Orange Beach, AL; Destin, Madeira Beach, and Naples, FL.

Additionally, public comments may be accepted at the following Council meetings and during public hearings that will be announced in future **Federal Register** notices:

July 11–14, 2005, Diamondhead All-Suite Beach Resort, 2000 Estero Boulevard, Ft. Myers Beach, FL 33931; and

September 12–15, 2005, New Orleans, LA (Location TBA).

The meetings will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Gulf Council (see **ADDRESSES**).

The completed DSEIS associated with the draft Moratorium Amendment will be filed with the U.S. Environmental Protection Agency (EPA), announced in the **Federal Register**, and open to public comment for a 45–day period. This procedure is pursuant to regulations issued by the Council on Environmental Quality (CEQ) for implementing the National Environmental Policy Act (NEPA), and to NOAA's Administrative Order 216–6 on complying with NEPA and the CEQ regulations.

The Council will consider public comments received on the DSEIS in developing the final supplemental environmental impact statement (FSEIS), and before taking final action on the Moratorium Amendment. The Council will submit both the final amendment and the supporting FSEIS to NMFS for Secretarial review, approval, and implementation under the requirements of the Magnuson-Stevens Fishery Conservation and Management Act.

NMFS will announce, through a document published in the **Federal Register**, the availability of the final Moratorium Amendment for public review during the Secretarial review period. During Secretarial review, NMFS will also file the FSEIS with the EPA for a final 30–day public comment period. This comment period will be concurrent with the Secretarial review period and will end prior to final agency action to approve, disapprove, or partially approve the final Moratorium Amendment.

NMFS will announce, through a notice published in the **Federal Register**, all public comment periods on the final Moratorium Amendment, any proposed implementing regulations, and its associated FSEIS. NMFS will consider all public comments received during the Secretarial review period, whether they are on the final amendment, any proposed regulations, or the FSEIS, prior to final agency action.

Dated: April 1, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 05–6939 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040405B]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Groundfish Stock Assessment Review (STAR) Panel for gopher rockfish, cowcod, California scorpionfish, and vermilion rockfish will hold a work session which is open to the public.

DATES: The gopher rockfish, cowcod, California scorpionfish, and vermilion rockfish STAR Panel will meet beginning at 8 a.m., Monday, May 9, 2005. The meeting will continue through Friday, May 13, 2005, beginning at 8 a.m. every morning. The meetings will end at 5 p.m. each day, or as necessary to complete business.

ADDRESSES: The gopher rockfish, cowcod, California scorpionfish, and vermilion rockfish STAR Panel meeting will be held at NMFS, Southwest Regional Office, 501 West Ocean Boulevard, Long Beach, CA 90802–4213; telephone: 562–980–4000.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Ms. Stacey Miller, Northwest Fisheries Science Center; telephone: 206–860–3480; or Mr. John DeVore, Pacific

Fishery Management Council; telephone: 503–820–2280.

SUPPLEMENTARY INFORMATION: The purpose of the STAR Panel meeting is to review draft stock assessment documents and any other pertinent information, work with the Stock Assessment Teams to make necessary revisions, and produce a STAR Panel report for use by the Council family and other interested persons. No management actions will be decided by the STAR Panel. The STAR Panel's role will be development of recommendations and reports for consideration by the Council at its June meeting in Foster City, CA.

Although nonemergency issues not contained in the meeting agenda may come before the STAR Panel participants for discussion, those issues may not be the subject of formal STAR Panel action during this meeting. STAR Panel action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the STAR Panel participants' intent to take final action to address the emergency.

Entry to the Southwest Regional Office requires visitors to show a valid picture ID and register with security. A visitor's badge, which must be worn while at the Southwest Region Facility, will be issued to non-federal employees participating in the meeting.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at 503–820–2280 at least 5 days prior to the meeting date.

Dated: April 4, 2005.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Servicee.

[FR Doc. E5–1592 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040405A]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Ad Hoc Allocation Committee (Committee) will hold a working meeting, which is open to the public.

DATES: The Committee meeting will be held Monday, May 2, 2005, from 1 p.m. until business for the day is completed. The Committee meeting will reconvene Tuesday, May 3, 2005, from 8:30 a.m. until business for the day is completed.

ADDRESSES: The Committee meeting will be held in Portland, Oregon at a location to be determined. The Pacific Fishery Management Council will distribute notice of the meeting location to interested parties on their groundfish mailing list and will post this information as well on their website at *www.pcouncil.org*.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, Oregon 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. John DeVore, Groundfish Management Coordinator; telephone: 503–820–2280.

SUPPLEMENTARY INFORMATION: The purpose of the Committee meeting is to consider allocational issues associated with development of an individual quota (or dedicated access) program initiative for the Pacific Coast groundfish trawl fishery, as well as initiatives pursuant to implementing bycatch reduction measures frameworked in Amendment 18 to the Pacific Coast Groundfish Fishery Management Plan. The Committee will discuss the types of provisions that may be necessary to prevent further overfishing, to reduce bycatch of overfished species in the various groundfish fisheries, and to reduce bycatch in nongroundfish fisheries. No management actions will be decided by the Committee. The Committee's role will be development of recommendations for consideration by the Council at its June meeting in Foster City, California.

Although nonemergency issues not contained in the meeting agenda may come before the Committee for discussion, those issues may not be the subject of formal Committee action during this meeting. Committee action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Committee's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at 503–820–2280 at least 5 days prior to the meeting date.

Dated: April 4, 2005.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1593 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040105D]

National Marine Fisheries Service, Regional Fishery Management Council Chairs and Executive Directors Meeting; April 26–29, 2005

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Council) is hosting the Regional Fishery Management Council (RFMC) Chairs and Executive Directors Meeting on Tuesday, April 26, 2005 through Friday, April 29, 2005, in Dana Point, California. The purpose of the meeting is to enable NMFS, NOAA, and other officials to exchange information with and obtain views of the Council Chairs and Executive Directors (CCED).

DATES: The CCED will meet April 26–29, 2005. There will be non-public administrative sessions on Tuesday, April 26, 2005, from 8 a.m. to 5 p.m. and on Friday, April 29, 2005, from 8 a.m. to 12 p.m. The public general sessions will be held Wednesday, April 27, 2005 and Thursday, April 28, 2005, beginning each day at 8 a.m. through 5 p.m., or until business is concluded.

ADDRESSES: The meetings will be held at the Laguna Cliffs Marriott Hotel, 25135 Park Lantern, Dana Point, California 92629; telephone 800–545–7483.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Dr. Donald O. McIsaac, Executive Director; telephone: 503–820–2280.

SUPPLEMENTARY INFORMATION: The following items are on the Regional Fishery Management CCED general session agenda for April 27–28, 2005, but not necessarily in this order:

A. Congressional Staff Briefing

B. Magnuson-Stevens Fishery Conservation and Management Act Reauthorization and Associated Legislation

1. Review 2002 Administration Positions and Current Administration Perspectives

2. Review 2002 Council Chairs' Positions and Current Regional Councils' Positions

C. Budget Issues

1. RFMC Funding

2. NMFS Funding Issues

3. Schedule for Interim CCED Meeting on Budget Issues

D. Ocean Commission Report: President's U.S. Ocean Action Plan

E. Ecosystem Management Approaches

1. NOAA-Councils Work Group Report on Guidelines

2. NOAA Activities

3. Councils Fishery Ecosystem Plan Update

F. Council Member Training

G. Next CCED Meeting

Although non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at 503–820–2280 at least five days prior to the meeting date.

Dated: April 4, 2005.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1594 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 030805B]

Endangered Species; File No. 1510

AGENCY: National Marine Fisheries Service (NMFS),National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of permit.

SUMMARY: Notice is hereby given that the Liberty Science Center (Richard Weddle, Principal Investigator), 251 Phillip Street, Jersey City, New Jersey 07305, has been issued a permit to take shortnose sturgeon (*Acipenser brevirostrum*) for purposes of enhancement through educational display.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)713–0376; and

Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930-2298; phone (978)281–9200; fax (978)281–9371.

FOR FURTHER INFORMATION CONTACT: Jennifer Jefferies or Amy Sloan, (301)713–2289.

SUPPLEMENTARY INFORMATION: On December 15, 2004, notice was published in the **Federal Register** (69 FR 75047) that a request for an enhancement permit to take shortnose sturgeon had been submitted by the above-named organization. The requested permit has been issued under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The Liberty Science Center is authorized to receive and use five individual, captive-bred, non-releaseable shortnose sturgeon for an educational display exhibit. This project of displaying endangered captive bred shortnose sturgeon responds directly to a recommendation of the NMFS recovery outline for this species. In addition, the facility will formulate a public education program and exhibit to increase awareness of the shortnose sturgeon and its status. This project will educate the public on shortnose sturgeon life history and the reason for its declining numbers.

Issuance of this permit, as required by the ESA, was based on a finding that this permit (1) was applied for in good faith, (2) will not operate to the disadvantage of the endangered species which is the subject of the permit, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: March 31, 2005.

Stephen L. Leathery,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 05–6938 Filed 4–6–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Chief of Naval Operations (CNO) Executive Panel

AGENCY: Department of the Navy, DOD.

ACTION: Notice of closed meeting.

SUMMARY: The CNO Executive Panel is to report the findings and recommendations of the East Asia Strategy Study Group to the Chief of Naval Operations. The meeting will consist of discussions on a maritime strategy for East Asia.

DATES: The meeting will be held on Friday, April 22, 2005, from 11 a.m. to 12 p.m.

ADDRESSES: The meeting will be held at the Chief of Naval Operations office, Room 4E540, 2000 Navy Pentagon, Washington, DC 20350.

FOR FURTHER INFORMATION CONTACT: Commander Steve Vincent, CNO Executive Panel, 4825 Mark Center Drive, Alexandria, VA 22311, 703–681–4906.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), these matters constitute classified information that is specifically authorized by Executive Order to be kept secret in the interest of national defense and are, in fact, properly classified pursuant to such Executive Order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

Dated: April 1, 2005.

I. C. Le Moyne Jr.,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 05–6913 Filed 4–6–05; 8:45 am]

BILLING CODE 3810–FF–P

ELECTION ASSISTANCE COMMISSION

Publication of State Plans Pursuant to the Help America Vote Act

AGENCY: U.S. Election Assistance Commission (EAC).

ACTION: Notice.

SUMMARY: Pursuant to sections 254(a)(11)(A) and 255(b) of the Help America Vote Act (HAVA), Public Law 107–252, the U.S. Election Assistance Commission (EAC) hereby causes to be published in the **Federal Register** material changes to HAVA State plans previously submitted by Alaska and Ohio.

DATES: This notice is effective upon publication in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Bryan Whitener, Telephone 202–566–3100 or 1–866–747–1471 (toll-free).

Submit Comments: Any comments regarding the plans published herewith should be made in writing to the chief election official of the individual States at the address listed below.

SUPPLEMENTARY INFORMATION: On March 24, 2004, the U.S. Election Assistance Commission published in the **Federal Register** the original HAVA State plans filed by the 50 States, the District of Columbia and the Territories of American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands. 69 FR 14002. HAVA anticipated that States, Territories and the District of Columbia would change or update their plans from time to time pursuant to HAVA section 254 (a)(11) through (13). HAVA sections 254(a)(11)(A) and 255 require EAC to publish such updates.

The submissions from Alaska and Ohio address material changes in the administration of their original State plans and, in accordance with HAVA section 254(a)(12), provide information on how the State succeeded in carrying out the previous State plan. Ohio has received its 2003 and 2004 requirements payments. Alaska has not yet submitted a statement of certification for a requirements payment to EAC.

Upon the expiration of 30 days from April 7, 2005, these States will be eligible to implement any material changes addressed in the plans that are published herein, in accordance with HAVA section 254(a)(11)(C). At that time, in accordance with HAVA section 253(d), Alaska also may file a statement of certification to obtain its requirements payments. Such statements of certification must confirm that the State is in compliance with all of the requirements referred to in HAVA section 253(b) and must be provided to the Election Assistance Commission in order for the State to receive a requirements payment under HAVA Title II, Subtitle D.

EAC notes that plans published herein include only those that have already met the notice and comment requirements of HAVA section 256, as required by HAVA section 254(a)(11)(B). EAC wishes to acknowledge the effort that went into the revising the State plans and encourages further public comment, in writing, to the chief election official of the individual States at the address listed below.

Chief State Election Officials

Alaska

Ms. Laura A. Glaiser, Director, State of Alaska Division of Elections, PO Box 110017, Juneau, AK 99811–0017, Phone: 907–465–4611, Fax: 907–465–3203, e-mail: *elections@gov.state.ak.us.*

Ohio

The Honorable J. Kenneth Blackwell, Secretary of State, 180 E. Broad Street, 16th Floor, Columbus, OH 43215, Phone: 614–466–2655, Fax: 614–644–0649, e-mail: *election@sos.state.oh.us.*

Thank you for your interest in improving the voting process in America.

Dated: March 30, 2005.

Gracia M. Hillman,

Chair, U.S. Election Assistance Commission.

BILLING CODE 6820–YN–P

Director's Office
PO Box 110017
Juneau, Alaska 99811-0017
907.465.4611 · 907.465.3203 FAX
elections@gov.state.ak.us

Regional Offices
Anchorage 907.522.8683
Fairbanks 907.451.2835
Juneau 907.465.3021
Nome 907.443.5285

STATE OF ALASKA
Division of Elections
Office of the Lieutenant Governor

March 10, 2005

Dear Commissioners:

In accordance with section 255 of the Help America Vote Act of 2002 (HAVA), I am pleased to file with the Election Assistance Commission (EAC), for publication in the *Federal Register*, this letter and the following new pages that comprise Sections 6, 8 and 12 of the State of Alaska updated HAVA Plan. These new pages, together with non-substantive changes that we have made, constitute Alaska's HAVA State Plan for Fiscal Year 2005.

As required by section 254(a)(12) of HAVA, Section 12 of Alaska's State Plan, as amended, describes the material changes that Alaska made to the State Plan filed in 2003. In addition, Sections 6 and 8 contain important information on how Alaska's budget to implement the requirements of HAVA changed and how Alaska succeeded thus far in meeting specific HAVA requirements.

Please note that non-material changes to the Alaska State Plan can be found throughout every element of the Alaska State Plan. After consulting with EAC staff, the State of Alaska will not be submitting those types of changes for publication in the *Federal Register* as unnecessary under HAVA. Instead, we would direct the EAC and members of the public to Alaska's State Division of Elections' website (www.gov.state.ak.us/ltgov/elections/hava.htm) to view and print the complete 2005 Alaska State Plan.

The amendments to the Alaska State Plan were developed in accordance with section 255 of HAVA and the requirements for public notice and comment prescribed by section 256 of HAVA.

On behalf of the State of Alaska, I thank the Election Assistance Commission for its assistance. I look forward to our continued collaboration to improve the administration of elections in Alaska.

Laura A. Glaiser
Director

www.elections.state.ak.us

STATE OF ALASKA

Section 6. Alaska's Budget for Implementing HAVA

The State's proposed budget for activities under this part, based on the State's best estimates of the costs of such activities and the amount of funds to be made available, including specific information on-

(A) the costs of the activities required to be carried out to meet the requirements of Title III;
(B) the portion of the requirements payment which will be used to carry out activities to meet such requirements; and
(C) the portion of the requirements payment which will be used to carry out other activities.

Title I-Early payments:
HAVA authorized $650 million in one-time payments to states: $325 million for making improvements to the administration of elections and $325 million for the replacement of punch card and lever voting machines. States are not required to provide matching funds for Title I monies.

Title I mandated that each eligible state receives a minimum of $5,000,000. Alaska's portion was determined by the small state minimum and received $5,000,000 in April 2003 for making improvements to elections. Alaska was not eligible to receive funds under Section 102 since Alaska replaced its punch card voting system before 2000. However, Alaska did receive a one-time reimbursement payment made to states that replaced such equipment prior to 2000. (see "reimbursement payment" below.)

All Title I money has been distributed to the states.

Title II- Requirements payments:
Title II authorizes $3 billion in additional payments to states over a three year period, annually for meeting the requirements of Title III and for activities to improve the administration of elections if all Title III requirements have been satisfied.

Congress appropriated $830 million for FY 2003 and just under $1.5 billion for FY 2004 requirements payments to states. While the FY 2003 funding fell short of the $1.4 billion authorized in HAVA, FY 2004 funding exceeded the $1.0 billion authorized. Distribution of these funds began in June 2004. Alaska is in the process of submitting certification paperwork for these payments. Congress has not appropriated money for FY 2005.

Payments under Title II are formula based and require a 5% State match for all funds spent in each fiscal year. However, the State may draw down funds each fiscal year without providing the match if the State's Election Plan accounts for the 5% funds in future use. To determine the 5% State match based on the federal requirements payment, multiply Alaska's requirement's payment portion by .0526 (5 divided by 95). See Table 6.1 for Alaska's requirements payment amounts and State match funds.

Accessibility Grants:
Title II also authorizes the Secretary of Health and Human Services to distribute payments to states to assure access for individuals with disabilities. Alaska has applied for and received $200,000 in accessibility grants for FY 2003 and FY 2004. These funds will be expended in accordance with the requirements of Title II Section 261.

STATE OF ALASKA

Reimbursement Payment:
The Consolidated Appropriations Resolution, Public Law 108-7, signed February 20, 2003, provided $15,000,000 in Federal appropriated funds to the General Services Administration (GSA), for Election Reform Reimbursements. This one-time reimbursement was for states that purchased electronic voting equipment to replace punch card and lever voting machines prior to

2000 making them ineligible to receive funds under Title I Section 102 of HAVA. Alaska qualified for and received a one-time reimbursement of $1.1 million deposited back into the State's General Fund for electronic voting machines purchased in 1998 to replace all punch card voting equipment.

Table 6.1 outlines the portion of funds available according to GSA Estimates Requirements Payments to States FY03-FY04, Revised 3/31/04.

Table 6.1

Federal Fiscal Year	Federal Funds	Alaska's Payment Portion	5% State Match Requirement
(§ 101) Early Payment	$650,000.0	$5,000.0	None
(§ 252, 257) 2003	$830,000.0	$4,150.0	$218.3
(§ 252, 257) 2004	$1,500,000.0 ($ rounded up)	$7,446.8	$391.7
(§ 252, 257) 2005	$600,000.0	$3,000.0	$158.0
Total	$3,580,000.0	$19,596.8	$768.0

Alaska's budget in Table 6.2 is based on the levels of funding as shown in Table 6.1 and represents the cost of implementing requirements of Title III and "other" activities as specified in Title I of HAVA through calendar year 2006. Costs associated with the maintenance and operations of implementing these requirements are also reflected in the budget. It is important to note that the maintenance and operation costs associated with these requirements will have an impact on the State's budget in future years when federal funding is no longer available.

HAVA Requirements	Estimated Total Cost	Source of Funding			Implementation Period
Title III Requirements		Sec 101	Sec 252 & 257	State 5% Match	
(301) Voting System	$5,677.0		$5,378.4	$ 298.6	FY 2003 to FY2006
(302) Provisional Voting and voting information requirements	$ 650.2		$ 616.0	$ 34.2	FY 2003 to FY2004
(303) Computerized statewide voter registration list requirements and requirements for voters who register by mail.	$7,518.0	$3,118.1	$4,168.5	$ 231.4	FY 2003 to FY2004
"Other" activities					

STATE OF ALASKA

(25 ½) (3) Voter education, election official education and training, and poll worker training which will assist the State in meeting the requirements of Title III.	$1,800.0	$1,051.5	$ 709.1	$ 39.4	FY2003 to FY2006
(402) Establish a State-based *HAVA* administrative complaint procedures to remedy grievances	$ 110.0	$ 60.1	$ 47.3	$ 2.6	
(704) Improvements to military absentee voting program	$ 41.6	$ 20.2	$ 20.3	$ 01.1	
(101) Management of State Plan	$ 500.0	$ 51.1	$ 425.3	$ 23.6	FY2003 to FY2005
Technology planning/improvements	$1,300.0	$ 194.8	$1,047.1	$ 58.1	FY2003 to FY2006
Polling place accessibility	$2,000.0	$ 504.2	$ 1,417.1	$ 78.7	FY2003 to FY2006
TOTALS	$19,596.8	$5,000.0	$13,829.1	$767.7	

Additional Notes for Title III requirements:

(1) *Voting System*-Alaska purchased optical scan units in 1998 to replace its punch card voting system. Alaska has 439 voting precincts. Sixty-six percent of the precincts are equipped with optical scan and 34 percent are hand-count precincts. The estimated $5.5 million will be used to implement a HAVA-compliant DRE voting system and to purchase additional optical scan units for a portion of Alaska's precincts. In addition, the Division plans to purchase more memory cards for the Accu-Vote Optical Scan voting machines. Installation, training and maintenance costs are included in this figure.

Since Alaska purchased its computerized statewide voting system, replacing punch card voting equipment, prior to November of 2000, Alaska is not eligible to seek reimbursement under Title I, Sec 102 for these expenditures. However, outside of HAVA, PL 108-7 included $15 million in funds to states who purchased optical scan systems prior to the 2000 election. So far, only five states, which include Alaska, were eligible for compensation from the $15 million appropriation. Alaska received a $1.1million reimbursement that was deposited into the State's general fund and is not included in the State's budget for implementing requirements of HAVA.

(2) *Provisional Voting*- Provisional voting, known as questioned voting in Alaska, has been available to voters in Alaska since the early 1980s. There were minimal changes needed to meet the provisional voting requirements of the bill.

(3) *Computerized Statewide Voter Registration System*-Currently Alaska has a

mainframe based statewide Voter Registration Election Management System (VREMS) that has been in place for over 17 years. This system is no longer cost effective for the State to maintain, due to the Natural programming language it is written in and the complexity of the program. The State will use the estimated $7.5 million in funds to research and purchase a statewide voter registration system that is conducive to the administration of elections and is cost effective. The Request for Proposal (RFP) for this project will be available in early 2005.

The estimated costs associated with implementing the requirements in HAVA are based on the funding information available at the time that the plan was updated. The budget will be revised appropriately to reflect the most current information available on federal funding and according to changes that may be made in the implementation schedule.

Section 8. HAVA Performance Goals and Measures

How the State will adopt performance goals and measures that will be used by the State to determine its success and the success of units of local government in the State in carrying out the plan, including timetables for meeting each of the elements of the plan, descriptions of the criteria the State will use to measure performance and the process used to develop such criteria, and a description of which official is to be held responsible for ensuring that each performance goal is met.

The Division of Elections will establish performance goals in conjunction with the Alaska State Legislature during the deliberation of the annual operating budget. The "Missions and Measures" process undertaken by the Legislature in concurrence with the consideration of the annual operating budget has been established as a respected means for developing performance measures that accurately quantify program success.

The Director of the Division of Elections, as the "Chief State Election Official" under section 253(e), is responsible for coordination of the State's responsibilities under this Act. Therefore, the Director is ultimately responsible for ensuring that the Division meets each performance goal. In addition, the Legislature will be monitoring the Division's efforts through the annual preparation of the State's operating budget.

Plan Elements	Official	Time frame
Voting Systems §301	Director of Elections	Working 100 TS units purchased To be implemented by January 1, 2006
Provisional Voting §302	Director of Elections	Completed
Voter Registration §303(a) §303(b)	Director of Elections	§303(a) Implemented §303(b) Implemented
Other Activities		
§101 (b)(1), §251 (b)(2)		
Technical Infrastructure	Election Admin. Supervisor	Working
Free-Access System	Admin Asst. Supervisor	Toll-free phone system operational Over 8,000 calls received on Election

	HAVA Coordinator	Day
Education and Training §254(a)(3)	Regional Supervisors Election Special Assistant HAVA Coordinator	Ongoing Some training materials updated March 2004
Budget and Fiscal Controls §254(a)(2) §254(a)(6) §254(a)(7) §254(a)(10)	Admin. Asst. Supervisor Elections Special Assistant Director	Ongoing State monitors HAVA account each month
Complaint Procedures §254(a)(9) §402	Director of Elections in conjunction with Department of Law	Completed 08-29-03 Precleared by DOJ 6 AAC 25.400-490

Section 12. Changes to State Plan from Previous Fiscal Year

In the case of a State with a State Plan in effect under this subtitle during the previous fiscal year, a description of how the plan reflects changes from the State Plan for the previous fiscal year and of how the State succeeded in carrying out the State Plan for such previous fiscal year.

The State of Alaska's 2004 HAVA Updated State Plan remains consistent, with steady progress towards the goals established in the initial 2003 State Plan. The State of Alaska passed legislation to bring the state into compliance with HAVA requirements; new staff to manage HAVA; updated forms and training materials; and continues to design improved voter outreach programs.

In 2004, the Division established a toll-free access system to provide voter information in the form of a toll-free telephone number. This system allows the voter to determine if his or her questioned ballot was counted and, if not counted, why the vote or a portion of the vote did not count.

The Division also completed procedures to allow the Division of Elections to match identifying information provided by a first-time, by-mail registrant on his or her registration application to information maintained in the Division of Motor Vehicles (DMV) database.

Leading up to the 2004 General Election, the Division began "hub training" its election workers. The purpose of this training method is for the Division to more effectively train election workers closer to Election Day. Since there are many rural polling places in Alaska, the Division sent the chair from each selected rural precinct to one larger, more "central" community where all the chairs were trained simultaneously. The chairs then returned to their home and trained the election workers at their polling place. The Division was able to train more election workers closer to Election Day using the "hub training" method, and found this to be an effective means of outreach and training.

The Division has procedures established for conducting recounts on a statewide level, as well as State House and State Senate levels. In 2004, the Division conducted two recounts – one for a State House race and the other for the U.S. Senate race. This was the first time in Alaska history that a statewide

STATE OF ALASKA

recount was conducted with the Accu-Vote Optical Scan equipment, and there were no significant changes to the election results.

The Division used HAVA funds to purchase an additional 45 TS units, bringing the statewide total to 100 TS units. While intending to use the touch screens in a pilot project in the 2004 elections, the Division made the decision to delay implementation until the units are retrofitted with a voter verifiable paper record. In May 2004, the Legislature passed legislation (HB 459) requiring a voter verifiable paper trail for electronic voting machines.

The State of Alaska, Division of Elections succeeded in developing administrative regulations to establish the required complaint procedure. These regulations constitute a new article 6 AAC 25.400 – 490 that is now a part of the Division's administrative regulations set out at Title 6, Chapter 25 of the Alaska Administrative Code. These regulations satisfy the requirements of HAVA section 402 by providing a uniform and nondiscriminatory complaint procedure

Section 6 of the State Plan changed slightly due to the differences in the amount of federal funds initially authorized by Congress, and the actual amounts allocated to the State of Alaska for FY03 - FY04. The updated State Plan reflects the new percentages Alaska projects to spend in different areas to fulfill HAVA requirements.

J. KENNETH BLACKWELL
Ohio Secretary of State

180 E. Broad Street, 16th Floor, Columbus OH 43215
614.466.2655 / Toll Free: 877.767.6446 / Fax: 614.644.0649
e-mail: blackwell@sos.state.oh.us
www.state.oh.us/sos/

February 23, 2005

Dear Election Assistance Commission and Ohio Voters:

In accordance with section 2549(a)(11) of the Help America Vote Act of 2002 (HAVA), I am filing with the U.S. Election Assistance Commission (EAC) for publication in the *Federal Register* this letter and the following amended text of the Changing the Election Landscape in the State of Ohio, please see pages 25, 33, 41, 45 and 46.

The amended portion of our State Plan reflects the actual funding received to date from the Federal Government and the passage of the General Assembly Substitute House Bill 262, which requires all direct recording electronic voting machines (DRE) used in Ohio to include a voter verified paper audit trail.

Please note that non-material change may be found in other elements of the Ohio State Plan. After consulting with EAC staff, the State of Ohio has elected not to include those changes for publication in the Federal Register as unnecessary under HAVA. Instead, we would direct the EAC and members of the public to the Ohio Secretary of State's website (www.sos.state.oh.us) to view the complete Ohio State Plan.

On behalf of the State of Ohio, I thank the Commission for its assistance and look forward to our continued collaboration to improve the administration of elections.

Sincerely,

J. Kenneth Blackwell

J. Kenneth Blackwell

The Ohio Secretary of State gratefully acknowledges the State Plan Committee for their participation and assistance in the preparation and development of this plan for the strategic implementation of election reforms in the State of Ohio, pursuant to the Help America Vote Act of 2002.

HELP AMERICA VOTE ACT

The State Plan Committee

Chairwoman Judy Grady, *Director of Election Reform, Office of the Secretary of State(replaces Dana Walch)*

Ms. Donna Alvarado, *Commissioner, Ohio Commission on Hispanic/Latino Affairs*

Ms. Linda Carr, *Director of Institutional Initiatives, University of Toledo*

Mr. Michael Vu , Director, *Cuyahoga County Board of Elections(replaces Tom Coyne)*

Mr. Eric Duffy, *Director of Field Services, National Federation of the Blind*

Ms. Daisy Duncan Foster, *Coordinator of Academic Services, University of Dayton*

State Rep. Nancy Hollister, *R-Marietta*

Mr. Larry Long, *Executive Director, County Commissioners Association of Ohio*

State Sen. Mark Mallory, *D-Cincinnati*

Mr. Keith Cunningham, *Director, Allen County Board of Elections and President, Ohio Association of Election Officials (replaces Jeff Matthews, Stark County Board)*

Mr. Matthew Damschroder, *Director, Franklin County Board of Election (replaces Guy Reece)*

Ms. Catherine Turcer, *Legislative Director, Ohio Citizen Action*

Pastor Aaron Wheeler, *Chairman, Ohio Civil Rights Commission*

IV. State of Ohio Elections Systems

Ohio is, pervasively, a punch-card voting state. In total, 69 of Ohio's 88 counties use punch-card voting. Those 69 counties represent 72.5 percent of all the registered voters in Ohio and 74 percent of the 11,756 voting precincts in the state.

Among the 19 counties that use voting devices other than punch-card ballots, two use automatic voting machines, six have electronic voting devices, and 11 use optical scanning equipment.

The table below (that continues on the following pages) shows a county-by-county listing of the types of voting devices in each of Ohio's 88 counties. The table also reflects the number of precincts and registered voters in each of those counties as reflected in the November, 2002 General Election, which we use as base data throughout this report (unless otherwise indicated.)

COUNTY	PRECINCTS	REGISTERED VOTERS	TYPE DEVICE
ADAMS	35	15,446	PUNCHCARD
ALLEN	139	65,382	SCAN
ASHLAND	65	31,735	SCAN
ASHTABULA	127	58,022	PUNCHCARD
ATHENS	69	39,813	PUNCHCARD
AUGLAIZE	43	29,656	PUNCHCARD
BELMONT	84	42,800	PUNCHCARD
BROWN	55	25,415	PUNCHCARD
BUTLER	289	210,920	PUNCHCARD
CARROLL	26	18,799	PUNCHCARD
CHAMPAIGN	53	26,900	PUNCHCARD
CLARK	112	82,889	PUNCHCARD
CLERMONT	191	117,207	SCAN
CLINTON	32	23,529	PUNCHCARD
COLUMBIANA	103	73,355	PUNCHCARD
COSHOCTON	43	20,623	SCAN
CRAWFORD	67	28,992	PUNCHCARD
CUYAHOGA	1464	861,113	PUNCHCARD
DARKE	53	36,176	PUNCHCARD
DEFIANCE	46	24,536	PUNCHCARD

DELAWARE	122	82,215	PUNCHCARD
ERIE	101	51,523	SCAN
FAIRFIELD	118	76,212	PUNCHCARD
FAYETTE	38	13,676	PUNCHCARD
FRANKLIN	780	706,668	ELECTRONIC
FULTON	36	26,740	PUNCHCARD
GALLIA	36	21,646	PUNCHCARD
GEAUGA	96	57,087	SCAN
GREENE	142	93,742	PUNCHCARD
GUERNSEY	71	22,149	PUNCHCARD
HAMILTON	1025	522,307	PUNCHCARD
HANCOCK	62	44,603	SCAN
HARDIN	38	17,764	AVM
HARRISON	24	10,861	PUNCHCARD
HENRY	33	18,529	PUNCHCARD
HIGHLAND	46	25,360	PUNCHCARD
HOCKING	32	16,889	PUNCHCARD
HOLMES	27	16,638	PUNCHCARD
HURON	69	35,103	PUNCHCARD
JACKSON	40	23,431	PUNCHCARD
JEFFERSON	93	52,971	PUNCHCARD
KNOX	53	31,630	ELECTRONIC
LAKE	217	150,137	ELECTRONIC
LAWRENCE	84	38,636	PUNCHCARD
LICKING	125	99,182	PUNCHCARD
LOGAN	52	28,698	PUNCHCARD
LORAIN	246	166,092	PUNCHCARD
LUCAS	518	281,500	AVM
MADISON	44	23,288	PUNCHCARD
MAHONING	312	177,445	ELECTRONIC
MARION	84	39,580	PUNCHCARD

State Plan Committee
Help America Vote Act 2002
Revised State Plan Excerpts

J. Kenneth Blackwell
Ohio Secretary of State

MEDINA	145	101,054	PUNCHCARD
MEIGS	27	14,685	PUNCHCARD
MERCER	40	26,724	PUNCHCARD
MIAMI	82	66,743	SCAN
MONROE	29	9,866	PUNCHCARD
MONTGOMERY	593	334,787	PUNCHCARD
MORGAN	22	8,600	PUNCHCARD
MORROW	36	21,354	PUNCHCARD
MUSKINGUM	85	48,175	PUNCHCARD
NOBLE	27	8,173	PUNCHCARD
OTTAWA	78	26,905	SCAN
PAULDING	30	13,374	PUNCHCARD
PERRY	46	20,815	PUNCHCARD
PICKAWAY	53	27.505	ELECTRONIC
PIKE	24	17,849	PUNCHCARD
PORTAGE	129	94,711	PUNCHCARD
PREBLE	46	28,108	PUNCHCARD
PUTNAM	51	24,360	PUNCHCARD
RICHLAND	133	83,151	PUNCHCARD
ROSS	76	37,478	ELECTRONIC
SANDUSKY	73	39,768	SCAN
SCIOTO	107	43,062	PUNCHCARD
SENECA	73	35,707	PUNCHCARD
SHELBY	45	29,776	PUNCHCARD
STARK	364	246,562	PUNCHCARD
SUMMIT	507	334,515	PUNCHCARD
TRUMBULL	274	132,957	PUNCHCARD
TUSCARAWAS	81	53,930	PUNCHCARD
UNION	47	25,880	PUNCHCARD

VAN WERT	39	19,525	PUNCHCARD
VINTON	20	7,770	PUNCHCARD
WARREN	148	101,207	PUNCHCARD
WASHINGTON	81	37,705	SCAN
WAYNE	97	60,048	PUNCHCARD
WILLIAMS	44	24,670	PUNCHCARD
WOOD	104	75,660	PUNCHCARD
WYANDOT	40	14,780	PUNCHCARD
TOTAL	**11,756**	**7,104,549**	

Of note, two of Ohio's largest counties – Cuyahoga and Hamilton counties – currently use punch-card ballot devices, as do two other large urban centers in Ohio, Montgomery and Summit counties. Those four counties, alone, account for nearly 3,600 of Ohio's 11,756 precincts, and more than 2 million of the state's 7.1 million registered voters. Another large urban center in Ohio, Lucas County, is a lever-machine county. NOTE: In 2004, the number of registered voters grew to over 7.9 million and the number of precincts was reduced to 11,360.

In February 2001, the Secretary of State conducted an "Elections Summit."[1] Participants included academics, members of the media, local election officials, legislators, and community groups. The group reported the following:

1. Public confidence in the accuracy of punch card voting systems has been seriously undermined.
2. Boards of elections should upgrade their voting systems to new, more trustworthy technology.
3. Comprehensive voter education is critical to successful election operations.
4. A combination of federal, state, and local dollars may be appropriate to fund these technological improvements.
5. Ohio's current elections standards, based on a combination of secretary of state directives, advisory opinions and rulings, should be codified by the General Assembly.
6. These goals demand immediate attention, or our state runs the risk of repeating the problems of our nation's most recent presidential election – and suffering irreparable damage to the most important and basic concepts of democracy.

Subsequent to the Summit, a separate committee met to study Ohio's election systems. They concluded (by a 6-5 committee vote) that because of the safeguards and procedures in Ohio election law, the punch-card voting method was adequate and there

[1] *Ohio Elections Summit Report*, Office of the Secretary of State, published May 2001.

was no overwhelming need for a statewide overhaul, particularly without available funding.

While the Secretary of State notes that punch-card voting is not explicitly prohibited under the Help America Vote Act, other requirements of the Act make it impractical to use punch-card voting as a primary voting device in the state.

In a study of "over" and "under" voting in Ohio, it was clearly demonstrated that punch-card voting was unreliable to the extent votes cast by thousands of Ohioans were not being counted in the final election tabulation.

Over-voting occurs when a voter casts a vote for more than one candidate in an election and thus disqualifies their vote in that election. Under-voting occurs when a voter fails to mark a ballot in a particular race or votes for fewer than the number of candidates to be elected.

The following table tracks the combined under/over vote phenomenon in the 2000 presidential election in Ohio's 88 counties:

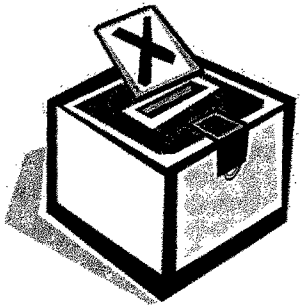
County	2000 Voting System	Total Votes Cast	Total Votes Counted	Difference	Percent Difference
Holmes	PUNCHCARD	9,937	9,145	792	7.97%
Pike	PUNCHCARD	11,084	10,560	524	4.73%
Vinton	PUNCHCARD	5,184	4,946	238	4.59%
Adams	PUNCHCARD	10,727	10,235	492	4.59%
Meigs	PUNCHCARD	10,228	9,795	433	4.23%
Noble	PUNCHCARD	6,210	5,988	222	3.57%
Monroe	PUNCHCARD	7,377	7,115	262	3.55%
Jackson	PUNCHCARD	12,918	12,490	428	3.31%
Gallia	PUNCHCARD	13,203	12,776	427	3.23%
Summit	PUNCHCARD	232,252	224,839	7,413	3.19%
Harrison	PUNCHCARD	7,380	7,161	219	2.97%
Tuscarawas	PUNCHCARD	38,246	37,118	1,128	2.95%
Mercer	PUNCHCARD	18,848	18,294	554	2.94%
Paulding	PUNCHCARD	9,214	8,946	268	2.91%
Belmont	PUNCHCARD	31,039	30,141	898	2.89%
Lawrence	PUNCHCARD	25,180	24,452	728	2.89%
Montgomery	PUNCHCARD	237,580	230,987	6,593	2.78%
Scioto	PUNCHCARD	30,786	29,945	841	2.73%
Guernsey	PUNCHCARD	15,855	15,430	425	2.68%
Morgan	PUNCHCARD	6,158	5,993	165	2.68%
Muskingum	PUNCHCARD	33,520	32,624	896	2.67%
Cuyahoga	PUNCHCARD	590,473	574,782	15,691	2.66%
Sandusky	PUNCHCARD	26,441	25,744	697	2.64%
Brown	PUNCHCARD	16,862	16,429	433	2.57%
Highland	PUNCHCARD	15,854	15,447	407	2.57%
Hocking	PUNCHCARD	11,034	10,756	278	2.52%
Carroll	PUNCHCARD	12,576	12,261	315	2.50%

Perry	PUNCHCARD	13,147	12,828	319	2.43%
Richland	PUNCHCARD	54,088	52,779	1,309	2.42%
Mahoning	SCAN	116,889	114,119	2,770	2.37%
Morrow	PUNCHCARD	13,145	12,839	306	2.33%
Seneca	PUNCHCARD	24,931	24,351	580	2.33%
Wyandot	PUNCHCARD	10,059	9,827	232	2.31%
Jefferson	PUNCHCARD	35,449	34,636	813	2.29%
Erie	SCAN	35,836	35,015	821	2.29%
Crawford	PUNCHCARD	19,622	19,176	446	2.27%
Putnam	PUNCHCARD	17,743	17,344	399	2.25%
Ashtabula	PUNCHCARD	40,378	39,472	906	2.24%
Clark	PUNCHCARD	58,876	57,559	1,317	2.24%
Trumbull	PUNCHCARD	98,440	96,239	2,201	2.24%
Defiance	PUNCHCARD	16,610	16,242	368	2.22%
Champaign	PUNCHCARD	16,035	15,680	355	2.21%
Marion	PUNCHCARD	25,371	24,815	556	2.19%
Darke	PUNCHCARD	23,784	23,267	517	2.17%
Fayette	PUNCHCARD	9,484	9,278	206	2.17%
Washington	SCAN	27,080	26,515	565	2.09%
Lorain	PUNCHCARD	114,480	112,180	2,300	2.01%
Greene	PUNCHCARD	66,524	65,204	1,320	1.98%
Stark	PUNCHCARD	163,061	159,844	3,217	1.97%
Huron	PUNCHCARD	21,788	21,360	428	1.96%
Madison	PUNCHCARD	14,960	14,667	293	1.96%
Logan	PUNCHCARD	18,823	18,455	368	1.96%
Clinton	PUNCHCARD	15,366	15,070	296	1.93%
Clermont	SCAN	71,242	69,877	1,365	1.92%
Columbiana	PUNCHCARD	45,294	44,427	867	1.91%
Van Wert	PUNCHCARD	13,471	13,219	252	1.87%
Preble	PUNCHCARD	18,506	18,166	340	1.84%
Portage	PUNCHCARD	64,026	62,899	1,127	1.76%
Henry	PUNCHCARD	13,484	13,252	232	1.72%
Athens	PUNCHCARD	25,888	25,447	441	1.70%
Hamilton	PUNCHCARD	384,336	377,899	6,437	1.67%
Wayne	PUNCHCARD	43,151	42,436	715	1.66%
Miami	SCAN	43,555	42,841	714	1.64%
Butler	PUNCHCARD	138,992	136,737	2,255	1.62%
Licking	PUNCHCARD	63,490	62,466	1,024	1.61%
Auglaize	PUNCHCARD	20,212	19,892	320	1.58%
Coshocton	SCAN	14,493	14,268	225	1.55%
Williams	PUNCHCARD	16,170	15,919	251	1.55%
Union	PUNCHCARD	17,288	17,024	264	1.53%
Fairfield	PUNCHCARD	54,913	54,094	819	1.49%
Warren	PUNCHCARD	70,109	69,078	1,031	1.47%
Medina	PUNCHCARD	67,850	66,883	967	1.43%
Fulton	PUNCHCARD	19,161	18,896	265	1.38%
Ashland	SCAN	21,535	21,258	277	1.29%

Ross	ELECTRONIC AVB: scan	26,348	26,016	332	1.26%
Wood	PUNCHCARD	52,832	52,194	638	1.21%
Hancock	SCAN	30,958	30,617	341	1.10%
Ottawa	SCAN	20,185	19,968	217	1.08%
Knox	ELECTRONIC AVB: scan	21,488	21,260	228	1.06%
Delaware	PUNCHCARD	55,959	55,403	556	0.99%
Pickaway	ELECTRONIC AVB: scan	17,912	17,740	172	0.96%
Allen	SCAN	44,207	43,795	412	0.93%
Franklin	ELECTRONIC AVB: Punchcard	417,800	414,074	3,726	0.89%
Geauga	SCAN	42,963	42,600	363	0.84%
Lake	ELECTRONIC AVB: Punchcard	103,347	102,564	783	0.76%
Hardin	Precinct: AVM AVB: Punchcard	12,159	12,068	91	0.75%
Lucas	Precinct: AVM AVB: Punchcard	188,419	187,350	1,069	0.57%
Shelby[2]	PUNCHCARD	19,670	19,670	0	0.00%
TOTALS		**4,795,989**	**4,705,457**	**90,532**	**1.89%**

The data shows 29 counties with the highest over/under vote percentage in the 2000 election were all counties that use the punch-card method of voting. The seven counties with the lowest over/under vote percentage in the 2000 election were all counties that did not use punch cards as their primary voting system.

The Ohio challenge in meeting the voter and election reforms envisioned by the Help America Vote Act is obvious. In simplest terms, Ohio is a large and populous state with a diverse mix of urban and rural voters that predominantly relies on punch-card voting as its prevailing voting mode. Modernizing the state's election systems will require widespread change throughout the state and in its most populous counties.



The transition will require a solution that must consider large and small counties, rural and urban areas, and adjustments that will affect an overwhelming majority of Ohio voters. The obvious corollary challenge is selecting a system configuration that meets the needs of all those counties, training election officials and poll workers to use new voting systems, and familiarizing Ohio voters with new voting devices.

While on its face, this appears to be a daunting challenge, we are confident Ohio's State Plan logically anticipates those factors and will meet the guidelines, demands, timetables and expectations of the Help America Vote Act.

[2] Shelby County, a punch-card county, reported no over/under vote in the county's vote tabulation in the 2000 presidential election cycle. This would appear to be a reporting error.

V. Voter Trends: the Context for Change and Reform

We pause only for a moment in this report to reflect on voter turnout in Ohio. We do so for several reasons, not the least of which Ohio contemplates election reform and system modernization to take place in a presidential election year when voter turnout is higher and demand on the election system is greatest.

We also explore voter turnout and trends as context for meeting the most desirable benefit and objective of the Act: to restore public confidence in the election system and, subsequently, increase voter participation. While new, more technologically proficient systems, increased voter registration, accessibility and accuracy are hallmarks of Help America Vote, the more encompassing aim of the Act is to invite more voters into the process to exercise their rights and responsibilities as qualified electors.

In developing the State Plan, we must anticipate that voter participation will increase, voter turnout percentages will climb, and demand on the election system will be greater. We can only gauge those factors based on Ohio's experience in past elections and the historical trends that will serve as a predictor of future trends.

The following table tracks Ohio voter turnout in both gubernatorial elections and presidential elections during the past 24 years.

Gubernatorial Election Years			Presidential Election Years		
Year	No. of Electors Voting	Turnout Percentage	Year	No. of Electors Voting	Turnout Percentage
1978	3,017,326	58.23%	1980	4,378,937	73.87%
1982	3,551,995	62.36%	1984	4,664,223	73.65%
1986	3,261,870	54.38%	1988	4,505,264	71.79%
1990	3,620,469	61.23%	1992	5,043,094	77.15%
1994	3,570,391	57.29%	1996	4,638,108	67.83%
1998	3,534,782	49.81%	2000	4,800,009	63.73%
2002	3,356,285	47.24%	2004	5,574,476	69.86%

The chart shows that during the course of the past six gubernatorial elections, voter turnout has averaged about 55.79 percent. During the past six presidential elections, voter turnout in Ohio has averaged 71.33 percent. Based on this historical data, Ohio can generally anticipate about 1.25 million more voters in a presidential election year than in a gubernatorial election cycle.

Even a modest 5 percent gain in that average means 62,500 more voters. Subsequently, based on projected population growth and increased voter participation as a result of election reforms and modernization, our State Plan assumes 150,000 new voters during peak presidential elections growing at an annual rate, after initial implementation of new systems and election reforms, of 3 percent per annum.

As a result, our Plan assumes that growth rate and the recommended voting systems design model proposed in this report anticipates that growth and demand on the state's election system in future peak presidential voting years. We use the presidential voting cycle as a base for our plan because that assumes the heaviest potential voter turnout and the busiest times for local boards of elections.

Since 1978, voter participation in the state's gubernatorial elections has grown from 3 million voters to about 3.3 million voters. Since 1980, voter participation in presidential elections has grown from about 4.3 million voters to about 4.8 million voters. Factoring population growth during those decades, those statistics would imply that voter participation has remained relatively flat and, in all likelihood, is trending lower.

We have a high confidence level that the election reforms of the Help America Vote Act will produce more voter activity and a greater number of voters. Ohio doesn't view the Act as a final effort to produce greater voter participation, but the beginning of an expanded effort to entice more voters to exercise their rights and responsibilities to participate in the election process.

We believe modernization and reform require us to actively engage in voter education and to continue to evaluate programs that will produce greater participation in the democratic process. We pledge our effort to continue to explore new and innovative programs that will achieve those objectives.

VIII. Distribution of Resources to Local Governments

We first explore our proposed distribution of aid to local government under Title I. Under guidelines of the Act, these funds must be used assuming the following criteria:

- These funds may be used as a reimbursement for costs associated with punch-card or lever machine replacement incurred after Jan. 1, 2001.
- There is a presumption states must ensure compliance in time for the November, 2004 Federal Election.
- Within six months after the date of enactment, Ohio must certify that the state will use the money for punch-card/lever machine replacement, the state will comply with federal laws, and the voting system will meet new voting system standards.

We anticipate that no change in state law or new legislation will be required to carry out the activities required for certification.

At the initial writing, the Congressional Research Service (CRS) estimated that full-funding under the Act, for both Title I and Title II receipts, would total $155,251,155. CRS estimates $116,423,155 of that amount represents Title II funding under the Requirements Payments component of the Act. However, as of this revision date, the Congress has not appropriated the full funding as prescribed in Public Law 107-252.

In addition, the state has appropriated $5.8 million in matching funds for Title II payments, as required by the Act, which means total available funds for implementation of the State Plan in Ohio will be approximately $132 million.

All money in Title II is based on the state's portion of the nation's voting age population. The most recent estimate is that Ohio's 8.5million voting-age population represents 3.97 percent of the nation's voting age population of 215.1 million.

Because of the prevalence of punch-card voters in Ohio, we are keenly focused on the distribution of funds under Title I and, more precisely, the buy-out program. The Act stipulates the funds will be distributed to states by multiplying the number of qualifying precincts by $4,000. However, based on available federal funds for this purpose and the number of punch-card and lever-machine jurisdictions in the U.S., it now appears that number likely will be about $3,354 per precinct. As previously mentioned, Ohio has 69 counties designated as punch-card counties.

In addition, two Ohio jurisdictions – Hardin and Lucas counties – feature lever voting machines and would be eligible for funding under the guidelines.

In total, under the formula, the 69 punch-card counties and two lever-machine counties in Ohio means the state would be eligible for about $31 million in federal funds under the buyout program.

However, we know $31 million is insufficient for the counties to purchase modern, reliable voting systems capable of meeting requirements of the Act. Subsequently, our budget for voter and election reforms in Ohio presumes the state will require about $24.2 million to establish a centralized voter registration database and related support for voter education and poll worker training. Our plan calls for the remainder of the Title funds to be allocated to Ohio's 88 counties to help subsidize installation of new systems and implement other required activities under the Act.

Following is the budget we envision for distribution of the $161 million in funds in Ohio to meet requirements of the Help America Vote Act:

Activity	Fund Distribution	Jurisdiction	Purpose
Voter Registration Database	$5 million	State and Counties	Develop statewide voter registration database
Voter Education	$5 million	State and Counties	Administered by the State in coordination with the counties
Poll Worker Training	$5 million	State	To be distributed as grants to counties
Administrative Expenses	$2 million	State	For state personnel to administer and monitor HAVA implementation
Provisional Voter Hotline	$250,000	State	To establish a state hotline for provisional voters
Miscellaneous	$2 million	State	For associated costs of implementing HAVA

Voting Equipment and other Activities	$116 million	State on behalf of Counties	For new voting equipment and to meet other HAVA requirements

In simplest terms, this allocates Help America Vote funds where the money is needed most: in Ohio counties. While it is the responsibility of the Ohio Secretary of State to monitor performance and ensure implementation of the Act, the execution of the Ohio plan, ultimately, will take place at the county level. On that basis, we believe it prudent to maximize resources for election reform in the counties where election reform will occur.

While much of the focus is on the counties with punch card and lever-machine voting systems, in reality, all 88 Ohio counties will be expected to conduct some form of system modification and upgrade to make the system in Ohio uniform and compliant with the Act. Subsequently, the premise of the Ohio Plan is to look at the voter and election system statewide, based on the distribution of registered voters in each of the 88 counties.

Viewed in that context, the $116 million to be allocated to the counties will be distributed in the following priority order, as federal funds become available:

- Replacement of punch-card and lever-machine voting equipment to the extent that new voting systems would be installed immediately in the 71 affected counties;
- Installation of voting devices compliant with the disability requirements of the Act in all 88 counties;
- Bringing remaining counties into compliance with Section 301 of the Act by funding necessary upgrades and refinements of all other existing systems and equipment.

The Secretary of State reserves the right to distribute the funds to counties based on need and special circumstances.

The Secretary of State defines "need and special circumstances" to mean that it is possible some counties will need less funding and others more funding to meet the compliance standards of the Help America Vote Act. On that basis, the Secretary of State will shift funds as he deems necessary to bring all counties into compliance.

The Secretary of State acknowledges that one county, Mahoning County, took the initiative to convert their voting system to electronic voting after Jan. 1, 2001. Funding consideration will be given to all six Ohio counties using electronic voting equipment to bring those counties into compliance with HAVA.

We think this model provides us with great flexibility to allocate Title I and Title II funds in a way that assures full compliance with the requirements of the Act. Invariably some funds would be shifted away from counties that demonstrate a lesser need and reallocated to counties that demonstrate a greater need. But the allocation method is a fair method that will further assure all counties that adequate funds will be available to fully fund the requirements of the Act at the local level.

The Ohio Secretary of State will establish guidelines as part of the performance measurement for county compliance. When compliant systems are purchased for the counties, the Secretary of State will require transition to new voting systems by all punch-card and lever-machine counties by May 2, 2006. The Secretary of State will provide counties with a list of acceptable vendors to supply the new voting equipment and counties must choose from that approved list by no later than Sept. 1, 2003.

Since the Secretary of State will centralize and oversee this process, the Secretary will ensure compliance with all requirements of the Help America Vote Act. The performance timeline requires the Secretary to establish the list of approved vendors by Aug. 1, 2003, providing county boards of elections with ample time to review the list, choose the vendor and establish transition to the new voting systems.

To ensure uniformity and compliance, the Secretary of State will stipulate design specifications for voting equipment. If a county fails to select a vendor by Sept. 1, 2003, the Secretary of State will designate a vendor for that county and order installation of new voting equipment in that jurisdiction .

Although the Act required the replacement of punch-cards and lever machines by the General Election in 2004, the Secretary of State wanted these new systems in place in Ohio for the Primary Election to ensure a smooth, seamless transition and full operational capability in time for the presidential election. Due to extenuating circumstances, a waiver was granted in December 2003 giving the Secretary of State until the Primary Election in 2006 to replace punch-card and lever machines.

On May 7, 2004, Governor Taft signed into law Substitute House Bill 262. The Act requires all direct recording electronic voting machines used in Ohio to include a voter verified paper audit trail and changes the process for counties to acquire voting systems using funds made available pursuant to the Help America Vote Act (HAVA) of 2002. As the result of this additional legislative requirement, the Secretary of State was forced to revisit the original decision to allow counties to select between Direct Recording Electronic (DRE) and Precinct Count Optical Scan (PCOS) voting systems. A logical analysis of the requirements of both HAVA and SHB262 showed that in order for the state of Ohio to be in compliance with both federal and state law, meeting both time, costs and certification constraints, the Secretary of State must purchase Precinct Count Optical Scan voting systems through existing contracts already approved by the Controlling Board to satisfy HAVA requirements. While this change limits the flexibility previously offered to the counties when selecting between voting systems, the use of Precinct Count Optical Scan voting systems introduces a new opportunity for counties in the form of improved operational processes. Furthermore, the Secretary of State will allow counties to re-select their vendor based upon the additional mandated requirements of Substitute House Bill 262. All counties must submit in writing to the Secretary of State their vendor selection by February 9, 2005.

The Secretary of State has already established a fund account for all federal monies designated for Ohio under the Act and those funds, as applicable, will be disbursed from that account as our plan is implemented. This account is segregated to reflect federal funds designated for county buy-outs, election administration and Requirements payments.

Reports will be generated to show the allocation and distribution of these funds and that report will be forwarded to the Election Assistance Commission along with a performance report to show the state's progress and performance in implementing provisions of the Act.

X. Voter Education, Election Official and Poll Worker Training

Achieving the mechanical and technological change of the Help America Vote Act of 2002 is only part of the challenge of enacting true modernization and reform of Ohio's voting system. While devices will enhance the efficiency of Ohio's voting and election process, voter education and training of election officials and poll workers is critical to full implementation of the reforms to the benefit of Ohio voters.

We are mindful of an exciting objective of the Help America Vote Act: to engage high school and college students in the process. Several State Plan Committee members noted the desire to better engage young Ohioans in the election process as both a means to recruit bright, knowledgeable students as poll workers and as an opportunity to make more young people stakeholders in the process.

Earlier in this report, we alluded to research currently being conducted by the Secretary of State's office to improve poll worker recruitment, training, education and retention. That effort addresses the reality that many of our current poll workers are from a generation that places a premium on voting, elections and the democratic process. Many of our poll workers are senior citizens who very much value freedom and free election processes as a result of their experiences in growing up in the World War II and Korea era.

To these marvelous citizens, voting isn't just a right it's an obligation and a precious American birthright that has been paid for with the blood, sweat and tears of those who sacrificed their lives on foreign soil. As these citizen patriots retire from the poll worker ranks in Ohio's election system, we are looking to the future to determine how best we can recruit the next generation of poll workers who will embrace this important Election Day service with the same degree of commitment, enthusiasm and competence of our older poll workers.

We are mindful of an exciting objective of the Help America Vote Act: to engage high school and college students in the process. Several State Plan Committee members noted the desire to better engage young Ohioans in the election process as both a means to recruit bright, knowledgeable students as poll workers and as an opportunity to make more young people stakeholders in the process. Our research is exploring that challenge and opportunity to pass the torch to the next generation. But the research is also looking at other creative options to ensure Ohio has a ready, able and competent corps of poll workers.

Obviously, these poll workers must be adequately trained to render assistance to voters in a competent and knowledgeable way, not only in terms of helping them understand and use the new technology that accompanies election reform, but also by applying the laws and addressing the myriad of Election Day issues that invariably arise.

Provisional voting, for example, was a challenge for many of our poll workers during past election cycles as Ohio aggressively implemented new procedures to accommodate provisional voters. Our poll workers have successfully navigated provisional voting and have successfully met the needs of provisional voters.

But to adequately train poll workers, we must first train election officials. The Secretary of State will meet that challenge with a number of programs and initiatives. New training seminars will precede each election in Ohio where election directors and their staff will be given an opportunity to learn about new procedures and changes.

The Secretary of State also will enhance its electronic communication with election officials by providing updates and advisories about changes in state and federal election law. Our goal is to provide this information as soon as we have the information in hand.

Additionally, the Secretary of State will conduct an inventory of current training materials and produce new information and guidelines in both written and video formats. The Secretary also has asked his staff to provide election directors with new materials that can supplement the training of poll workers.

To ensure seamless transition to new voting systems, we are asking system vendors to partner with us in the production of clear, graphically-driven pamphlets and brochures that tell voters how the voting devices work. Earlier we mentioned the use of simulators and internet-based simulation of new voting devices to provide voters with an opportunity to try out the new technology even before they enter the voting booth to cast their official ballot.

We think these enhancements and initiatives will advance our implementation of the Help America Vote Act in Ohio and pave the way for a smooth transition to new voting devices and election processes. Some of our preparation for new election processes in Ohio includes some structural changes. We are asking each county board of elections, for example, to designate a training coordinator who will communicate directly with an election training coordinator in the Secretary of State's office.

It is our aim for these coordinators to meet frequently throughout the year, exchange information and help us think about ways to improve the election system in Ohio.

After the election, we will gather from all 88 counties a report from these coordinators detailing issues, questions and problems they encountered and how they addressed the situation. From these reports, the Secretary of State will use that data and information to respond to election issues and disseminate that information to election directors so they can make refinements at the local level in subsequent elections.

But to glean a voters-eye view of the process and how we can improve the election system, we will distribute to a selected sample of voters in every county a short survey device that will track their voting experience and give them an opportunity to provide us with feedback on how we can improve the process. The survey will be

distributed to a pre-determined number sample of voters throughout the state as they exit the voting booth.

We think this innovation is important to better understand voter needs and to view our election process through the eyes of the "consumer." Information we collect from both coordinators and the sample voters will guide us in developing relevant and meaningful training materials for both election officials and poll workers in future elections.

The Secretary of State also will develop a new "get-out-the-vote" program in Ohio that will encourage more voters to participate in the election process. While such programs currently exist in the Secretary of State's office, personnel will be dedicated to conducting research and learning more about voter behavior in Ohio.

In early 2004, the Secretary of State launched "Your Vote Counts," a comprehensive voter education program aimed at better preparing voters for the November 2, 2004 election. The goal was to provide all Ohio voters with the information they need to vote so that we can reduce the opportunity for difficulties on Election Day. This effort entails ensuring every voter gets the same consideration.

The program's Web site, www.YourVoteCountsOhio.org, features educational materials and instructional videos showing how to vote using punch card, optical scan and DRE (electronic) voting machines. Also included in the program printed material and public service messages for television and radio. In addition, the Secretary of State has made a special effort to reach out to students with his "Xpect More" campaign. The "Xpect More" advertising campaign is aimed at inviting young voters between the age of 18 and 24 into the democratic process. To date, more than 623,000 "Xpect More" brochures have been distributed to students through schools and across Ohio.

In many states, the appeal is often directed at those who are registered to vote, were registered to vote or who have voted in the past. The Secretary of State would like to target potential new first-time voters by coordinating voter recruitment with civics and government teachers in high schools throughout Ohio where there is a captive audience of potential new voters. Additionally, the Secretary would like to initiate research that targets Ohioans who have never voted to learn more about their decision not to participate in the election process and to determine if there are programs and initiatives that can be implemented to address their concerns and entice them to the polls.

Understanding more about voter behavior and non-voter behavior, we believe, is a proactive step we must take to fully embrace the spirit, intent, principles and objectives of the Help America Vote Act.

Understanding more about voter behavior and non-voter behavior, we believe, is a proactive step we must take to fully embrace the spirit, intent, principles and objectives of the Help America Vote Act.

The proposed budget for these activities is $2.5 million earmarked for voter education, and $5 million set aside for election official and poll-worker training. We propose making election official and poll-worker training funds available as state grants to the counties to supplement local activities and initiatives of the county boards of elections.

As counties deliberate equipment and voting systems, we will encourage them to consider appropriation of available residual funds to voter education and poll worker training. In crafting local budgets to achieve the objectives of the Help America Vote Act, we believe counties must give consideration to these initiatives to supplement state efforts for education and training.

In order to qualify for these funds, counties must submit to the Secretary of State a detailed plan that identifies proposed programs and initiatives and how the funds would be used. After each General Election, counties would be required to report on the deployment of these programs and their assessment of the value of the education and training.

XVI. Estimated Timelines for Implementation of the State Plan

Following are key dates and the proposed timetable for implementation of our State Plan:

- **March 18, 2003:** State Plan Advisory Committee named, public input process defined.
- **April 3-4, 2003:** State Plan Advisory Committee conducts public hearings.
- **April 9, 2003:** RFP released for statewide voter registration system.
- **April 17, 2003:** State Plan Advisory Committee reconvenes to review draft State Plan.
- **May 7, 2003:** Competitive bids due for voter registration system.
- **May 13, 2003:** State Plan finalized and published for 30-day review.
- **May 16, 2003:** RFP released for voting system vendors.
- **June 2, 2003:** Secretary of State awards bids for voter registration system.
- **June 16, 2003:** State Plan submitted to federal Elections Assistance Commission for publication in the Federal Register. Competitive bids due for election system.
- **Aug. 1, 2003:** Secretary of State awards bids for election systems. County boards of elections notified of eligible system vendors.
- **Sept. 2, 2003:** County boards of elections must notify Secretary of State which vendor they have chosen for election system improvements.
- **November 21, 2003:** Direct Recording Electronic (DRE) Technical Security Assessment Report prepared by Compuware submitted to Secretary of State.
- **Dec. 1, 2003:** Statewide voter registration system installed and fully operational.
- **Dec. 19, 2003:** Requested a waiver from the Federal Government on deployment of the computerized voter registration system.
- **March 2, 2004:** Primary Election. (Ohio General Assembly considering change of Primary to May, 2004.)
- **April 29, 2004:** Clinton County first to establish Centralized Voter Registration File processes between the county and the Secretary of State.
- **May 7, 2004:** Substitute House Bill 262 enacted.

- **August 18, 2004:** Diebold Direct Recording Electronic (DRE) Technical Security Re-Assessment Report prepared by Compuware submitted to Secretary of State.
- **Nov. 2, 2004:** General Election
- **November 17, 2004:** VVPAT requirements distributed for comments.
- **January 3, 2005:** Diebold Direct Recording Electronic (DRE) Technical Security Re-Assessment Report Addendum prepared by Compuware submitted to Secretary of State.
- **January 3, 2005:** VVPAT rules filed with JCARR.
- **January 1, 2006:** Centralized Statewide Voter Registration File fully implemented.
- **May 2, 2006:** Replacement of punch-card and lever machine complete.

XVIII. The State Plan Committee: HAVA and Beyond

We reserve this section of the report to capture the comments and thoughts of our State Plan Committee. While many of the committee's recommendations and much of their input is reflected in preceding sections of the report, it was clear this panel of distinguished Ohioans went beyond merely thinking about minimum requirements of the Help America Vote Act and insisted on expanding their mission to address issues that will produce broad and meaningful election reform in our state.

That kind of visionary thinking is precisely what the Secretary of State had in mind when he impaneled the State Plan Committee.

If there was a universal theme that resonated from the committee's deliberations, it was consensus that Ohio must aggressively engage the next generation of voters and make young people in our state understand their role as stakeholders in the democratic process. It is insufficient, the panel said, to merely invite high school and college students into the election process. Ohio, the State Plan Committee said, must be proactive in educating young people about the election process and instill a deeper commitment to engendering student participation in the election process.

State Rep. Nancy Hollister noted that this report should underscore for Ohioans that implementation of the Help America Vote Act in Ohio signals a "change in the governance of the election system" in the state. HAVA, she said, places more responsibility on the Secretary of State to assure a fair, equitable and inclusive election process in Ohio.

Linda Carr, Daisy Duncan Foster and Pastor Aaron Wheeler were particularly passionate in their remarks about this issue and said Ohio should be creative in developing new programs and initiatives to bring young voters into the process. The Committee urged the Secretary of State to aggressively seek available funds under Title V and Title VI funding of the Help America Vote Act to accomplish this critical task.

Additionally, some committee members recommended working with the Ohio Department of Education and the Ohio Board of Regents to explore ways to better educate and encourage political participation by high school

and college students. Pastor Wheeler suggested Ohio public schools should ponder curriculum requirements that focus exclusively on voting and election processes.

State Rep. Nancy Hollister noted that this report should underscore for Ohioans that implementation of the Help America Vote Act in Ohio signals a "change in the governance of the election system" in the state. HAVA, she said, places more responsibility on the Secretary of State to assure a fair, equitable and inclusive election process in Ohio. "We need to acknowledge that," she said.

But Rep. Hollister and other committee members said that shift in governance does not minimize the necessary independence, ongoing role or responsibility of counties to execute election policies within the new governing framework created by the Help America Vote Act.

Committee member Jeff Matthews said county boards of elections must be independent to effectively achieve the objectives of the Help America Vote Act, and Ms. Duncan Foster said boards of elections must feel "some ownership of the process." In that context, it was the consensus of the State Plan Committee that full compliance with the Help America Vote Act requires critical coordination and a strong working relationship between the Secretary of State's office and local boards of elections.

Election officials Guy Reece and Tom Coyne, along with Mr. Matthews, agreed that innovation doesn't end with the Help America Vote Act. They said Ohio must constantly be looking for new methods, new procedures and new ideas to keep the election process viable and invite more Ohioans to exercise their right to vote.

Ms. Alvarado noted the projected growth of Hispanic populations both nationally and in the State of Ohio. Several committee members agreed that rather than addressing this issue later and incurring cost for conforming equipment, the RFP should anticipate the language requirement and it should be purchased now while federal funds are available to help Ohio make the transition to new voting equipment.

Mr. Reece invited future exploration of election innovations being tested in other states such as open voting, early voting, ballot on demand and expanded availability and use of absentee ballots. Catherine Turcer asked that the Secretary of State consider the flexibility of voting devices that would allow for concepts such as instant runoff voting and proportional representation.

Ms. Turcer also recommended the Secretary of State ensure that the RFP for new voting equipment carefully consider the necessity for strong auditing capability that would provide a spot-check feature for pre-testing. Ms. Turcer and Donna Alvarado said alternative language capability also should be included in the RFP in anticipation of changing future demographics in the state.

Ms. Alvarado noted the projected growth of Hispanic populations both nationally and in the State of Ohio. Several committee members agreed that rather than addressing this issue later and incurring cost for conforming equipment, the RFP should anticipate the language requirement and it should

be purchased now while federal funds are available to help Ohio make the transition to new voting equipment.

She said language requirements also need to be considered in education products produced by vendors and election officials in how to use the new voting equipment, as well as in training of poll workers and election officials. She said alternative language issues need to be considered in creation and execution of the grievance process and procedures.

She suggested the Secretary of State consider alternative language policies that exceed the 5 percent threshold.

While preceding sections of the report address monitoring procedures for implementation of the Help America Vote Act in Ohio, Ms. Alvarado said compliance monitoring should be "futuristic" and focus on outcomes. While measuring accomplishments, she said the state and local jurisdictions also should be forward looking and report, for example, where the state expects to be in the next five years and beyond.

She said monitoring and compliance should address issues such as where Ohio wants to be as a state, how we achieve those objectives, who is responsible for implementing these plans, what the funding sources will be for implementation and what will be different when changes, modifications or new procedures are implemented in the election process.

Rep. Hollister agreed there needs to be periodic evaluation of Ohio's progress in meeting voting and election reforms. She suggested a need to pause from time to time to reflect on what has been accomplished, what future reforms need to be considered, and what revenues are available to achieve those objectives.

Mr. Long acknowledged that there might be offsetting costs and efficiencies that could be realized from conversion to electronic voting systems, but he stressed the necessity for full funding of the plan and timely allocation of federal payments to the state to avoid financial burdens on counties already adversely affected by the economy and cuts imposed by the State Legislature.

A primary focus in the deliberation of the State Plan Committee was how Ohio could best address disability issues related to implementation of the Help America Vote Act. Eric Duffy said the issue of physical barriers is a real and pressing issue that calls for creative solutions in Ohio. He emphasized that Ohio must consider not only what takes place inside the voting place, but what physical barriers exist that hinder access outside the building.

Pastor Wheeler, chairman of the Ohio Civil Rights Commission, offered the assistance of that agency in working with the Secretary of State in exploring solutions to that issue.

As expected, much of the panel's deliberation was focused on funding and whether the federal allocation to Ohio was adequate to effect the wholesale change in voting systems in the state. A key voice in that discussion was Larry Long, executive director of the County Commissioners Association of Ohio.

Mr. Long noted that there is concern among county commissioners about whether the federal funding anticipated for implementation of the Help America Vote Act is sufficient to purchase the voting equipment needed to make Ohio HAVA compliant. But a comparable concern, he said, is consideration of future maintenance and replacement costs, as well as related cost issues such as storage requirements for the new equipment.

He acknowledged that there might be offsetting costs and efficiencies that could be realized from conversion to electronic voting systems, but he stressed the necessity for full funding of the plan and timely allocation of federal payments to the state to avoid financial burdens on counties already adversely affected by the economy and cuts imposed by the State Legislature.

Rep. Hollister also discussed the funding issue, suggesting the state, at some future date, might consider bonding options to assist in paying for ongoing costs associated with implementation of the Act, as well as making funds available for voter education, system upgrades and youth participation in the election process.

Further, she said that although there appears to be no immediate need for sweeping changes in state election laws, the state should constantly evaluate that need and enact legislative change as required.

Mr. Coyne emphasized the need for the Secretary of State and local boards of elections to fashion voter system reforms in a way that keeps the process from becoming "vendor-driven." He said county boards need time to assess and evaluate the unique demands in each jurisdiction and recommended the Secretary of State consider meeting the disability requirements of HAVA in time for the 2004 election, but proceed more deliberately on installment of new voting equipment.

In May 2004, Substitute House Bill 262 was enacted into law by Governor Taft which requires all direct recording electronic voting machines used in the State of Ohio to include a voter verified paper audit trail (VVPAT). Substitute House Bill 262 mandates the Secretary of State shall establish by rule standards for the certification of the VVPAT. In addition, the bill created a county electronic voting machine maintenance fund.

XIX. Summary of the State Plan

Section 254 of the Help America Vote Act of 2002 lists the required components of the State Plan and this document fulfills those requirements.

This report demonstrates that Ohio, because of its widespread use of punch-card voting, is perhaps challenged more than other states to reform its election methods and modernize its voting systems. The size of the state, ranking seventh among the 50 states in total population, and the mix of rural and urban population makes the transition even more challenging.

Ohio, the Secretary of State believes, must be a full participant in the election process and every eligible voter must be afforded the opportunity to be counted as we ponder the critical decisions affecting our local communities, state and nation.

Recognizing the enormity of the task confronting Ohio, some members of the State Plan Committee and witnesses who testified before the committee counseled the Secretary of State to invoke waivers that would allow the state to delay its full implementation of the plan until the 2006 election cycle.

The Secretary of State, however, believes Ohio cannot afford to delay its implementation of the plan because every election cycle that passes is another election where voters are potentially disenfranchised and Ohio votes are lost or miscounted. Ohio, the Secretary of State believes, must be a full participant in the election process and every eligible voter must be afforded the opportunity to be counted as we ponder the critical decisions affecting our local communities, state and nation.

As election officials, if we know voters are disenfranchised and that legitimately cast ballots are being discounted, we have not only a moral obligation to immediately embrace a solution, but a legal obligation to find a remedy and enact measures to prevent that from happening. If even one voter is denied the right to vote, we are obligated, by law, to determine the cause and forge a solution. The evidence is overwhelming that thousands of Ohio voters have been disenfranchised by antiquated voting equipment and that many thousands more have lost confidence in the reliability and accuracy of voting devices currently in use in most of Ohio's 88 counties.

The Secretary of State has confidence in the election professionals who conduct and administer elections in the State of Ohio, and believes Ohio has the capability to enact reforms that have already taken place in other states.

We are emboldened in our decision to press forward with implementation of this plan based on the experience of Knox and Lake counties in executing successful elections after implementing new systems only weeks before the General Election. The Knox County Board of Elections, which has only four employees, received delivery of new electronic voting devices in October, 1996, a presidential election year, and deployed them in the November General Election.

Lake County issued a request for proposal in April 1999, awarded bids in July of that year, took delivery of a new voting system the following September, and conducted a successful election weeks later in the November General Election.

Under the timetable established in this plan, new voting systems would be installed and operational in time for the Primary Election in 2004, providing local boards of elections with an opportunity to test the new systems before fully engaging them in the 2004 presidential election cycle.

However, we refer to the preceding section of this plan. Full implementation of this plan presumes full funding by the federal government. If the Secretary of State determines that federal funding for implementation of this plan is not forthcoming from the federal government in a timely manner, we will notify the Elections Assistance Commission of our intent to revise this plan and adjust the timetable for implementation.

Since the Federal Government has not appropriated the remaining funding for HAVA, it was necessary for the Secretary of State to modify our state plan and adjust the timetable for implementation. Initially, we had set an aggressive and ambitious full implementation for November 2004. Unfortunately, due to the delays in receiving funding and the establishment of the Elections Assistance Commission, we project full implementation of all HAVA requirements by May 2006.

Boards of Elections should be assured that the Secretary of State will focus all of its available personnel and resources to assist counties in enacting these reforms and meeting the requirements of the Help America Vote Act.

Boards should also be assured the Secretary of State will work with county officials and elections administrators to ensure available resources are distributed as quickly as possible and that cost containment efforts will be undertaken to minimize implementation costs to counties. Based on our analysis, which was reinforced in the testimony of Doug Lewis of The Election Center, we believe conversion of the state's punch-card voting system to direct recording electronic (DRE) voting devices will generate certain cost efficiencies we believe will minimize cost and expenses to counties, or at least offset some of the implementation costs.

We include in this definition of electronic voting devices the option for some counties to choose optical scanning devices that are HAVA compliant. In counties which have invested in this equipment and prefer these optional voting devices, the Secretary of State will consider deployment of this equipment as acceptable if certain modifications are made to ensure compliance with statewide voting standards. These counties, however, would be required to feature at voting locations electronic voting equipment that accommodates the needs of people with disabilities.

Based on our analysis, which was reinforced in the testimony of Doug Lewis of The Election Center, we believe conversion of the state's punch-card voting system to direct recording electronic (DRE) voting devices will generate certain cost efficiencies we believe will minimize cost and expenses to counties, or at least offset some of the implementation costs.

We presume the transition to electronic voting equipment will, at minimum, reduce printing costs in most counties. We believe there are further savings and efficiencies that will be derived from electronic voting that will reduce personnel and labor costs.

The DRE option also will introduce added efficiencies in the election process that will eliminate issues related to "over-votes," recounts and ensuring full voter participation by persons with disabilities. We also believe an electronic-based voting system will enhance training

and education across the spectrum for election officials, voters and poll workers if the system is sufficiently user-friendly.

Based on the foregoing, following is a summary of the State Plan for Ohio based on the requirements delineated in Section 254 of Public Law 107-252:

(1) How the State will use the requirement payment to meet the requirements of Title III, and, if applicable under section 251(a)(2), to carry out other activities to improve the administration of elections.

Ohio will implement new voting systems and procedures that meet the general requirements of Title III ensuring the systems have audit capacity, disability access, and alternative language accessibility, where applicable, and that the systems meet error rate thresholds established by the Federal Elections Commission.

(2) How the State will distribute and monitor the distribution of the requirements payment to units of local government or other entities in the State for carrying out the activities described in paragraph (1).

Ohio anticipated federal funding and state matching funds would be about $161 million. Unfortunately full federal funding was not appropriated and the total federal funding and state matching funding is approximately $137 million. The Secretary of State will allocate about $106 million of that amount for installation of new voting equipment and upgrades of existing voting equipment in Ohio counties, and use the remaining portion to implement statewide voter registration and establish a provisional voting hotline. Disbursements in the amount of $5 million will be available to Ohio's 88 counties for election official and poll worker training. Additionally, the Secretary of State will make $5 million available for administration of a statewide voter education program. The Secretary of State will draft guidelines and reporting requirements to monitor distribution of these funds and to ensure county compliance with the Help America Vote Act of 2002.

(3) How the State will provide for programs for voter education, election official education and training, and poll worker training which will assist the State in meeting the requirements of title III.

See response to No. 2. Additionally, the Secretary of State, in establishing an authorized vendor list for deployment of new voting equipment, will require vendors to include, as part of their bid proposal, fund allocation that includes voter education, election official education and training, and poll worker training. The Secretary of State also will implement new programs and procedures to supplement these vendor requirements and efforts at the county level to address these issues.

(4) How the State will adopt voting system guidelines and processes which are consistent with the requirements of section 301.

See preceding responses. Ohio will replace punch-card voting in the State and require deployment and installation of electronic-based voting devices that meet the requirements of the Act. The request for proposal for new voting equipment will be crafted to presume required features and safeguards that ensure a uniform voting standard and compliance in all Ohio counties with specific requirements of the Act.

(5) How the State will establish a fund described in subsection (b) for the purposes of administering the State's activities under this part, including information on fund management.

Such a fund has already been established by the Secretary of State and will be monitored by both the Secretary of State and the Auditor of State, as Ohio law applies to state auditing requirements and reporting procedures. Fund management procedures include quarterly reports to the Election Assistance Commission to detail receipt and expenditure of funds, and how those funds were used to meet the objectives of the Act.

(6) The State's proposed budget for activities under this part, based on the State's best estimates of the costs of such activities and the amount of funds to be made available.

See response to No. 2 and the fund distribution table on page 23 of the State Plan. The Secretary of State believes full implementation of the plan will require all available federal funding and state matching funds to meet the requirements of the Act.

(7) How the State, in using the requirements payment, will maintain the expenditures of the State for activities funded by the payment at a level that is not less than the level of such expenditures maintained by the State for the fiscal year ending prior to November 2000.

(*See Section XV. Requirements Payments: Maintenance of Effort.*) Attached to this State Plan are budget materials that show the level of spending for election services by the Secretary of State in FY 2000 and projected levels of spending for FY 2004-05. The Secretary certifies that no federal funds for Requirements payments earmarked for voter reforms and system modernization will be used to supplement the state budget for operation and administration of the office.

(8) How the State will adopt performance goals and measures that will be used by the State to determine its success and the success of units of local government in the State in carrying out the plan, including timetables for meeting each of the elements of the plan, descriptions of criteria the State will use to measure performance and the process used to develop such criteria, and a description of which official is to be held responsible for ensuring that each performance goal is met.

The Secretary of State assumes full responsibility for ensuring compliance with the Act. Specific timetables are included in this plan which requires all punch-card and lever machine counties to install and deploy new voting equipment that meets the uniform standards of the Act by May 2, 2006. The plan also calls for a statewide voter registration system to be in place and fully operational by January 1, 2006. See Section XIV for ongoing performance measurement.

(9) A description of the uniform, nondiscriminatory State-based administrative complaint procedures in effect under section 402.

See attached procedure and refer to Section XIII of the State Plan, Administrative Complaint Procedures and Grievances.

(10) If the State received any payment under Title I, a description of how such payment will affect the activities proposed to be carried out under the plan, including the amount of funds available for such activities.

See response to No. 2. Ohio will use funds from Title I for antiquated systems buyout and to improve election administration activities and procedures. See the fund distribution table on page 23 of the State Plan and allocation and distribution formula described on page 24.

(11) How the State will conduct ongoing management of the plan.

See Section XIV, Ongoing Performance Measurement. Throughout this State Plan is a description of the management practices and procedures outlined by the Secretary of State to ensure compliance with the Act. Any material change in this plan will result in a resubmission of the Plan in accordance with Sections 255 and 256 of the Act.

(12) In the case of a State with a State Plan in effect under this subtitle during the previous fiscal year, a description of how the plan reflects changes from the State Plan for the previous fiscal year and how the State succeeded in carrying out the State Plan for such previous fiscal year.

This State Plan represents Ohio's initial submission of a State Plan to the Elections Assistance Commission. The changes reflected in the revised State Plan did not have any financial impact for the previous fiscal year.

(13) A description of the committee which participated in the development of the State Plan in accordance with section 255 and the procedures followed by the committee under such section and section 256.

See page 3, The State Plan Committee, and Section VI, How Ohio Developed its State Plan.

This State Plan respectfully submitted to the Elections Assistance Commission, in accordance with U.S. Public Law 107-252, this 16th day of June, 2003.

J. KENNETH BLACKWELL
Secretary of State

[FR Doc. 05–6750 Filed 4–6–05; 8:45 am]

BILLING CODE 6820–YN–C

ELECTION ASSISTANCE COMMISSION

Sunshine Act Notice

AGENCY: United States Election Assistance Commission.

ACTION: Notice of public hearing agenda.

Date & Time: Tuesday, April 26, 2005, 12:30 p.m.–4:30 p.m.

Place: Massachusetts Institute of Technology (MIT), Bartos Theater, 20 Ames Street (lower level), Cambridge, MA 02142–1308. (Massachusetts Bay Transit Station Stop: Kendall Square.)

Agenda: The Commission will conduct a public hearing to present proposed voluntary guidance to the states on implementing statewide voter registration databases and to solicit comments on that guidance from members of the election community and public.

The Commission will hear presentations by a panel of persons involved with the development of voter registration databases as well as a panel of persons who will use guidance on the databases.

EAC will provide a one-hour public comment period. Members of the public who wish to speak should contact EAC via e-mail at *testimony@eac.gov*, or via mail addressed to the U.S. Suite 1100, Washington, DC 20005, or by fax at 202/566–3127. Comments will be strictly limited to 3 minutes per person or organization to assure that all constituent or stakeholder groups are represented. All speakers will be contacted prior to the hearing.

EAC also encourages members of the public to submit written testimony via e-mail, mail or fax. All public comments will be taken in writing via e-mail at *testimony@eac.gov*, or via mail addressed to the U.S. Election Assistance Commission 1225 New York Ave, NW., Suite 1100, Washington, DC 20005, or by fax at 202/566–3127.

CONTACT FOR FURTHER INFORMATION: Bryan Whitener, Telephone: (202) 566–3100.

Ray Martinez III,

Commissioner, U.S. Election Assistance Commission.

[FR Doc. 05–7065 Filed 4–5–05; 1:32 pm]

BILLING CODE 6820–YN–M

DEPARTMENT OF ENERGY

[Docket No. EA–273–A]

Application To Export Electric Energy; Rainy River Energy Corporation

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: Rainy River Energy Corporation (Rainy River) has applied to renew its authority to transmit electric energy from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before May 9, 2005.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Systems (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Xavier Puslowski (Program Office) 202–586–4708 or Michael Skinker (Program Attorney) 202–586–2793.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated and require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On March 24, 2003, the Office of Fossil Energy (FE) of the Department of Energy (DOE) issued Order No. EA–273 authorizing Rainy River to transmit electric energy from the United States to Canada as a power marketer. That two year authorization will expire on March 24, 2005.

On March 14, 2005, Rainy River applied to FE to renew its authorization for a five-year term. Rainy River proposes to arrange for the delivery of exports over the international transmission facilities owned by Basin Electric Power Cooperative, Bonneville Power Administration, Citizens Utilities Company, Eastern Maine Electric Cooperative, International Transmission Company, Joint Owners of the Highgate Project, Long Sault, Inc., Maine Electric Power Company, Maine Public Service Company, Minnesota Power, Inc., Minnkota Power Cooperative, New York Power Authority, Niagara Mohawk Power Corporation, Northern States Power, Vermont Electric Transmission Company.

The construction of each of the international transmission facilities to be utilized by Rainy River, as more fully described in the application, has previously been authorized by a Presidential permit issued pursuant to Executive Order 10485, as amended.

Procedural Matters: Any person desiring to become a party to this proceeding or to be heard by filing comments or protests to this application should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the dates listed above.

Comments on the Rainy River application to export electric energy to Canada should be clearly marked with Docket EA–273–A. Additional copies are to be filed directly with Christopher D. Anderson, Counsel for Rainy River Energy Corporation, 30 West Superior Street, Duluth, MN 55802.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at *http://www.fe.doe.gov*. Upon reaching the Fossil Energy Home page, select ''Electricity Regulation,'' and then ''Pending Proceedings'' from the options menus.

Issued in Washington, DC, on March 31, 2005.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Fossil Energy.

[FR Doc. 05–6929 Filed 4–6–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket No. EA–301]

Application to Export Electric Energy; WPS Energy Service, Inc.

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: WPS Energy Services, Inc. (WPS ESI) has applied for authority to transmit electric energy from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before May 9, 2005.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Systems (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Steven Mintz (Program Office) 202–586–9506 or Michael Skinker (Program Attorney) 202–586–2793.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated and require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On March 16, 2005, the Office of Fossil Energy (FE) of the Department of Energy (DOE) received an application from WPS ESI to transmit electric energy from the United States to Canada. WPS ESI is an indirect wholly-owned subsidiary of WPS Resources Corporation (WPSR), an exempt public utility holding company. WPS ESI has requested an electricity export authorization with a 5-year term. The electric energy which WPS ESI proposes to export to Canada would be purchased from electric utilities and Federal power marketing agencies within the U.S.

WPS ESI proposes to arrange for the delivery of electric energy to Canada over the existing international transmission facilities owned by Basin Electric Power Cooperative, Bonneville Power Administration, Eastern Maine Electric Cooperative, International Transmission Company, Joint Owners of the Highgate Project, Long Sault, Inc., Maine Electric Power Company, Maine Public Service Company, Minnesota Power Inc., Minnkota Power Cooperative, New York Power Authority, Niagara Mohawk Power Corporation, Northern States Power/Excel, Vermont Electric Power Company and Vermont Electric Transmission Company.

The construction, operation, maintenance, and connection of each of the international transmission facilities to be utilized by WPS ESI, as more fully described in the application, has previously been authorized by a Presidential permit issued pursuant to Executive Order 10485, as amended.

Procedural Matters

Any person desiring to become a party to this proceeding or to be heard by filing comments or protests to this application should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with DOE on or before the date listed above.

Comments on the WPS ESI application to export electric energy to Canada should be clearly marked with Docket EA–301. Additional copies are to be filed directly with Ivan L. Henderson, WPS Energy Services, Inc., 600 Superior Ave. East, Cleveland, OH 44114 and Thomas McCann Mullooly, Esquire, Foley & Lardner LLP, 777 East Wisconsin Avenue, Milwaukee, WI 53202–5306.

A final decision will be made on this application after the environmental impacts have been evaluated pursuant to the National Environmental Policy Act of 1969, and a determination is made by the DOE that the proposed action will not adversely impact on the reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at *http://www.fe.de.gov.* Upon reaching the Fossil Energy Home Page, select ''Electricity Regulation,'' and then ''Pending Procedures'' from the options menus.

Issued in Washington, DC, on March 31, 2005.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Fossil Energy.

[FR Doc. 05–6930 Filed 4–6–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–85–000]

Adrian Energy Associates, LLC, Cadillac Renewable Energy, LLC, Genesee Power Station, LP, Grayling Generating Station, LP, Hillman Power Company, LLC, T.E.S. Filer City Station, LP, Viking Energy of Lincoln, Inc., Viking Energy of McBain, Inc., Complainants, Michigan Public Service Commission, Commissioner J. Peter Lark, Commissioner Robert B. Nelson, Commissioner Laura Chapelle, Respondents; Notice of Complaint

March 31, 2005.

Take notice that on March 30, 2005, Adrian Energy Associates, LLC, Cadillac Renewable Energy, LLC, Genesee Power Station, LP, Grayling Generating Station, LP, Hillman Power Company, LLC, T.E.S. Filer City Station, LP, Viking Energy of Lincoln, Inc. and Viking Energy of McBain, Inc. (collectively, Michigan QFs), filed a formal complaint and petition against the Michigan Public Service Commission (MPSC), and Commissioner J. Peter Lark, Commissioner Robert B. Nelson, and Commissioner Laura Chapelle, alleging that:

1. The MPSC, in an opinion and order issued February 28, 2005, failed to Implement and enforce the Public Utility Regulatory Policies Act of 1978 (PURPA), including 16 U.S.C. 824a–3(f) *et seq.* and the rules of the Federal Energy Regulatory Commission, including 18 CFR 292.401 *et seq.*;

2. The MPSC's February 28, 2005, opinion and order contravenes the Federal Power Act, 16 U.S.C. 791a *et seq.*, 16 U.S.C. 824(b), the PURPA And the FERC rules; and

3. The MPSC's February 28, 2005, opinion and order improperly and unlawfully alters pre-existing Power Purchase Agreements, subjecting the Qualifying Facilities (QFs) to utility-type regulation in violation of 16 U.S.C. 824a–3(e)(1) and 18 CFR 292.602, and unlawfully discriminating against the QFs in violation of 16 U.S.C. 824e–3(b)(2) and 18 CFR 292.304.

The Michigan QFs certify that copies of the complaint were served on the contacts for the Michigan Public Service Commission, Commissioner J. Peter Lark, Commissioner Robert B. Nelson, and Commissioner Laura Chapelle as listed on the Commission's List of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protest must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC

Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: April 20, 2005.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–1604 Filed 4–6–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–86–000]

Quest Energy, L.L.C. Complainant v. Midwest Independent Transmission System Operator, Inc., Respondent; Notice of Complaint and Request for Fast Track Processing

April 1, 2005.

Take notice that on March 31, 2005, Quest Energy, L.L.C. (Quest) filed a Complaint against Midwest Independent Transmission System Operator, Inc. (MISO) pursuant to section 206 of the Federal Power Act, 16 U.S.C. and Rule 206 of the Commission's Rules of Practice and Procedure, 18 CFR 385.206 (2004). Quest alleges that MISO violated its tariff by unilaterally modifying Quest's Load Zone Commercial Price Node in the Consumers Energy control area and then refusing to restore Quest's Load Zone Nodes. Quest has requested fast track processing of the Complaint.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protest must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: April 20, 2005.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–1603 Filed 4–6–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC05–65–000, et al.]

ITC Holdings Corp., et al., Electric Rate and Corporate Filings

March 31, 2005.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. ITC Holdings Corp. and International Transmission Company

[Docket No. EC05–65–000]

Take notice that on March 30, 2005, ITC Holdings Corp. (ITC Holdings) and International Transmission Company (International Transmission) (collectively, Applicants) filed with the Federal Energy Regulatory Commission (Commission) a joint application for authorization of a disposition of jurisdictional facilities under section 203 of the Federal Power Act and notification of change in ownership structure, as required under *ITC Holdings Corp., et al.*, 102 FERC ¶ 61,182 at P 44 (2003), *reh'g denied,* 104 FERC ¶ 61,033 (2003). Applicants also request that the Commission confirm that International Transmission will remain independent from any Market Participant following public offering of the stock of its parent, ITC Holdings.

Comment Date: 5 p.m. eastern time on April 13, 2005.

2. South Jersey Energy Company

[Docket No. ER97–1397–012]

Take notice that on March 24, 2005, South Jersey Energy Company filed an amendment to its market-based rate tariff to reflect the change-in-status reporting requirement adopted in Order No. 652, *Reporting Requirement for Changes in Status for Public Utilities with Market-Based Rate Authority,* Order No. 652, 110 FERC ¶ 61,097 (2005).

Comment Date: 5 p.m. eastern time on April 14, 2005.

3. South Jersey Energy Company

[Docket No. ER97–1397–013]

Take notice that on March 24, 2005, South Jersey Energy Company tendered for filing an updated generation market power analysis in compliance with the Commission's order in *Acadia Power Partners, L.L.C.,* 107 FERC ¶ 61,168 (2004).

South Jersey Energy Company states that copies of the filing were served on parties on the official service list in the above-captioned docket.

Comment Date: 5 p.m. eastern time on April 14, 2005.

4. Elkem Metals Company—Alloy L.P.

[Docket No. ER00–2093–002]

Take notice that on March 24, 2005, Elkem Metals Company—Alloy L.P. (Elkem-Alloy) submitted its market power update in compliance with the Commission's May 13, 2004 in *Acadia Power Partners, LLC,* 107 FERC ¶ 61,168 (2004).

Elkem-Alloy states that copies of the filing were served on parties on the official service list in the captioned proceedings.

Comment Date: 5 p.m. eastern time on April 14, 2005.

5. Elkem Metals Company—Alloy L.P.

[Docket No. ER00–2093–003]

Take notice that on March 24, 2005, Elkem Metals Company—Alloy L.P. (Elkem-Alloy) submitted for filing revisions to its FERC Electric Tariff, Second Revised Volume No. 1 to reflect the change-in-status reporting requirement adopted in Order No. 652, *Reporting Requirement for Changes in Status for Public Utilities with Market-Based Rate Authority,* 110 FERC ¶ 61,097 (2005).

Elkem-Alloy states that it has served copies of this filing on parties on the official service list.

Comment Date: 5 p.m. eastern time on April 14, 2005.

6. Northern Indiana Public Service Company, EnergyUSA–TPC Corp., Whiting Clean Energy, Inc.

[Docket Nos. ER00–2173–004, ER00–3219–004, and ER01–1300–005]

Take notice that on March 28, 2005, Northern Indiana Public Service

Company, EnergyUSA–TPC Corp., (NISPCO) and Whiting Clean Energy, Inc. (the NiSource Companies) tendered for filing certain workpapers and spreadsheets regarding their updated market power analysis filed on February 8, 2005.

Comment Date: 5 p.m. eastern time on April 7, 2005.

7. Naniwa Energy LLC

[Docket No. ER01–457–004]

Take notice that on March 24, 2005, Naniwa Energy LLC (Naniwa) submitted an amendment to its FERC Rate Schedule No. 1 to reflect the change-in-status reporting requirement adopted in the Commission's Order No. 652, *Reporting Requirement for Changes in Status for Public Utilities with Market-Based Rate Authority,* 110 FERC ¶ 61,097 (2005).

Naniwa states that copies of the filing were served on parties on the official service list in this proceeding.

Comment Date: 5 p.m. eastern time on April 14, 2005.

8. Power Contract Finance, L.L.C.

[Docket No. ER02–1485–006]

Take notice that on March 24, 2005, Power Contract Finance, L.L.C. (PCF) submitted an amendment to its FERC Rate Schedule No. 1 to reflect the change-in-status reporting requirement adopted in the Commission's Order No. 652, *Reporting Requirement for Change in Status for Public Utilities with Market-Based Rate Authority,* 110 FERC ¶ 61,097 (2005).

PCF states that copies of the filing were served on parties on the official service list.

Comment Date: 5 p.m. eastern time on April 14, 2005.

9. MS Retail Development Corp.

[Docket No. ER03–1315–004]

Take notice that, on March 24, 2005, MS Retail Development Corp. (MS Retail) submitted an amendment to its FERC Rate Schedule No. 1 to reflect the change-in-status reporting requirement adopted in the Commission's Order No. 652, *Reporting Requirement for Change in Status for Public Utilities with Market-Based Rate Authority,* 110 FERC ¶ 61,097 (2005).

MS Retail states that copies of the filing were served on parties on the official service list.

Comment Date: 5 p.m. eastern time on April 14, 2005.

10. Williams Power Company, Inc., Williams Energy Marketing & Trading Company, Williams Generation Company—Hazleton, Williams Flexible Generation, LLC

[Docket Nos. ER03–1331–004, ER99–1722–005, ER97–4587–006 and ER00–2469–003]

Take notice that on March 24, 2005, Williams Power Company, Inc. (Williams Power), Williams Energy Marketing & Trading Company, Williams Generation Company—Hazleton (Williams Hazleton) and Williams Flexible Generation, LLC (Williams Flex Generation) submitted their joint triennial market power update pursuant to *Acadia Power Partners, L.L.C.* 107 FERC ¶ 61,168 (2004) and *AEP Power Marketing, Inc.,* 107 FERC ¶ 61,018 (2004). Williams Power, Williams Hazleton and Williams Flex Generation also submitted revised tariff sheets reflecting the change in status reporting requirement adopted by the Commission in Order No. 652, *Reporting Requirements for Changes in Status for Public Utilities with Market-Based Rate Authority,* 110 FERC ¶ 61,097 (2005).

Comment Date: 5 p.m. eastern time on April 14, 2005.

11. Progress Ventures, Inc.

[Docket No. ER05–391–001]

Take notice that on March 24, 2005, Progress Ventures, Inc. (Progress Ventures), in response to the Commission's deficiency letter issued February 24, 2005, submitted an amendment to its December 29, 2004, filing for a cost-based power sales tariff for Progress Ventures to permit short-term sales of capacity and energy by Progress Ventures in Florida at the same price at which Progress Ventures purchases the power. Progress Ventures requests an effective date of June 14, 2004.

Progress Ventures states that copies of the filing were served upon the Florida Public Service Commission, the North Carolina Utilities Commission and affected customers.

Comment Date: 5 p.m. eastern time on April 14, 2005.

12. Carolina Power & Light Company

[Docket No. ER05–722–000]

Take notice that on March 24, 2005, Carolina Power & Light Company, filed revisions to a Power Supply Agreement between North Carolina Electric Membership Corporation (NCEMC) and Progress Energy Carolinas, Inc., Rate Schedule FERC No. 134. Carolina Power and Light Company request an effective date of January 1, 2001.

Carolina Power and Light Company states that copies of the filing were served upon NCEMC, the North Carolina Utilities Commission and the South Carolina Public Service Commission.

Comment Date: 5 p.m. eastern time on April 14, 2005.

13. PJM Interconnection, L.L.C.

[Docket No. ER05–724–000]

Take notice that on March 24, 2005, PJM Interconnection, L.L.C. (PJM) and Duquesne Light Company (Duquesne) (together, Applicants) tendered for filing an amended network integration service agreement between PJM and Allegheny Power.

Applicants state that copies of the filing were served upon Allegheny Power and the state commissions in the Allegheny Power region.

Comment Date: 5 p.m. eastern time on April 14, 2005.

Deephaven RV Sub Fund Ltd.

[Docket No. ER05–725–000]

Take notice that on March 24, 2005, Deephaven RV Sub Fund Ltd. (Deephaven) submitted for filing, pursuant to section 205 of the Federal Power Act, and part 35 of the Commission's regulations, an application for authorization to make sales, as a power marketer, of capacity, energy, and certain Ancillary Services at market-based rates; to reassign transmission capacity; and to resell firm transmission rights. Deephaven further requests certain waiver and blanket authorizations under Commission regulations. Deephaven requests an effective date for its proposed rate schedule of April 25, 2005.

Comment Date: 5 p.m. eastern time on April 14, 2005.

15. CPN Pleasant Hill Operating, LLC

[Docket No. ER05–726–000]

Take notice that on March 24, 2005, CPN Pleasant Hill Operating, LLC filed a Notice of Cancellation of its Rate Schedule FERC No. 1 and Service Agreement Nos. 1 and 2.

Comment Date: 5 p.m. eastern time on April 14, 2005.

Standard Paragraph

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–1605 Filed 4–6–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OECA–2004–0035; FRL–7895–6]

Agency Information Collection Activities; Submission for OMB Review and Approval; Comment Request; NESHAP for Marine Tank Vessel Loading Operations (Renewal), ICR Number 1679.05, OMB Control Number 2060–0289

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act, this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on May 31, 2005. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before May 9, 2005.

ADDRESSES: Submit your comments, referencing docket ID number OECA–2004-0035, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, Mail Code 2201T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Dan Chadwick, Compliance Assessment and Media Programs Division, Office of Compliance, 2223A, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–7054; fax number: (202) 564–0050; e-mail address: *chadwick.dan@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On September 14, 2004 (69 FR 55430), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OECA–2004–0035, which is available for public viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket and Information Center is: (202) 566–1752. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, *see* EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: NESHAP for Marine Tank Vessel Loading Operations (Renewal).

Abstract: This information collection request addresses Clean Air Act information collection requirements in standards published at 40 CFR part 63, subpart Y, which have mandatory recordkeeping and reporting requirements. The information collected under these requirements concern compliance with emissions standards relating to loading of marine tank vessels with petroleum and gasoline. Records collected under the National Emission Standards for Hazardous Air Pollutants (NESHAP) must be retained by the owner or operator for at least five years, so that the recorded can be shown to inspectors when requested. In general, the required collections consist of emissions data and other information deemed not to be private (40 CFR 63.15).

Delegated states and EPA Regional Offices use the information collected under these requirements to determine compliance with the NESHAP. In the absence of such information collection requirements, enforcement personnel would be unable to determine whether the standards are being met on a continuous basis, as required by the Clean Air Act.

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. The OMB Control Numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 12 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Entities potentially affected by this action are marine tank vessel loading operations at marine terminals.

Estimated Number of Respondents: 804.

Frequency of Response: On occasion, Semi-annually, Annually.

Estimated Total Annual Hour Burden: 9,872 hours.

Estimated Total Annual Costs: $629,850 which includes $0 annualized capital/startup costs, $0 annual O&M costs, and $629,850 in Respondent Labor costs.

Changes in the Estimates: There is a decrease of 18,259 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is due to a change in the estimated number of facilities that submit reports from 105 to 38 and correction of the frequency of HAP control efficiency reports from quarterly to annually.

Balancing these decreases are three sources of increase in burden. Recordkeeping burden for facilities that keep records but do not report, not considered in previous versions of the ICR, is included here at one hour for each of 766 facilities. Industry labor rates increased by an average of 16.7% from those in the active ICR. Calculated burden also increased by including managerial and clerical labor, which had not been included in the previous ICR.

Dated: March 25, 2005.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 05–6849 Filed 4–6–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[RCRA–2005–0005, FRL–7895–7]

Agency Information Collection Activities: Proposed Collection; Comment Request; RCRA Expanded Public Participation, EPA ICR Number 1688.05, OMB Control Number 2050–0149

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB). This is a request an existing approved collection. This ICRis scheduled to expire on August 31, 2005. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before June 6, 2005.

ADDRESSES: Submit your comments, referencing docket ID number RCRA–2005–0005, to EPA online using EDOCKET (our preferred method), by e-mail to *RCRA-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, RCRA Docket, mail code 5305T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Norma Abdul-Malik, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–308–8753; fax number: 703–308–8617; e-mail address: *abdul-malik.norma@epamail.epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number RCRA–2005–0005, which is available for public viewing at the RCRA Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the RCRA Docket is (202) 566–0270. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov./edocket.*

Affected Entities: Entities potentially affected by this action are facility owners or operators applying for an initial Part B permit or a Part B permit renewal.

Title: RCRA Expanded Public Participation.

Abstract: Section 7004(b) of RCRA gives EPA broad authority to provide for, encourage, and assist public participation in the development, revision, implementation, and enforcement of any regulation, guideline, information, or program under RCRA. In addition, the statute specifies certain public notices (*i.e.*, radio, newspaper, and a letter to relevant agencies) that EPA must provide before issuing any RCRA permit. The statute also establishes a process by which the public can dispute a permit and request a public hearing to discuss it. EPA carries out much of its RCRA public involvement at 40 CFR parts 124 and 270.

In 1995, EPA expanded the public participation requirements under the RCRA program by promulgating the RCRA Expanded Public Participation Rule (60 FR 63417; December 11, 1995). The rule responded to calls by the

Administration and stakeholders (*e.g.*, States and private citizens) to provide earlier and better public participation in EPA's permitting programs, including procedures for more timely information sharing. In particular, the rule requires earlier public involvement in the permitting process (*e.g.*, pre-application meetings), expanded public notice for significant events (*e.g.*, notices of upcoming trial burns), and more opportunities for the exchange of permitting information (*e.g.*, information repository).

The required activities and information are needed to help assure timely and effective public participation in the permitting process. The requirements are intended to provide equal access to information to all stakeholders in the permitting process: the permitting agency, the permit applicant, and the community where a facility is located. Some facilities may be required to develop information repositories to allow for expanded public participation and access to detailed facility information as part of the permitting process.

EPA sought to reduce the reporting frequency to the minimum that is necessary to ensure compliance with the rule. It would not be possible to collect this information less frequently and still assure that the requirements of permit and public involvement regulations are met by owners or operators. The reporting frequency is essential to assure that any changes in the trial burn plans or in the anticipated permit application contents are made known to EPA and to the public.

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. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

The EPA would like to solicit comments to:

(i) 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;

(ii) 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;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) 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.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 91 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Estimated Number of Respondents: 33.

Frequency of Response: On occasion.

Estimated Total Annual Hour Burden: 3,005 hours.

Estimated Total Annualized Capital, O&M Cost Burden: $4.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: March 29, 2005.

Maria Parisi Vickers,

Acting Director, Office of Solid Waste.

[FR Doc. 05–6850 Filed 4–6–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2003–0006; FRL–7896–4]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Highway Vehicle Activity and Emissions (Renewal), EPA ICR Number 0619.10, OMB Control Number 2060–0078

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on March 31, 2005. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before May 9, 2005.

ADDRESSES: Submit your comments, referencing docket ID number OAR–2003–0006, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *a-and-r-docket@epa.gov*, or by mail to: Environmental Protection Agency, EPA Docket Center (EPA/DC), Air and Radiation Docket and Information Center, Mail code 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Carl Scarbro, Assessment and Standards Division, Office of Transportation and Air Quality, AATC, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (734) 214–4209; fax number: (734) 214–4939; e-mail address: *scarbro.carl@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On Friday, January 24, 2003 (68 FR 3524), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received a single request for information

concerning the ICR. EPA forwarded the requested information to the requestor.

EPA has established a public docket for this ICR under Docket ID No. OAR–2003–0006, which is available for public viewing at the Office of Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Office of Air and Radiation Docket is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket*. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket*.

Title: Highway Vehicle Activity and Emissions (Renewal).

Abstract: EPA is initiating a data collection to target two research objectives related to emissions inventory estimation for highway vehicles. The first is to examine differences in vehicle speed among differing vehicle types and road types. The second is to measure emission rates for samples of vehicles stratified by year of manufacture and regulatory class. Data to be collected include ''in-use'' or ''real world'' vehicle speed and emission rates.

The collection is a survey, to be conducted by the Office of Transportation and Air Quality (OTAQ) in the Office of Air and Radiation (OAR). Development of rapid in-use instrumentation promises to substantially reduce the cost of emissions measurement for highway vehicles. This study will combine rapid in-use measurement capability with statistical survey design to contribute to the development of usage and emission rates for the EPA Motor Vehicle Emissions Simulator (MOVES) model. Response to the survey is voluntary.

The target population is highway vehicles registered in the study area. EPA shall recruit vehicles from State registration databases and from regional or state Inspection and Maintenance Programs (I/M).

Emissions and usage will be measured using portable on-board electronic instrumentation. Emissions instrumentation will measure carbon dioxide (CO_2) and several air pollutants with one second resolution during normal operation over a period of one to three days. Air pollutants to be measured include, but are not limited to, carbon monoxide (CO), total hydrocarbons (THC), and oxides of nitrogen (NO_X). The usage instrument will measure with one second resolution engine on/off, vehicle speed, and vehicle location over a period of approximately one month.

Data will be collected during normal operation. Following quality-assurance and analysis, the data will be stored in OTAQ's Mobile Source Observation Database. The information collection will involve 1,285 respondents, requiring 1,327 hours at a total cost to those respondents of $35,672. For the agency, the collection will require 26,327 hours at a total cost to the agency of $1,532,629.

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. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 1.0 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Owners of highway vehicles.

Estimated Number of Respondents: 1,285.

Frequency of Response: One time.

Estimated Total Annual Hour Burden: 1,327.

Estimated Total Annual Cost: $35,672, which includes $0 annualized capital/startup costs, $0 annual O&M costs, and $35,672 annual labor costs.

Changes in the Estimates: There is a decrease of 322 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is due to installing instruments at a vehicle's ''depot location'' versus having owners commute to a central location. The total costs to the respondent will decline in kind based on the total hours.

Dated: March 31, 2005.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 05–6943 Filed 4–6–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL –7896–1]

Science Advisory Board Staff Office; Notification of an Upcoming Science Advisory Board Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference meeting of an SAB Quality Review Committee (QRC) to discuss and to review a draft SAB report, Identifying and Calculating Economic Benefit that Goes Beyond Avoided and/or Delayed Costs: An SAB Draft Advisory.

DATES: April 29, 2005. A public telephone conference meeting of the SAB Quality Review Committee (QRC)

will be held on April 29, 2005, from 1 p.m. until 3 p.m. (eastern time) to discuss the draft SAB report, Identifying and Calculating Economic Benefit that Goes Beyond Avoided and/or Delayed Costs: An SAB Draft Advisory.

ADDRESSES: The meeting for this review will be held by telephone only. Members of the public who wish to obtain the call-in number for this meeting should contact the Designated Federal Officer (DFO) for this meeting. The SAB mailing address is: U.S. EPA, Science Advisory Board (1400F), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. General information about the SAB, as well as any updates concerning the meeting announced in this notice, may be found on the SAB Web site at: *http://www.epa.gov/sab*.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain information regarding this teleconference meeting may contact Mr. Thomas O. Miller, DFO, at (202) 343–9982 or e-mail at *miller.tom@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA's Office of Enforcement and Compliance Assurance (OECA) requested that the EPA Science Advisory Board review the OECA White Paper entitled Identifying and Calculating Economic Benefit that Goes Beyond Avoided and/or Delayed Costs, dated May 25, 2003. Accordingly, the SAB Staff Office formed an Ad Hoc Panel to review the EPA White Paper. This was announced in a notice in the **Federal Register** of August 6, 2003 (68 FR 46604) in which the SAB Staff Office solicited nominations for Panel membership. The Panel held several meetings to discuss and draft its advisory as announced in **Federal Register** notices published on June 25, 2004 (69 FR 35599) and January 6, 2005 (70 FR 1244). These notices can be found on the SAB Web site at: *http://www.epa.gov/sab/panels/icaebapanel.html*.

The White Paper addressing ''illegal competitive advantage'' (ICA) issues is related to EPA's policy of recapturing violators' economic benefit from environmental noncompliance. Most of the Agency's cases involving this type of economic benefit focus on the financial gain that arises from delayed and/or avoided pollution control costs. In these situations, the Agency calculates the economic benefit using the ''BEN'' (Benefits) computer model. EPA's White Paper provides an approach to capture economic benefits from situations that are not covered by the BEN model's focus on avoided and/or delayed expenditures.

The SAB is now conducting a quality review of the Panel's draft advisory report. The purpose of the QRC is to determine whether: (i) The original charge questions to the SAB review panel have been adequately addressed, (ii) the report is clear and logical, and (iii) any conclusions drawn, or recommendations provided, are supported by the body of information in the advisory report. The outcome of the QRC review will be one, or a combination of one or more, of the following: (i) Recommend SAB approval of the report without substantive change, (ii) return the report to the review panel for further work, or (iii) reject the work of the review panel and request a reconsideration and a revised report in the future.

Availability of Review Material for the Board Meeting: Documents that are the subject of this meeting are available on the SAB Web site at: *http://www.epa.gov/sab/panels/icaebapanel.html*.

Procedures for Providing Public Comment: The SAB Staff Office accepts written public comments of any length, and accommodates oral public comments whenever possible. The SAB Staff Office expects that public statements presented at SAB meetings will not be repetitive of previously submitted oral or written statements. *Oral Comments:* In general, each individual or group requesting an oral presentation at a teleconference meeting will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Interested parties should contact the DFO noted above in writing via e-mail at least one week prior to the meeting in order to be placed on the public speaker list for the meeting. Speakers should provide an electronic copy of their comments for distribution to interested parties and participants in the meeting. *Written Comments:* Although written comments are accepted until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the DFO at the address/contact information above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 98/2000/XP format).

Meeting Accommodations: Individuals requiring special accommodation to access these meetings, should contact the DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: March 31, 2005.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 05–6945 Filed 4–6–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 20, 2005.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528

1. *William B. Gossett,* Beaufort, South Carolina, to acquire additional voting shares of Islands Bancorp, Beaufort, South Carolina, and thereby indirectly acquire Islands Community Bank, National Association, Beaufort, South Carolina.

B. Federal Reserve Bank of Chicago (Patrick Wilder, Managing Examiner) 230 South LaSalle Street, Chicago, Illinois 60690–1414

1. *Jutta Hansen,* DeWitt, Iowa, and *Chris Hansen III,* Grand Mound, Iowa, individually and as trustees of the Chris F. Hansen, Jr. Trust, DeWitt, Iowa; *Pamela A. Swahn IRA,* Granite Bay, California; *Pamela A. Swahn,* Granite Bay, California; *Anne H. Fergus,* Whitefish Bay, Wisconsin; and *Melanie K. Boosalis,* Long Grove, Iowa, to acquire voting shares of DeWitt Bancorp, Inc., DeWitt, Iowa, and thereby indirectly acquire DeWitt Bank and Trust Company, DeWitt, Iowa.

Board of Governors of the Federal Reserve System, April 1, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–6860 Filed 4–6–05; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at *http://www.ffiec.gov/nic/.*

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 2, 2005.

A. Federal Reserve Bank of Cleveland (Stephen J. Ong, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. Community Trust Bancorp, Inc., Pikeville, Kentucky; to acquire 100 percent of the voting shares of Heritage Community Bank, Danville, Kentucky.

B. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Bank of America and NB Holdings Corporation, Charlotte, North Carolina; to acquire 100 percent of the voting shares of Bank America Rhode Island, National Association, Providence, Rhode Island.

Board of Governors of the Federal Reserve System, April 1, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–6859 Filed 4–6–05; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Notice

TIME AND DATE: 9 a.m. (e.d.t.), April 18, 2005.

PLACE: 4th Floor Conference Room, 1250 H Street, NW., Washington, DC.

STATUS: Parts will be open to the public and parts closed to the public.

MATTERS TO BE CONSIDERED:

Parts Open to the Public

1. Approval of the minutes of the March 21, 2005, Board member meeting.
2. Thrift Savings Plan activity report by the Executive Director.
3. Quarterly Investment Policy report.

Parts Closed to the Public

4. Procurement.
5. Personnel.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: April 5, 2005.

Elizabeth S. Woodruff,

Secretary to the Board, Federal Retirement Thrift Investment Board.

[FR Doc. 05–7128 Filed 4–5–05; 3:43 pm]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Assistant Secretary for Administration and Management; Office of Budget, Technology and Finance; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended to Chapter AJ, ''Office of the Assistant Secretary for Administration and Management (OASAM),'' as last amended at 68 FR 36808–12, dated June 19, 2003; and Chapter AM, ''Office of Budget, Technology and Finance (OBTF),'' as last amended at 68 FR 57695–98, dated October 6, 2003. The amendment is to reflect the transfer of the grants management and policy function from OASAM to OBTF. The changes are as follows:

1. Under Chapter AJ, ''Office of the Assistant Secretary for Administration and Management,'' make the following changes:

A. Under Section AJ.00 Mission, delete all reference to the ''grants'' function.

B. Under Section AJ.10 Organization, delete the ''Office of Grants Management and Policy (AJB).''

C. Under Section AJ.20 Functions, delete paragraph E, ''Office of Grants Management and Policy (AJB),'' in its entirety.

II. Under Chapter AM, ''Office of Budget, Technology and Finance (OBTF),'' make the following changes.

A. Under Section AM.00 Mission, delete in its entirety and replace with the following:

Section AM.00 Mission. The mission of the Office of Budget, Technology and Finance (OBTF) is to provide advice and guidance to the Secretary on budget, financial management, information technology, and grants management; and to provide for the direction and coordination of these activities throughout the Department.

B. Under Section AM.10 Organization, delete in its entirety and replace with the following:

Section AM.10 Organization: The Office of Budget, Technology, and Finance is headed by the Assistant Secretary for Budget, Technology and Finance (ASBTF). The Assistant Secretary for Budget, Technology, and Finance is the Departmental Chief Financial Officer (CFO), and reports to the Secretary. The office consists of the following components:

- Immediate Office of the ASBTF (AM)
- Office of Budget (AML)
- Office of Information Resources Management (AMM)
- Office of Finance (AMS)
- Office of Grants (AMT)

C. Under Section AM.20 Functions, add the following new paragraph:

E. Office of Grants (AMT)

Section AMT.00 Mission. The Office of Grants (OG) provides functional management directions in the areas of grants policy, grants management, electronic grants, and grants streamlining. Provides Department-wide leadership in these areas through policy development, oversight and training. Provides Departmental and government-

wide leadership on PL106–107 implementation, Electronic Grants, and other HHS-led initiatives. Represents the Department in dealing with OMB, GSA and other Federal agencies and Congress in the areas of mandatory and discretionary grants, and electronic grants. Fosters creativity, collaboration, consolidation, and innovation in the administration of grants functions through the Department.

Section AMT.10 Organization. The Office of Grants (OG), is headed by a Deputy Assistant Secretary for Grants who reports directly to the Assistant Secretary for Budget, Technology and Finance, and consists of the following components:

- Immediate Office of Grants (AMT)
- Division of Grants Policy (AMT1)
- Division of Grants Oversight and Review (AMT2)

Section AMT.20 Functions

I. Immediate Office of Grants (AMT). The Immediate Office of Grants provides leadership, policy, and guidance and supervision, as well as coordinating long and short-range planning to constituent organizations. The office supports the government-wide electronic grants initiative, including the outreach to grantors and grantees efforts, and interface with OMB, Federal CIO Council, and HHS leadership on the Grants.gov systems. Also, provides technical assistance to the Operating Divisions and evaluates effectiveness of their grant programs, including the development of performance standards and grant processing systems.

2. Division on Grants Policy (AMT1). The Division of Grants Policy provides leadership in the area of grants through policy development, oversight and training. The Division is responsible for the following:

a. Formulates Department-wide grants policies governing the management of grants throughout the Department.

b. Provides advice and technical assistance on grants policy to the Department's Operating Divisions.

c. Monitors the adoption of grants policies by the Department's Operating Divisions to ensure consistent policy interpretation and application.

d. Develops, participates in and evaluates grants training programs for Department staff. Establishes and manages training and certification programs for grants management professionals throughout the Department.

e. Researches, analyzes and tests innovative ideas, techniques and policies in the area of grants. Makes studies of problems requiring creation of new policies or revision of current policies, including the application of Departmental policies and best practices related to the Department's grant activities; resolves issues arising from implementation of those policies; maintains relationships and associations with grantor and grantee organizations.

f. Serves as the Department's liaison in the area of grants and maintains working relationships with OMB, GSA and other Federal agencies to coordinate and assist in the development of policy.

g. Makes studies of problems requiring creation of new policies or revision of current policies.

h. Formulates Department-wide grant policies governing the award and administration of grant activities. Publishes these in regulations and other directives.

i. Leads government-wide and Departmental design and implementation of PL106–107 streamlining initiatives. Identifies ways to streamline grants processes and implements policies that foster streamlining and other best practices.

3. *Division of Grants Oversight and Review (ATM2).* The Division of Grants Oversight and Review provides leadership in the area of mandatory and discretionary grants through oversight and review. The Division has functional responsibility for reviewing grants for compliance with Department-wide grants policies and grant regulations. In addition, the Division is responsible for oversight of the HHS grants management operations and the following:

a. Manages oversight of the award and administration of mandatory and discretionary grants and other forms of Federal financial assistance throughout the Department.

b. Monitors the adoption of grant policies as they affect grant management procedures by the Department's Operating and Staff Divisions to ensure consistent implementation and operations.

c. Provides advice and technical assistance to the Department's Operating and Staff Divisions and to the general public on matters relating to the administration of grants and other forms of Federal financial assistance.

d. Conducts special studies of grants management issues to identify and implement improvements in the way the Department awards and administers grants and other forms of Federal financial assistance; and designs and assists in execution of demonstrations, experimentation and tests of innovative approaches to grants management.

e. Develops, analyzes and tests innovative ideas, techniques, and implementations in grants management. Fosters creativity in the administration of grants.

f. Establishes and manages improved grants management information and monitoring systems.

g. Conducts performance measurements of the Department's Grants System and operates the Department-wide grants reporting systems.

h. Provides advice and technical assistance on grants implementation and processes to the Department's Operating Divisions.

i. Oversees the implementation of grants function throughout the Department.

III. *Continuation of Policy:* Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to the Office of the Assistance Secretary for Administration and Management and the Office of Budget, Technology and Finance heretofore issued and in effect prior to this reorganization are continued in full force and effect.

IV. *Delegation of Authority:* All delegations and redelegations of authority made to officials and employees of the Office of the Assistant Secretary for Administration and Management and the Office of Budget, Technology and Finance will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

V. *Funds, Personnel and Equipment:* Transfer of organizations and functions affected by this reorganization shall be accompanied by direct and support funds, positions, personnel, records, equipment, supplies, and other sources.

Dated: April 1, 2005.

Ed Sontag,

Assistant Secretary for Administration and Management.

[FR Doc. 05–6934 Filed 4–6–05; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05BP]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the

Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 or send comments to Seleda M. Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

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 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 collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Healthier Worksite Initiative-CDC Employee Needs Assessment—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's National Center for Chronic Disease Prevention and Health Promotion, Division of Nutrition and Physical Activity, Healthier Worksite Initiative (HWI), proposes to conduct a baseline measurement of employee health practices and ongoing monitoring of the awareness and reaction to planned HWI interventions.

In October, 2002 the CDC Director began a Healthier Worksite Initiative for CDC, focusing on the four pillars of the President's HealthierUS Workforce directive—physical activity, healthy eating, preventive screening, and making healthy choices. This was in line with the Department of Health and Human Services initiative within its own agencies. The Division of Nutrition and Physical Activity (DNPA), within NCCDPHP, was designated to lead the initiative within CDC.

The purpose of the Healthier Worksite Initiative is to: (1) Develop and evaluate worksite health promotion interventions for CDC employees, culminating in a model worksite health promotion program; (2) establish an evidence base for worksite health promotion interventions; and (3) develop a web-based tool kit to share information learned with other Federal agencies, as they refine or develop their own employee health promotion programs.

The HWI infrastructure is centered around two entities: the Healthier Worksite Advisory Committee and the Healthier Worksite Workgroup. The Advisory Committee includes representatives from all interested Centers, Institutes, and Offices within CDC. The committee meets monthly to review the progress of and to provide direction for the Healthier Worksite Initiative. The Healthier Worksite Workgroup develops innovative worksite health program ideas and tests them in demonstration projects. An outcome of this project will be a Web site which will serve as a resource for all government agencies and the general public for implementation of HealthierUS pillars in work settings.

One of the key components in successful worksite health promotion programs is a needs assessment. This request for OMB approval is to conduct a needs assessment by surveying all CDC employees. The HWI assessment of employee behaviors and needs will provide a foundation of information to determine the direction and requirements to build a successful worksite health promotion program. In addition, ongoing monitoring to continually assess and improve the effectiveness of the HWI programs and progress is essential in keeping the initiative on the cutting-edge in provision of worksite health programs.

The initial employee needs assessment will be a web-based survey of all CDC employees (including contractors, fellows and guest researchers). Future periodic monitoring methods may include: e-mail surveys, telephone surveys, telephone or in-person focus groups, web-based surveys, or intercept interviews. Tracking and evaluation of program effectiveness are standard health promotion tools. There is no cost to respondents except for their time to participate in the survey.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses/ respondent	Average burden per response (in hours)	Total burden hours
CDC Employees (to include contractors, fellows, and guest researchers)	16,500	1	10/60	2750
Total	.....	.....	.....	2750

Dated: March 31, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–6902 Filed 4–6–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Cooperative Agreement for Building System Capacity To Apply Law as a Public Health Tool

Announcement Type: New.

Funding Opportunity Number: RFA AA036.

Catalog of Federal Domestic Assistance Number: 92.283.

Key Dates: Application Deadline: May 23, 2005.

I. Funding Opportunity Description

Authority: 42 U.S.C. 247b(k)(2).

Purpose: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2005 funds for a cooperative agreement program to assist public health related professions and organizations to strengthen their capacity to apply law as a tool for improving the health of the public through prevention and health

promotion. The focus will be on public health priorities established by CDC. The initial highest priority will be preparedness for, and response to, public health emergencies such as those associated with terrorism, influenza and other infectious disease epidemics, and natural disasters. Additional initial high priorities will include prevention of obesity and chronic disease, and promotion of adolescent health. Priorities may change during the grant period. This program addresses the ''Healthy People 2010'' focus area Public Health Infrastructure.

For the purpose of this program, public health-related professions include, at a minimum: Elected and appointed public officials who make or influence the use of law as a public health tool; public health policy makers and practitioners; attorneys; emergency response and law enforcement professionals; the judiciary; researchers; and educators and trainers and organizations serving those professions. The main emphasis will be on professions, or organizations serving them, active at the state and local levels but federal agency professionals and organizations (*e.g.*, CDC programs) may be addressed as well.

The program has two goals within its overarching purpose. Goal 1 is to strengthen public health law-related competencies, to improve information resources on public health law, to translate applied public health law research findings into practice, and to expand partnerships among organizations active in public health law. Goal 2 is to co-sponsor, with CDC, an annual conference series in public health law. Organizations may apply to conduct work on Goal 1, on Goal 2, or on both goals. An organization that wishes to apply to conduct work on both goals must submit two separate applications. Work on both goals will be conducted in collaboration with the CDC Public Health Law Program.

Measurable outcomes of the program will be in alignment with the following Public Health Improvement performance goal in the final FY 2005 Government Performance and Results Act (GPRA) Annual Performance Plan: ''Increase the number of frontline public health workers at the state and local level that are competent and prepared to respond to bioterrorism, infectious disease outbreaks, and other public health threats and emergencies and prepare frontline state and local health departments and laboratories to respond to current and emerging public health threats.''

This announcement is only for non-research activities supported by CDC/ATSDR. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: *http://www.cdc.gov/od/ads/opspoll1.htm*

Activities: In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in Recipient Activities, and CDC will be responsible for the activities listed in CDC Activities.

Recipient activities for this program are as follows:

With respect to Goal 1:

Recipient Activities

1. Strengthen the competencies of public health-related professions to apply law effectively as a public health tool:

a. Prepare a plan to strengthen the competencies of public health-related professions by January 1, 2006, and revise the plan as indicated thereafter

b. Develop and deliver education, training, and continuing education in public health law, beginning no later than February 1, 2006.

c. Evaluate and report on the recipient's education, training, and continuing education at least annually, beginning no later than July 1, 2006.

2. Develop and provide information, and opportunities for information exchange, on public health law to public health-related professions:

a. Prepare a plan to develop and provide information, and for information exchange, by January 1, 2006, and revise the plan as indicated thereafter

b. Implement the plan, beginning no later than February 1, 2006, including, at a minimum:

i. National or international teleconferences

ii. Information provided through the recipient's Web site

iii. Information provided through the recipient's newsletters, and other publications, and

iv. Information provided to other organizations for dissemination to public health-related professions.

c. Evaluate and report on the recipient's information and information exchange activities at least annually, beginning no later than July 1, 2006.

3. Translate applied public health law research findings into public health-related professional's practice

a. Prepare a plan for translating research findings into practice by January 1, 2006, and revise the plan as indicated

b. Implement the plan, including, at a minimum, one annual symposium or meeting on translating research findings into practice, beginning no later than April 1, 2006.

c. Evaluate and report on the recipient's research translation activities at least annually, beginning no later than July 1, 2006.

4. Stimulate development of partnerships among the recipient and other organizations that serve public health-related professions

a. Prepare a plan for stimulating partnership development by January 1, 2006, and revise the plan as indicated

b. Implement the plan, beginning no later than April 1, 2006

c. Evaluate and report on the recipient's partnership-related activities at least annually, beginning no later than July 1, 2006.

5. Submit four quarterly progress reports in each 12-month budget period. These progress reports must contain the following information:

a. Work accomplished related to each recipient activity

b. Measures of effectiveness in accomplishing the program objectives

c. Compliance with the project timeline

Progress reports are due no later than December 31, March 31, June 31 and September 31 of each year.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities

1. Collaborate with the recipient in identifying priorities and activities, services and products consistent with Recipient activities 1–4.

2. Collaborate with the recipient in identifying priority public health-related professions for education, training, continuing education, information, and research translation services and products and in identifying organizations with partnership potential.

3. Provide limited technical guidance to the recipient in conducting its activities under this corporative agreement.

With respect to Goal 2:

Recipient Activities

1. Co-sponsor with CDC an annual series of public health law conferences targeted at public health-related professions, beginning no later than June 2006

a. Prepare a plan for the substantive program of the 2006 conference by November 1, 2005, and revise as indicated

b. Prepare a plan for faculty selection and for development of lasting educational products for the 2006 conference by January 1, 2006

c. Collaborate with CDC in organizing and conducting the 2006 conference, including managing overall conference logistics, organizing travel for conference faculty, assisting in marketing and promotional efforts, identifying or providing continuing education credits, including, at a minimum, Continuing Medical Education (CME) and Continuing Legal Education (CLE), among others.

d. Develop and disseminate conference proceedings and other products

e. Evaluate all aspects of the conference

f. Collaborate with other CDC conference collaborating organizations

g. Repeat activities a–f for the 2007 and 2008 annual conferences

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities

1. Collaborate with the recipient in co-sponsoring the annual series of public health law conferences, including, among other activities:

a. Identifying potential members of conference planning committees
b. Identifying potential topics for the substantive conference program, learning objectives, faculty, and lasting educational products
c. Disseminating conference proceedings and other products

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2005.

Approximate Total Funding: Approximately $100,000 is available in FY 2005 to fund activities related to Goal 1. Approximately $300,000 is available in FY 2005 to fund activities related to Goal 2.

Approximate Number of Awards: Two.

Approximate Average Award: $100,000 with respect to goal 1 and $300,000 with respect to goal 2. (These amounts are for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: $50,000 for goal 1 and $150,000 for goal 2.

Ceiling of Award Range: $150,000 for goal 1 and $350,000 for goal 2.

Anticipated Award Date: August 31, 2005.

Budget Period Length: 12 months.

Project Period Length: Up to three years. Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Universities.
- Colleges.
- Research institutions.
- Hospitals.
- Community-based organizations.
- Faith-based organizations.
- Federally recognized Indian tribal governments.
- Indian tribes.
- Indian tribal organizations.
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).
- Political subdivisions of States (in consultation with States).

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching

Matching funds are encouraged but not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

Special Requirements: If your application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

- Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.
- Recipients are required to collaborate with organizations and professionals active in public health practice and public health law at the local, state, national, and international levels.
- **Note:** Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161–1 (OMB Number 0937–0189).

Electronic Submission: CDC strongly encourages you to submit your application electronically by utilizing the forms and instructions posted for this announcement on *http://www.Grants.gov*, the official Federal agencywide E-grant Web site. Only applicants who apply online are permitted to forego paper copy submission of all application forms.

Paper Submission: Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm*.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Application: Electronic Submission: You may submit your application electronically at: *http://www.grants.gov*. Applications completed online through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the application to www.grants.gov. Electronic applications will be considered as having met the deadline if the application has been submitted electronically by the applicant organization's Authorizing Official to Grants.gov on or before the deadline date and time.

It is strongly recommended that you submit your grant application using

Microsoft Office products (*e.g.*, Microsoft Word, Microsoft Excel, etc.). If you do not have access to Microsoft Office products, you may submit a PDF file. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may result in your file being unreadable by our staff.

CDC recommends that you submit your application to Grants.gov early enough to resolve any unanticipated difficulties prior to the deadline. You may also submit a back-up paper submission of your application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. The paper submission must be clearly marked: ''BACK–UP FOR ELECTRONIC SUBMISSION.'' The paper submission must conform with all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

Paper Submission: If you plan to submit your application by hard copy, submit the original and two hard copies of your application by mail or express delivery service. Refer to Section IV.6. Other Submission Requirements for submission address.

You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 30. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unreduced.
- Single spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and should consist of, at a minimum, the following sections: Goals and Objectives; Methods and Collaboration Plan; Capacity and Program Management; Background and Need; Evaluation Plan; and Requested Budget and Justification.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curricula Vitae.
- Resumes.
- Organizational Charts and Articles of Incorporation or Charter.
- Letters of Support.
- Project Plan and Timeline.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm*. If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

Application Deadline Date: May 23, 2005.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you submit your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on application content, submission address, and deadline. It supersedes information provided in the application instructions. If your submission does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that you did not meet the submission requirements.

Electronic Submission: If you submit your application electronically with Grants.gov, your application will be electronically time/date stamped which will serve as receipt of submission. In turn, you will receive an e-mail notice of receipt when CDC receives the application. All electronic applications must be submitted by 4 p.m. eastern time on the application due date.

Paper Submission: CDC will not notify you upon receipt of your paper submission. If you have a question about the receipt of your LOI or application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html*.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds may not be used for research.
- Funds may not be used for construction or purchase of facilities or space.
- Funds may not be used to supplant other available applicant or collaborating agency funds.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Guidance for completing your budget can be found on the CDC web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm*.

IV.6. Other Submission Requirements

CDC strongly encourages applicants to submit electronically at: *http://www.Grants.gov*. You will be able to download a copy of the application package from *http://www.Grants.gov*, complete it offline, and then upload and submit the application via the Grants.gov site. E-mail submissions will not be accepted. If you are having

technical difficulties in Grants.gov they can be reached by e-mail at *http://www.support@grants.gov* or by phone at 1–800–518–4726 (1–800–518–GRANTS). The Customer Support Center is open from 7 a.m. to 9 p.m. eastern time, Monday through Friday.

Paper Submission: If you chose to submit a paper application, submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—AA036, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

V. Application Review Information

V.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate accomplishment of the objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goal stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Goals and Objectives (25 Points)

(a) The extent to which the applicant clearly describes specific short- and long-term goals and measurable objectives for each recipient activity.

(b) The extent to which the application specifies concrete products and services to be developed and made available to public health-related professionals and organizations.

2. Methods and Collaboration Plan (25 points)

(a) The soundness of the methods the applicant proposes to use to conduct each recipient activity.

(b) The specificity, relevance, and feasibility of the applicant's plan and timeline to complete each recipient activity. A plan and a timeline must be included in the application. (The timeline may take the form of an attachment.)

(c) The extent to which the applicant demonstrates experience in collaborating with organizations and professionals active in public health practice and public health law at the local, state, national, and international levels in relation to recipient activities.

(d) The extent to which the applicant has included, as attachments, signed letters of substantive commitment from organizations and professionals active in public health and public health law to collaborate with the applicant on recipient activities.

3. Capacity and Program Management (20 Points)

(a) The extent to which the applicant demonstrates that its board of directors and staff have expertise and experience in public health law related to the recipient activities.

(b) The extent to which the applicant specifies the role its staff and board of directors will play in carrying out recipient activities.

(c) The extent to which the applicant demonstrates the capacity of its management systems to support accomplishment of recipient activities and the purpose and goals of the cooperative agreement.

4. Background and Need (20 Points)

(a) The extent to which the applicant demonstrates concrete accomplishments in the field of public health law relevant to the recipient activities.

(b) The extent to which the articles of incorporation and/or charter of the applicant authorize national and international scope of operation and membership relevant to the recipient activities.

5. Evaluation Plan/Measures of Effectiveness (10 Points)

The extent to which the applicant provides a detailed description of the methods to be used to evaluate effectiveness, including identification of the variables to be evaluated, identification of the person(s) or organization(s) that will conduct evaluations, and specification of the time line for evaluations.

6. Requested Budget and Justification (Not Scored)

(a) The extent to which the budget is clearly explained, adequately justified, reasonable, sufficient for the proposed project activities, and consistent with the intended use of the cooperative agreement funds.

(b) The applicant should provide a detailed budget with complete line-item justification of all proposed costs consistent with the stated activities in the program announcement. The budget must also include a narrative justification for all requested costs. The applicant should provide a list of any sources of additional funding beyond the amount stipulated in this cooperative agreement.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the Office of the Chief of Public Health Practice (OCPHP.) Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel consisting of CDC members outside the funding center will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above. Three reviewers from CDC staff that are not employees of the cognizant center will review and present their findings to the panel. The panel will vote to approve or disapprove based on this information and each application will be scored and ranked.

In addition, the following factors may affect the funding decision:

- Availability of funds.
- Relevance to program priorities.

CDC will provide justification for any decision to fund out of rank order.

V.3. Anticipated Announcement and Award Dates

The anticipated date for the award announcement is September 1, 2005 and the award dates will be 15–30 days after the announcement.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Parts 74 and 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

An additional Certifications form from the PHS5161–1 application needs to be included in your Grants.gov electronic submission only. Refer to *http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf.* Once the form is filled out attach it to your Grants.gov submission as Other Attachments Form.

The following additional requirements apply to this project:

- AR–7 Executive Order 12372.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities.
- AR–14 Accounting System Requirements.
- AR–15 Proof of Non-Profit Status.
- AR–20 Conference Support.
- AR–23 States and Faith-Based Organizations.
- AR–25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
   a. Current Budget Period Activities Objectives.
   b. Current Budget Period Financial Progress.
   c. New Budget Period Program Proposed Activity Objectives.
   d. Budget.
   e. Measures of Effectiveness.
   f. Additional Requested Information.
2. Financial status report no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact: Montrece M. Ransom, JD, Project Officer, Public Health Law Program, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., Mail-stop K–36, Atlanta, GA 30341, lephone: 770–488–8286, E-mail: *mransom@cdc.gov.*

For financial, grants management, or budget assistance, contact:

Mattie B. Jackson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2696, E-mail: *mij3@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Please visit our Web site at: *http://www.phppo.cdc.gov/od/phlp/index.asp.*

Dated: March 31, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–6901 Filed 4–6–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Oak Ridge Y–12 Plant

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services gives notice of a decision to evaluate a petition to designate a class of employees at the Y–12 Plant, also known as the Oak Ridge Y–12 Plant, in Oak Ridge, Tennessee to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 CFR 83.12 (e)). The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Y–12 Plant, Oak Ridge, Tennessee.

Locations: Building 9201–5 and the Beta Building at Y–12.

Job Titles and/or Job Duties: All Control Operators.

Period of Employment: January 1944 through December 1945.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV.*

Dated: March 30, 2005.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 05–6900 Filed 4–6–05; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5029–N]

Medicare Program; Rural Hospice Demonstration

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice provides interested parties with the information necessary to apply for participation in the rural hospice demonstration. The demonstration is designed to test whether hospice services provided by a demonstration hospice program to Medicare beneficiaries who lack an appropriate caregiver and who reside in rural areas results in wider access, improved hospice services, benefits to the rural community, and a sustainable pattern of care. A competitive application process will be used to select up to three hospice organizations or agencies to participate in this demonstration. The demonstration is planned for up to 5 years.

DATES: Applications will be considered timely if we receive them on or before June 6, 2005.

ADDRESSES: Mail applications to—Centers for Medicare & Medicaid Services, Attention: Cindy Massuda, Mail Stop: C4–17–27, 7500 Security Boulevard, Baltimore, Maryland 21244.

Because of staff and resource limitations, we cannot accept applications by facsimile (FAX) transmission or by e-mail.

FOR FURTHER INFORMATION CONTACT: Cindy Massuda at (410) 786–0652 or *RURALHOSPICEDEMO@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative Authority

Section 409 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) authorizes the Secretary to conduct a demonstration project for the delivery of hospice care to Medicare beneficiaries in rural areas. Under the demonstration, Medicare beneficiaries who are unable to receive hospice care

at home for lack of an appropriate caregiver are provided care in a facility of 20 or fewer beds that offers, within its walls, the full range of services provided by hospice programs under section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

Under the demonstration project, the hospice program shall comply with otherwise applicable requirements, except that it shall not be required to offer services outside of the hospice facility or to meet the requirements of section 1861(dd)(2)(A)(iii) of the Social Security Act (SSA) regarding the 20-percent cap on inpatient care days.

The Secretary may require the hospice demonstration to comply with additional quality assurance standards for provision of services. Upon completion of the project, the Secretary shall submit a report to the Congress on the project including recommendations regarding extensions to hospice programs serving rural areas.

B. The Rural Hospice Demonstration

The demonstration will be offered to up to three hospice programs and will not exceed a period of 5 years. The demonstration is designed to test whether hospice services provided by a demonstration hospice program to Medicare beneficiaries who lack an appropriate caregiver and who reside in rural areas results in wider access, improved hospice services, benefits to the rural community, and a sustainable pattern of care. Hospice provides palliative care to individuals who have a terminal illness with a prognosis of 6 months or less. The care is provided typically in the individual's home or place of residence with family members present. Individuals who lack family or someone to serve as the primary caregiver need proportionately more support from hospice staff. Due to long distances and difficult terrain, it can be particularly difficult to provide the Medicare hospice benefit efficiently in rural areas. There may be situations where the hospice benefit could be provided to beneficiaries who would not otherwise be able to receive these services if the location of hospice care is altered. This demonstration will allow a hospice with up to 20 beds to provide all levels of hospice services within its walls to individuals who reside in rural areas and lack an appropriate caregiver, while not having to provide services outside of the hospice facility or comply with the 20-percent cap on inpatient care days.

While the demonstration provider will not have to meet the limit on inpatient care days or provide care outside of the facility, it will not alter the level of care requirements for general inpatient care. In order to provide general inpatient care to hospice patients, a hospice participating in the demonstration must assure that the need for general inpatient care is met according to Medicare guidelines. The demonstration will test whether hospice services provided by a facility that does not meet the limit on inpatient care days or provide services outside of the facility for hospice individuals residing in rural areas who lack an appropriate caregiver results in wider access, improved hospice services, benefits to the rural community, and a sustainable pattern of care.

The demonstration is designed for a demonstration hospice to provide the full range of services within its facility to Medicare beneficiaries who reside in rural areas and lack an appropriate caregiver. If a demonstration hospice provides care to any patient who either lives outside a rural area or has an appropriate caregiver, then the hospice must comply with all of Medicare hospice requirements at 1861(dd) of the SSA for these patients since they are not considered part of the demonstration.

We plan to make up to three awards. Interested parties can obtain complete solicitation and supporting information on the CMS Web site at: *http://www.cms.hhs.gov/researchers/demos/rmbh/default.asp.* Paper copies can be obtained by writing to Cindy Massuda at the address listed in the **ADDRESSES** section of this notice.

II. Collection of Information Requirements

Since CMS will receive less than 10 applications to this solicitation, the information collection requested reference in this solicitation are not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Authority: Section 409 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).

(Domestic Assistance No. 93.773 Medicare—Hospital insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: March 10, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–6861 Filed 4–1–05; 4:42 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0119]

Preparation for the International Conference on Harmonization Meetings in Brussels, Belgium; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to provide information and receive comments on the International Conference on Harmonization (ICH) in advance of its next next Steering Committee and Expert Working Group meetings in Brussels, Belgium, May 9 through 12, 2005. Scheduled for the ICH meetings is an Efficacy Brainstorming Session focusing on the review of the existing efficacy guidelines and their need for updating as well as potential new topics for consideration. To promote a fuller discussion of this topic the public meeting will be expanded to include public input on initiatives related to current ICH efficacy guidelines and consider needs for further information both within and between existing guidances. These initiatives include electronic source data, clinical development plan summaries, Health Level 7 structured product labeling, and other initiatives including information exchange standards (e.g., Electronic Common Technical Document (eCTD) and terminology standards).

Date and Time: The meeting will be held on April 20, 2005, from 9 a.m. to 5:30 p.m.

Location: The meeting will be held at The DoubleTree Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD. A block of rooms for those wishing to attend the meeting have been set aside at the government rate. Please contact the hotel directly for your reservation: DoubleTree Hotel and Executive Meeting Center, 301–468–1100, FAX: 301–468–0308.

Contact Person: Sema Hashemi, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3050, FAX: 301–480–0716, e-mail: *Sema.Hashemi@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and FAX number), and written material and

requests to make oral presentations, to the contact person by April 14, 2005.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

If you need special accommodations due to a disability, please contact Sema Hashemi at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

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 medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among the following 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, Labor, 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. The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by April 14, 2005, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, FAX, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting and ICH Expert Working Groups. One of the topics for the upcoming ICH meeting is an Efficacy Brainstorming Session focusing on the review of the existing efficacy guidelines and their need for updating as well as potential new topics for consideration. The complete set of ICH Efficacy Guidelines may be found at *http://www.ich.org/* or *http://www.fda.gov/cder/guidance/index.htm*. To promote a fuller discussion of this topic the public meeting will be expanded to include public input on initiatives related to current ICH efficacy guidelines and consider needs for further information both within and between existing guidances. These initiatives include electronic source data, clinical development plan summaries, Health Level 7 structured product labeling, and other initiatives including information exchange standards (e.g., eCTD and terminology standards).

The agenda for the public meeting will be made available on April 15, 2005, via the internet at *http://www.fda.gov/cder/meeting/ICH_Spring2005.htm*.

Dated: April 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7020 Filed 4–5–05; 11:53 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods for High-Efficiency Single Genome Sequencing of HIV

Drs. John Coffin, Mary Kearney, Frank Maldarelli and Sarah E. Palmer (NCI), *et al.*

U.S. Provisional Application filed 25 Jan 2005 (DHHS Reference No. E–022–2005/0–US–01).

Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov*.

The invention is directed to a method for efficiently obtaining single genome sequences (SGS) of HIV from a biological sample. The invention has the following advantages over the current commercial genotyping in use: (1) It might improve the sensitivity of diagnosis of drug resistant HIV in newly infected HIV patients; (2) It might provide a more affordable diagnostic tool for early detection of drug resistance since the invention is adaptable to an automated approach for the high-throughput processing of a large number of patient sample; (3) It might improve patient outcome since SGS has the ability to identify low level mutation and will permit a more comprehensive evaluation of resistance in patients and might potentially change the clinical approach to treating resistant virus. In summary, this

invention might be a new important diagnostic tool for AIDS patients.

Reference: Sarah Palmer *et al.*, ''Multiple, Linked Human Immunodeficiency Virus Type 1 Drug Resistance Mutations in Treatment-Experienced Patients are Missed by Standard Genotype Analysis,'' J. Clin. Microbiol. (Jan 2005) 43(1):406–413.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

HIV Neutralization by Structure-Based Enhancements of CD4-Molecular Mimicry

Peter D. Kwong, Chih-chin Huang, and Tongqing Zhou (NIAID), *et al.*

U.S. Provisional Patent Application No. 60/623,762 filed 29 Oct 2004 (DHHS Reference No. E–333–2004/0–US–01).

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*.

Available for licensing are compositions and methods for inhibiting CD4–gp120 interactions. HIV infectivity is mediated by interactions between the lymphocyte cellular protein CD4 and HIV exterior gp120 envelope glycoprotein. The invention presents crystal structures of a number of co-complexes between CD4 mimics, CD4M33, F23, and others disclosed herein, with gp120, as well as other mimics and molecules, which interact with gp120. CD4M33 has greater affinity than F23 for HIV–1 primary isolates, whereas F23 is a better mimic of CD4 and showed greater neutralization breadth than CD4M33 against diverse isolates from HIV–1, HIV–2, and SIVcpz. These results provide a basis for the development of anti-HIV antagonists with increased breadth of neutralization. Moreover, methods are disclosed for the identification of a mimic of CD4 with possible broad-spectrum activity. These methods can be used for drug screening and variant CD4 mimic production. Also, methods are provided for characterizing and evaluating protein structure, for designing candidate ligands, and for constructing CD4 mimetic antagonist or the interfacial cavity binding compounds.

Finally, provided are methods for producing mono- and polyclonal antibodies for use in vaccines. Mimics binding to gp120 cause conformational change in the protein, thus exposing epitope regions for antibody recognition. The uses of the mimetics and also of a mimetic-based immunogen in inhibiting, reducing, or preventing HIV infection are also discussed. Suggestions are presented for therapeutic uses of the antibodies in preventing a decline in CD4 T cell levels in HIV-positive patients.

Candidate DNA HIV Vaccine

Gary J. Nabel *et al.* (NIAID).

U.S. Provisional Application No. 60/588,378 filed 16 Jul 2004 (DHHS Reference No. E–267–2004/0–US–01).

Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov*.

NIH is pleased to announce as available for licensing technology related to HIV vaccines, which involves a vaccine candidate that is in phase I clinical trials. The subject technology is from a broad scientific program directed toward development of an HIV vaccine that will generate cellular and humoral immunity to HIV from different clades, which vary in regions throughout the world and which is a critical aspect to be addressed by an HIV vaccine to be administered worldwide. The vaccine candidate described herein is one of the first multiclade-component HIV vaccines to enter into clinical trials. This technology describes a candidate HIV vaccine comprising six DNA constructs, each expressing different HIV proteins, HIV Env from clades A, B, and C, and the Gag, Pol, and Nef proteins from clade B. Phase I clinical trials for this vaccine combination are currently underway. The DNA expression vectors described herein were designed to maximize protein expression levels. This technology offers a promising approach in the HIV vaccine field.

HIV Vaccine Immunogens and Immunization Strategies

Gilad Ofek *et al.* (NIAID).

U.S. Provisional Application No. 60/570,883 filed 14 May 2004 (DHHS Reference No. E–218–2004/0–US–01).

Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov*.

This invention relates to novel immunogens that generate an immune response against HIV–1 gp41 in mammals. The immunogens bind to the broadly neutralizing 2F5 monoclonal antibody as well as to antibodies 4E10 and Z13. The immunogens were designed based on structural considerations from peptide-2F5 complexes. These complexes were characterized and found to have specific features, necessary to elicit an antibody response. It has been difficult to elicit broadly neutralizing antibodies against HIV–1, and this technology offers a potential solution.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Template Methods and Devices for Preparing Sample Arrays

Stephen Hewitt (NCI).

U.S. Patent Application No. 10/928,656 filed 26 Aug 2004 (DHHS Ref. E–098–2004–0–US–01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435–4507; *thalhamc@mail.nih.gov*.

Available for licensing and commercial development is a simple and inexpensive device and method for preparing tissue microarrays. The method includes placing a template defining an array of openings over a surface of the recipient block with receptacle holes, such that a needle or punch that contains a sample can be inserted through the openings of the template and the sample is then inserted into the receptacle hole in the recipient block. Tissue microarrays can include hundreds or even thousands of about 1mm discs of tissue specimens, fixed and arranged on a single microscope slide. Currently available tools provide means to generate hundreds of copies of this kind of slide. However, the equipment currently available can be quite complex and expensive, and thus it is often beyond the resources of many researchers.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Chimeric HIV/SIV Polypeptide Trimers as HIV/AIDS Vaccine Candidates

Bernard Moss (NIAID).

U.S. Provisional Application No. 60/510,952 filed 10 Oct 2003 (DHHS Reference No. E–356–2003/0–US–01); PCT Application filed 12 Oct 2004 (DHHS Reference No. E–356–2003/0–PCT–02).

Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov*.

The technology describes recombinant chimeric polypeptides of HIV Env in which all or part of the N-terminal portion (85 amino acids) of gp41 is replaced with the corresponding region of SIV. These chimeric polypeptides may be potential HIV/AIDS vaccine candidates. The substitution described above promotes efficient trimerization of the Env protein, which has been found in functional virions to have almost exclusively a trimeric structure. Therefore, by mimicking native HIV structure, the chimeric polypeptides

described in this technology could be used as immunogens for the generation of neutralizing antibodies that would bind to native HIV. The chimeric polypeptide that contains only the N-terminal portion of SIV in an HIV–1 background is particularly interesting, because several broadly neutralizing HIV–1 epitopes are present in the C-terminal segment of gp41.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Antibodies Against the Amino Terminus Region of Circumsporozoite Protein Prevent the Onset of Malaria

Dharmendar Rathore, Thomas McCutchan (NIAID).

U.S. Provisional Application No. 60/532,676 filed 23 Dec 2003 (DHHS Reference No. E–176–2003/0–US–01); PCT filed.

Licensing Contact: Robert Joynes; 301/594–6565; *joynesr@mail.nih.gov*.

Malaria is one of the 5 major diseases of the world and a leading cause of childhood death in sub-Saharan Africa. Furthermore, the economic devastation of the disease is measured in the billions of dollars of lost wages and lowered productivity for the endemic areas of the world. In the U.S., it is a concern of travelers as well the military having to serve in those parts of the world. To date, there is no vaccine and one is not expected for another decade.

The invention presented here focuses on the ability of the malarial sporozoite to infect liver cells. Previous vaccines have focused on the carboxyl end of the circumsporozoite (CSP) protein and have few successes to show. This invention utilizes the finding that the amino terminal portion of the CSP protein is required for hepatic entry. The invention includes several CSP polypeptides and constructs encoding such polypeptides that have been shown to be required for hepatic entry for vaccine development, prevention and treatment are also claimed. Methods and kit claims are included for the detection of the CSP protein in biological samples as well as for the detection of circulating antibodies of the CSP protein are also included.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Determining Kinase Specificity

J.S. Shaw and Y. Liu (NCI).

U.S. Patent Application No. 10/660,370 filed 11 Sep 2003 (DHHS Reference No. E–054–2003/0–US–01) and International Application Number PCT/US04/029397 filed 10 Sep 2004 (DHHS Reference No. E–054–2003/1–PCT–01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435–4507; *thalhamc@mail.nih.gov*.

Available for licensing and commercial development are methods, articles, software and kits for determining the spectrum of peptidyl sequences that are recognized and phosphorylated by a kinase, such as those sites on proteins involved in signal transduction pathways. More specifically, the following is disclosed:

(a) Methods involving a degenerate library approaches to identify kinase specificity by identifying peptide sequences around such phosphorylation sites and ranking the peptides in preferential order after calculating a predictive score, such as the widely used position-specific scoring matrix (PSSM). The method also provides an informative graphical format for visually representing that information and software to output data in that format. The method provides significant improvements over other methods currently used for such purpose;

(b) Peptide sequences identified by the method of the invention, such as: (i) The spectrum of peptidyl sequences that are recognized and phosphorylated by a kinase, (ii) peptides that include kinase recognition sites and (iii) binding entities that specifically distinguish phosphorylated versus non-phosphorylated peptidyl sequences; and

(c) Kits for identifying kinase substrates including anti-peptide antibodies for research and diagnostic uses.

The technology is further described in: Fujii K, Zhu G, Liu Y, Hallam J, Chen L, Herrero J, Shaw S. 2004. Kinase peptide specificity: Improved determination and relevance to protein phosphorylation. Proc Natl Acad Sci USA 101:13744–9 (PMID: 15356339) and Zhu G, Fujii K, Belkina N, Liu Y, James M, Herrero J, Shaw S. 2005. Exceptional disfavor for proline at the P+1 position amongst AGC and CAMK kinases establishes reciprocal specificity between them and the proline-directed kinases. J Biol Chem 280:10743–8: (PMID: 15647260).

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

MVA Expressing Modified HIV Envelope, Gag, and Pol Genes

Bernard Moss (NIAID), Patricia Earl (NIAID), Linda Wyatt (NIAID), Leigh Anne Steinmeyer (EM), Thomas VanCott (EM), Matthew Harris (EM).

U.S. Provisional Application No. 60/459,175 filed 28 Mar 2003 (DHHS Reference No. E–023–2003/0-US–01); PCT Application filed 28 Mar 2004, which published as WO 2004/087201 on 14 Oct 2004 (DHHS Reference No. E–023–2003/0–PCT–02).

Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@mail.nih.gov.*

This invention claims Modified Vaccinia Ankara (MVA), a replication-deficient strain of vaccinia virus, expressing Human Immunodeficiency Virus (HIV) env, gag, and pol genes, where the genes are isolated from Ugandan Clade D isolates, Kenyan Clade A isolates, and Tanzanian Clade C isolates. In a rhesus macaque SHIV model, DNA priming followed by a recombinant MVA (rMVA) booster controlled a highly pathogenic immunodeficiency challenge. Both the DNA and the rMVA components of the vaccine expressed multiple immunodeficiency virus proteins. Two DNA inoculations at zero (0) and eight (8) weeks and a single rMVA booster at twenty-four (24) weeks effectively controlled an intrarectal challenge administered seven (7) months after the booster. Additionally, the inventors have generated data showing that inoculations of rMVA induce good immune responses even without DNA priming.

The inventors are continuing preclinical work on the vaccine, and have generated further data on the vaccine. Furthermore, the inventors are continuing to optimize the vaccine by genetically modifying the genes. This vaccine will be the subject of an upcoming Phase I clinical trial. These findings provide hope that a relatively simple multiprotein DNA/MVA vaccine can help to control the Acquired Immune Deficiency Syndrome (AIDS) epidemic.

CC Chemokine Receptor 5 DNA, New Animal Models and Therapeutic Agents for HIV Infection

C. Combadiere, Y. Feng, E.A. Berger, G. Alkahatib, P.M. Murphy, C.C. Broder, P.E. Kennedy (NIAID).

U.S. Provisional Application No. 60/018,508 filed 28 May 1996 (DHHS Reference No. E–090–1996/0–US–01);

U.S. Patent Application No. 08/864,458 filed 28 May 1997 (DHHS Reference No. E–090–1996/0–US–04);

U.S. Patent Application No. 10/439,845 filed 15 May 2003 (DHHS Reference No. E–090–1996/0–US–05);
U.S. Patent Application No. 10/700,313 filed 31 Oct 2003 (DHHS Reference No. E–090–1996/0–US–06);
U.S. Patent Application No. 10/846,185 filed 14 May 2004 (DHHS Reference No. E–090–1996/0–US–07);
PCT Application No. PCT/US97/09586 filed 28 May 1997 (DHHS Reference No. E–090–1996/0–PCT–02);
European Patent Application No. 97929777.7 filed 28 May 1997 (DHHS Reference No. E–090–1996/0–EP–03).
Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@mail.nih.gov.*

Chemokine receptors are expressed by many cells, including lymphoid cells, and function to mediate cell trafficking and localization. CC chemokine receptor 5 (CCR5) is a seven-transmembrane, G protein-coupled receptor (GPCR) which regulates trafficking and effector functions of memory/effector T-lymphocytes, macrophages, and immature dendritic cells. Chemokine binding to CCR5 leads to cellular activation through pertussis toxin-sensitive heterotrimeric G proteins as well as G protein-independent signalling pathways. Like many other GPCR, CCR5 is regulated by agonist-dependent processes which involve G protein coupled receptor kinase (GRK)-dependent phosphorylation, beta-arrestin-mediated desensitization and internalization.

Human CCR5 also functions as the main coreceptor for the fusion and entry of many strains of human immunodeficiency virus (HIV–1, HIV–2). HIV-1 transmission almost invariably involves such CCR5-specific variants (designated R5); individuals lacking functional CCR5 (by virtue of homozygosity for a defective CCR5 allele) are almost completely resistant to HIV–1 infection. Specific blocking of CCR5 (*e.g.* with chemokine ligands, anti-CCR5 antibodies, CCR5-blocking low MW inhibitors, etc.) inhibits entry/infection of target cells by R5 HIV strains. Cells expressing CCR5 and CD4 are useful for screening for agents that inhibit HIV by binding to CCR5. Such agents represent potential new approaches to block HIV transmission and to treat infected people. A small animal expressing both human CCR5 along with human CD4 supports entry of HIV into target cells, a necessary hurdle that must be overcome for development of a small animal model (*e.g.* transgenic mouse, rat, rabbit, mink) to study HIV infection and its inhibition.

The invention embodies the CCR5 genetic sequence, cell lines and transgenic mice, the cells of which coexpress human CD4 and CCR5, and which may represent valuable tools for the study of HIV infection and for screening anti-HIV agents. The invention also embodies anti-CCR5 agents that block HIV env-mediated membrane fusion associated with HIV entry into human CD4-positive target cells or between HIV-infected cells and uninfected human CD4-positive target cells.

This technology was reported in Alkhatib *et al.*, ''CC CKR5: a RANTES, MIP–1alpha, MIP–1beta receptor as a fusion cofactor for macrophage-tropic HIV–1,'' Science 272:1955–1958 (1996). The technology is available for exclusive or nonexclusive licensing.

Dated: March 25, 2005.

Steven M. Ferguson, Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–6895 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Identification of Molecular Markers for Endometriosis in Blood Lymphocytes Using DNA Microarrays

Idhaliz Flores (NHGRI), *et al.*
U.S. Provisional Application filed 18 Feb 2005 (DHHS Reference No. E–068–2005/0–US–01).
Licensing Contact: Marlene Shinn-Astor; (301) 435–4426; *shinnm@mail.nih.gov.*

Endometriosis is a common, non-malignant gynecological disease that affects up to 20% of women during their reproductive years. Endometriosis is characterized by the growth of endometrial tissue outside the uterus. This growth of tissue causes recurring severe pain and can lead to infertility. As the current procedure used for diagnosis is invasive and not entirely accurate, there is a need for a fast, accurate, and minimally invasive test to test for endometriosis.

Using DNA microarray analysis of blood lymphocytes, the inventors have identified two gene markers expressed in blood that are able to discriminate between those women who have endometriosis and those that don't. The two gene markers identified are interleukin-2 receptor gamma (IL–2RG, a component of cytokine receptors) and lysyl oxidase-like 1 (LOXL1, which plays an important role in collagen synthesis and has also been implicated as a growth regulatory gene). Other genes identified in the same manner and which also represent potential biomarkers for endometriosis await further validation studies.

The test would be minimally invasive and quick using a blood sample from the patient. Currently, patients must undergo a laparoscopy with the diagnosis dependent upon the expertise of the surgeon performing the procedure.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Increased Protein Production

Drs. Shankar Adhya and Sudeshna Kar (NCI).
U.S. Provisional Application No. 60/571,943 filed 18 May 2004 (DHHS Reference No. E–261–2003/0-US–01).
Licensing Contact: Pradeep Ghosh; (301) 435–5282; *ghoshpr@mail.nih.gov.*

There is a continuing market need to identify biological measures to enhance recombinant protein production for therapeutic inventions for the treatment of diseases. In general, the field of recombinant protein production, including inducement of protein production both by cloning and non-cloning methods and incorporation of antibiotic resistance genes in vectors appeared to be relatively crowded.

However, this invention pertains to the creation of a specific 2.4 kb gene cassette that includes a specific gene that confers resistance to aminoglycoside antibiotics, increases protein levels inside a cell and increases yield of production of recombinatant proteins, when inserted. In particular, the inventors have identified a specific gene *aad*A1 (adenyltransferase gene) that codes for a 28.876 Kd protein that normally confers aminoglycoside resistance to cells. Further, the inventors have found that a ''gene cassette'' carrying the *aad*A1 gene which when transferred to bacterial strains induces enhancement of protein production and accumulation. Additionally, this inducement is not restricted by the nature of the vector, induction system or nature of protein. In short, the invention provides a method of reconstruction of a cell for increased yield of recombinant protein, which involves a ''one-step procedure of induction of a new gene into the cell.'' Therefore, the technology may have a substantial commercial value to the pharmaceutical industry.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Endothelial Protective Actions of Cytochrome P450 Epoxygenase-derived Eicosanoids

Darryl C. Zeldin (NIEHS), *et al.*

U.S. Patent Application No. 09/634,369 filed 09 Aug 2000, notice of allowance issued (DHHS Reference No. E–252–1999/0–US–02).

Licensing Contact: Marlene Shinn-Astor; (301) 435–4426; *shinnm@mail.nih.gov.*

Cytochrome P450s catalyze the NADPH-dependent oxidation of arachidonic acid to various eicosanoids found in several species including humans. The eicosanoids are biosynthesized in numerous tissues including pancreas, intestine, kidney, heart, and lung where they are involved in many different biological activities.

The NIH announces a new therapy wherein epoxyeicosatrienoic acid (EET) compositions have been found to be useful in preventing endothelial cell death due to hypoxia-reoxygenation. Given that endothelial injury is an important early event in the development of the atherosclerotic plaque and is associated with myocardial dysfunction in ischemic heart disease, reduced EET levels are speculated to be involved in the pathogenesis of these cardiovascular disorders.

This research is described in *Yang et al.,* Molecular Pharmacology 60: 310–320, 2001.

T-Cell Receptor Alternate Reading Frame Protein, (TARP) and Uses Thereof

Ira Pastan, Magnus Essand, Byungkook Lee, George Vasmatzis, Ulrich Brinkman, Paul Duray, and Curt Wolfgang (NCI).

U.S. Patent Application No. 10/031,158 filed 11 Jan 2002, and multiple National Stage foreign filings (DHHS Reference No. E–104–1999/2).

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

This invention relates to a tumor-associated protein, TARP, which is expressed in breast and prostate cancer cells. This antigen target might be a useful tool for the diagnosis and treatment of breast and prostate cancer. TARP has shown efficacy in vivo as a potential therapeutic for the treatment of cancer. TARP has been the subject of several publications, including: J. Biol. Chem. (2004 Jun 4) 279(23):24561–24568, Epub 2004 Mar 29 as doi:10.1074/jbc.M402492200; Cancer Res. (2004 Apr 1) 64(7):2610–2618; Endocrinology (2003 Aug) 144(8):3433–40; Cancer Res. (2001 Nov 15) 61(22):8122–8126; Proc. Natl. Acad. Sci. USA (2000 Aug 15) 97(17):9437–9442.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Method for Reducing the Immunogenicity of Antibody Variable Domains

Eduardo Padlan (NIDDK) *et al.*

U.S. Patent No. 6,797,492 issued 28 Sep 2004 (DHHS Ref. No. E–163–1991/2–US–02)

Licensing Contact: Jeff Walenta; (301) 435–4633; *walentaj@mail.nih.gov.*

The current invention addresses a limitation of monoclonal antibodies used in immunotherapy. Monoclonal antibodies with high selectivity for human antigens are commonly produced in mice. However, when introduced into humans for therapy, the antibodies can be neutralized by the human immune system and their duration and effectiveness limited. Modification of non-human antibodies to avoid the human immune system often produces antibodies with reduced affinity for the antigen and which remain antigenic in humans.

The current invention provides a method for producing ''humanized'' antibodies that retain antigen binding properties but which have eliminated or reduced antigenicity. The method comprises substituting residues in the variable region of the non-human antibody with residues found in the variable region of human antibodies, with particular emphasis on residues that are solvent exposed and that are not adjacent to complementarity determining regions.

When tested in monkeys, the serum longevity of the ''veneered'' antibodies produced by the current invention was significantly greater than that of mouse antibodies or chimeric mouse-human antibodies. Accordingly, the technology could enhance the effectiveness of monoclonal antibodies designed for therapy of cancer or other diseases.

Dated: March 25, 2005.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–6896 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, Loan Repayment Program Applications.

Date: April 18, 2005.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate loan Repayment applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Anne Schaffner, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892–9300, (301) 451–2020, *aes@nei.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 31, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6873 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, Visual Screening in Preschoolers (U10).

Date: April 11, 2005.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Samuel Rawlings, PhD, Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892–9300, 301–451–2020.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 31, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6877 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of 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 a meeting of the National Advisory Council for Human Genome Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.

Date: May 23–24, 2005.

Open: May 23, 2005, 8:30 a.m. to 12 p.m.

Agenda: Discuss matters of program relevance.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Closed: May 23, 2005, 1 p.m. to 5 p.m. on May 24, 2005.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Mark S. Guyer, PhD, Director for Extramural Research, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9305, Bethesda, MD 20892, 301–496–7531, *guyerm@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.genome.gov/11509849,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: March 30, 2005.

La Verne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6886 Filed 4–6–05; 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 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 a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: May 20, 2005.

Open: 8:30 a.m. to 11:30 a.m.

Agenda: Staff reports on divisional, programmatic and special activities.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: 11:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, PhD, Director, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892–7180, 301–496–8693, *jordanc@nidcd.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the

name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: *http://www.nidcd.nih.gov/about/councils/ndcdac/ndcdac.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: March 30, 2005.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6870 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel. P01's for AIDS: GI and Nutrition.

Date: April 21, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Hotel, 1743 West Nursery Road, Baltimore, MD 21240.

Contact Person: Dan E. Matsumoto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 749, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–5452, (301) 594–8894, *matsumotod@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6871 Filed 4–6–05; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, ZAA1 HH (34)—R01 Application Review.

Date: April 21, 2005.

Time: 12 to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Fishers Building, 5635 Fishers Lane, Room 3043, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lorraine Gunzerath, PhD., Scientific Review Administrator, National Institute on Alcohol Abuse and Alcoholism, Office of Extramural Activities, Extramural Project Review Branch, 5635 Fishers Lane, Room 3043, Bethesda, MD 20892–9304, 301–443–2369, *lgunzera@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue 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, HHS)

Dated: March 31, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6872 Filed 4–6–05; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(5), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel ZAA1 CC (33)—L30 and L40 Applications—Loan Repayment Program.

Date: April 13, 2005.

Time: 2 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Fishers Building, 5635 Fishers Lane, Room 3037, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mahadev Murthy, PhD, MBA, Scientific Review Administrator, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, MSC 9304, Room 3037, Bethesda, MD 20892–9304, (301) 443–8000, *mmurthy@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue 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, HHS)

Dated: March 31, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6874 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Centers of Excellence in Molecular Hematology.

Date: April 20–21, 2005.

Time: 7:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: John F. Connaughton, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 757, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797, *connaughtonj@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 31, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6875 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel Cultural and Cognitive Processes in Great Apes.

Date: April 29, 2005.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavillion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892, (301) 435–6911. *hopmannm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.684, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: , 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6876 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of 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 a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: May 12–13, 2005.

Closed: May 12, 2005, 10:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Open: May 12, 2005, 4 p.m. to 5 p.m.

Agenda: Discussion on NIMH program and policy issues.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Open: May 13, 2005, 8:30 a.m. to 12:30 p.m.

Agenda: Presentation of NIMH Director's report and discussion of NIMH program and policy issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6C10, Bethesda, MD 20892.

Contact Person: Jane A. Steinberg, PhD, Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–5047.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of any organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address,

telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page at: *http://www.nimh.nih.gov/council/advis.cfm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6880 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Studies in NeuroAIDS.

Date: April 20, 2005.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Andrea Sawczuk, DDS, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, 6001 Executive Boulevard, Room #3208, Bethesda, MD 20892, 301–496–0660, *sawczuka@ninds.nih.gov*.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Neurodevelopment Studies.

Date: April 21, 2005.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Andrea Sawczuk, DDS, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, 6001 Executive Boulevard, Room #3208, Bethesda, MD 20892, 301–496–0660, *sawczuka@ninds.nih.gov*.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Parkinson's.

Date: April 25–26, 2005.

Time: 7:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Katherine Woodbury, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd, Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–5980, *kw47o@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6881 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Specialized Neuroscience Research Program Review.

Date: April 17–19, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Springhill Suites Marriott Fairbanks, 575 First Avenue, Fairbanks, AK 99701.

Contact Person: Phillip F. Wiethorn, Scientific Review Administrator, DHHS/NIH/NINDS/DER/SRB, 6001 Executive Boulevard; MSC 9529, Neuroscience Center; Room 3203, Bethesda, MD 20892–9529, (301) 496–5388, *wiethorp@ninds.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: March 30, 2005

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6882 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commerical property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 05–41, Review Extramural Loan Repayment Applications.

Date: April 28, 2005.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mary Kelly, Scientific Review Specialist, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Bldg., Rm. 4AN44, Bethesda, MD 20892–6402, (301) 594–4809, *mary_kelly@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6883 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of 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 a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Aging, including consideration of personnel qualifications and performance, and the competence of individuals investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.

Date: May 17–18, 2005.

Closed: May 17, 2005, 8 a.m. to 9 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Open: May 17, 2005, 9 a.m. to 11:30 a.m.

Agenda: Committee Discussion.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Closed: May 17, 2005, 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Open: May 17, 2005, 12:30 p.m. to 2:30 p.m.

Agenda: Committee Discussion.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Closed: May 17, 2005, 2:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Open: May 17, 2005, 3:30 p.m. to 5:30 p.m.

Agenda: Committee Discussion.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Closed: May 17, 2005, 5:30 p.m. to 6 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Closed: May 18, 2005, 8 a.m. to 8:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Open: May 18, 2005, 8:30 a.m. to 11 a.m.

Agenda: Committee Discussion.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Closed: May 18, 2005, 11 a.m. to 12 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute of Aging, Gerontology Research Center, 5600 Nathan Shock Drive, Baltimore, MD 21224.

Contact Person: Dan L. Longo, MD, Scientific Director, National Institute of Aging, Gerontology Research Center, National Institutes of Health, 5600 Nathan Shock Drive, Baltimore, MD 21224–6825, 410–558–8110, *dl14q@nia.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6884 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets of commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Preschool Curricula: Outcomes and Developmental Processes.

Date: April 25, 2005.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marita R. Hopmann, PhD., Scientific Review Administrator, Division of Scientific Review, National Institutes of Child Health and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892, (301) 435–6911, *hopmannm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6885 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Bioengineering Applications.

Date: April 21, 2005.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Anne Krey, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, MD 20892, 301–435–6908.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6887 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, HLA Region Genetics in Immune-Mediated Diseases.

Date: April 21–22, 2005.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Sujata Vijh, PhD, Scientific Review Administrator, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–594–0985, *vijhs@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6888 Filed 4–6–05; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, ZAA1 CC (31)—RFA—AA—05—002 Initiative for Alcohol Sensing and Data Analysis System (SBIR).

Date: May 13, 2005.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mahadev Murthy, PhD, MBA, Scientific Review Administrator, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, MSC 9304, Room 3037, Bethesda, MD 20892–9304, (301) 443–0800, *mmurthy@mail.nih.gov.*

(Catalogue 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, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6889 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Medical Writing, Report Preparation, and Project Management.

Date: May 24, 2005.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1439, *lf33c.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Regulatory Affairs Support.

Date: June 7, 2005.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1439, *If33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6890 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, SBIR Phase II—''Automation Delineation and Quantification of WMSH''.

Date: May 26, 2005.

Time: 9 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1439, *If33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards, 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6891 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel NIDA–K Conflict Meeting.

Date: April 21, 2005.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Eliane Lazar-Wesley, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, 301–451–4530.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6892 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Partnerships for Topical Microbicides.

Date: April 6, 2005.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Hagit S. David, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 402–4596, *hdavid@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 29, 2005.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6893 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors, National Library of Medicine, May 12, 2005, 9 a.m. to May 13, 2005, 5 p.m., National Library of Medicine, Building 38, 2nd Floor, Board

Room, 8600 Rockville Pike, Bethesda, MD 20892 which was published in the **Federal Register** on March 16, 2005, 70 FR 12891.

Date and times of the meeting are changed due to scheduling conflicts. The date has been changed to May 5–6, 2005, with both days beginning at 8:30 a.m., with adjournment of 6 p.m. on May 5, and 12:30 p.m. on May 6. The meeting is partially Closed to the Public.

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6879 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Minority/Disability Predoctoral Fellowship.

Date: April 4, 2005.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Seetha Bhagavan, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3022D, MSC 7846, Bethesda, MD 20892, (301) 435–1211, *bhagavas@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Pathogenesis and Therapy of AIDS.

Date: April 5, 2005.

Time: 11 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mary Clare Walker, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 BDCN–F–13 Pharmacology and Diagnostics for Neuropsychiatric Disorders.

Date: April 7, 2005.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jerome R. Wujek, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 435–2507, *wujekjer@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Neurodegeneration and Myelination.

Date: April 8, 2005.

Time: 1 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Toby Behar, PhD, Scientific Review Administration, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435–4433, *behart@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Bioinformatics Data Management System.

Date: April 14, 2005.

Time: 2:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sally Ann Amero, PhD Scientific Review Administration, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7849, Bethesda, MD 20892, (301) 435–1159, *ameros@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Transcriptional Regulation of Human Angiotensin Receptor.

Date: April 27, 2005.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anshumali Chaudhari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, *chaudhaa@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6878 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 MDCN–F03.

Date: April 5, 2005.

Time: 5 p.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joanne T Fujii, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5204, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Viral Gene Delivery Special Emphasis Panel.

Date: April 5, 2005.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Steven J. Zullo, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7849, Bethesda, MD 20892, (301) 435–2810, *zullost@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Enzyme Function.

Date: April 11, 2005.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: George W. Chacko, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC 7849, Bethesda, MD 20892, (301) 435–1220, *chackoge@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Immune Responses to Parasites.

Date: April 12, 2005.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joanna M. Pyper, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435–1151, *pyperj@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cancer Prevention.

Date: April 12, 2005.

Time: 11 a.m. to 12 p.m. (noon).

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sally A. Mulhern, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, MSC 7804, Bethesda, MD 20892, (301) 435–5877, *mulherns@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Tumor Suppressor in Pediatric Tumors.

Date: April 13, 2005.

Time: 8 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, (301) 435–1779, *riverase@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel ZRG1 MDCN–F 02.

Date: April 13, 2005.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joanne T Fujii, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5204, MSC 7850, Bethesda, MD 20892, (301) 435–1778, *fujiij@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Receptor Studies—A.

Date: April 13, 2005.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michael A. Lang, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7850, Bethesda, MD 20892, (301) 435–1265, *langm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Neuronal Signaling and Development.

Date: April 15, 2005.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Syed Husain, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7850, Bethesda, MD 20892, (301) 435–1224, *husains@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Receptor Studies–B.

Date: April 19, 2005.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michael A. Lang, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7850, Bethesda, MD 20892, (301) 435–1265, *langm@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 30, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6894 Filed 4–6–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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 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 collection techniques or other forms of information technology.

Proposed Project: Targeted Capacity Expansion Grants for Jail Diversion Program Evaluation—In Use Without Approval

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) has implemented the Targeted Capacity Expansion Grants for Jail Diversion Programs. CMHS has developed a set of client outcome measures that will be collected over the length of the program.

Each jail diversion program participant has been approached to request their consent for participation. The main components of the baseline, 6- and 12-month interviews are Government Performance and Results Act (GPRA) measures. In addition to GPRA measures, the interviews include the following measures:

- DC Trauma Collaboration Study Violence and Trauma Screening to gauge traumatic events in the past year and lifetime (Baseline only)
- Colorado Symptom Index 1991 to gauge symptoms of mental illness (All interviews)
- Perceived Coercion Scale (from MacArthur Mandated Community Treatment Survey) to enter jail diversion programs (Baseline only)
- Mental Health Statistics Improvement Program quality of life measures (6 and 12 months only)
- Service use (6 and 12 months only)

In addition to data collected through interviews, grantees will collect the following information and will report it to the Technical Assistance and Policy Analysis (TAPA) Center:

- *Events Tracking:* This program captures the volume of activities (''events'') that jail diversion programs engage in to determine whom the program will serve.
- *Person Tracking:* This program is designed to record basic information on all individuals who are diverted and served with grant funds. It also helps grantees keep track of interview dates for those program participants who agree to take part in the evaluation.
- *Service Use:* Grantees collect self-reported data on services provided or information from official sources, such as statewide/agency management information systems or other agency records about the types of services received following diversion. This data must be provided to the TAPA Center.
- *Arrest and Jail Days Data:* Grantees report arrest and jail days data collected from official sources, such as a statewide criminal justice database, or that have been tracked for themselves for one year prior and one year following diversion.

As mentioned above, grantees collect this data from official sources or self-report data from their programs and submit it to the TAPA Center. This data is reported to the technical assistance provider through an electronic database system or through paper copies. Resulting compiled data is used to provide information of interest to policy makers, researchers, and communities engaged in developing jail diversion programs.

The following table summarizes the burden for the data collection:

Data collection activity	Number of respondents	Responses per respondent	Average hours per response	Annual hour burden
Client Interviews:				
Baseline Interview	360	1	.75	270
6-month Interview	306	1	.75	230
12-month Interview	306	1	.75	230
Record Management:				
Events Tracking	4,500	2	.017	153
Person Tracking	400	1	.025	10
Service Use Data	306	1	.133	41
Arrest and Jail Days Data	306	1	.133	41
Total:	4,500			975

Send comments to Summer King, SAMHSA Reports Clearance Officer, OAS, Room 7–1044, 1 Choke Cherry Road, Rockville, MD 20857. Written comments should be received by June 6, 2005.

Dated: April 1, 2005.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 05–6908 Filed 4–6–05; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–20894]

National Maritime Security Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meetings.

SUMMARY: The National Maritime Security Advisory Committee (NMSAC) will hold a teleconference meeting on May 6, 2005 to receive reports from the Credentialing Work Group. The NMSAC will physically meet on June 2, 2005 to discuss various issues relating to national maritime security. This notice announces the date, time, and location for the teleconference meeting and the physical meeting of the NMSAC.

DATES: The NMSAC will meet via teleconference on Friday, May 6, 2005, from 10:30 a.m. to 12 p.m. The NMSAC will meet in-person on Thursday, June 2, 2005, from 9 a.m. to 5 p.m. Both meetings may close early if all business is completed before the scheduled time. Written material and requests to make oral presentations at the May 6 meeting should reach the Coast Guard on or before April 30, 2005. Written material and requests to make oral presentations at the June 2 meeting should reach the Coast Guard on or before May 23, 2005.

ADDRESSES: The NMSAC teleconference meeting will be held in room 6103, U.S. Coast Guard Headquarters, 2100 Second St., SW., Washington, DC. For the June

2 meeting, the NMSAC will meet in the Conference Center at the Sheraton Suites, Old Town, 801 North St. Asaph St., Alexandria, VA. Send written material and requests to make oral presentations to LCDR Bruce Walker, Commandant (G–MPS–2), U.S. Coast Guard Headquarters, 2100 Second St., SW., Washington, DC 20593–0001. This notice is available on the Internet by performing a simple search for the docket number at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: LCDR Bruce Walker, Assistant to the Executive Director, telephone 202–267–4148, fax 202–267–4130.

SUPPLEMENTARY INFORMATION:

Procedural

The May 6 teleconference meeting is open to the public. Please note that the meeting may close early if all business is finished. Security requires that any member of the public who wishes to attend the public session at Coast Guard Headquarters provide his or her name and date of birth no later than 4 p.m., e.s.t., Friday, April 29, 2005, to LCDR Bruce Walker e-mail at *BKWalker@comdt.uscg.mil*, or via phone at (202) 267–4148. Photo identification will be required for entry into the building, and everyone in attendance must be seated by 10:15 a.m.

The June 2 meeting is open to the public. Please note that the meeting may close early if all business is finished. Members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify the LCDR Bruce Walker at *BKWalker@comdt.uscg.mil*, or via phone at (202) 267–4148, no later than May 23, 2005. If you would like a copy of your written material distributed to each member of the Committee in advance of the meeting, please submit 25 copies of the material to LCDR Bruce Walker no later than May 23, 2005.

Notice of both meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2 (Pub. L. 92–463, 86 Stat. 770).

Agenda of May 6 Teleconference

The agenda includes the following:

(1) Receive report from the Credentialing Work Group

Agenda of June 2 Meeting

The agenda includes the following:

(1) Briefings by Department of Homeland Security officials on national maritime security issues.

(2) Old committee business.

(3) New committee business.

(4) Staff administration issues.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request special assistance at the meetings, contact LCDR Bruce Walker as soon as possible at the address or phone number listed under **FOR FURTHER INFORMATION CONTACT** section.

Dated: April 1, 2005.

F. J. Sturm,

Captain, U.S. Coast Guard, Chief, Office of Port and Vessel and Facility Security.

[FR Doc. 05–6953 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4977–N–01]

Notice of Proposed Information Collection for Public Comment on Life After Transitional Housing; Family Movement and Family Follow-Up Interviews

AGENCY: Office of Policy Development and Research, HUD.

SUMMARY: The proposed information collection requirement 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 Date:* June 6, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW., Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Paul B. Dornan, Department of Housing and Urban Development, Office of Policy Development and Research, 451 7th Street, SW., Room 8140, Washington, DC 20410; telephone (202) 708–0574, extension 4486 (this is not a toll-free number). Copies of the proposed data collection instruments and other available documents may be obtained from Mr. Dornan.

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: Life after Transitional Housing: Tracking Homeless Families after They Leave HUD-Assisted Transitional Housing.

Description of the need for the information and proposed use: The Department of Housing and Urban Development has spent over $7 billion of public funds supporting Transitional Housing for homeless individuals and families. There is little research, however, that focuses on what the impact of that substantial public investment has meant in the lives of homeless people. These interview protocols are structured to find out what happens to formerly homeless families once they leave HUD-assisted Transitional Housing and what the impact of Transitional Housing is on the lives of those families. One survey will be conducted at moveout, and the other one will be conducted at 3-, 6- and 12-month intervals after families leave the transitional housing.

Members of affected public: Members of the following group will be surveyed: The mother and one child of a sample of 300 families who have left HUD-assisted Transitional Housing.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: Approximately 300 families will be interviewed once upon leaving the Transitional Housing and three times thereafter, at 3-, 6- and 12-month intervals. 45 minutes is scheduled for the initial interview, and 30 minutes for each of the follow-up ones. The total respondent burden would be 675 hours if all respondents had all four interviews. 540 to 570 total hours is likely taking into account

attrition and the use of retrospective recruitment.

Status of the proposed information collection: Pending OMB approval.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 30, 2005.

Dennis C. Shea,

Assistant Secretary for Policy Development and Research.

[FR Doc. 05–6857 Filed 4–6–05; 8:45 am]

BILLING CODE 4210–62–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4971–N–19]

Notice of Submission of Proposed Information Collection to OMB; Loan Guarantee Recovery Fund Established Pursuant to the Church Arson Prevention Act of 1996

AGENCY: Office of the Chief Information Officer, HUD

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been 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.

Section 4 of the Church Arson Prevention Act of 1996 authorizes the Secretary to guarantee loans made to certain nonprofit organizations whose properties have been damaged by an act or acts of arson or terrorism.

DATES: *Comments Due Date:* May 9, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2506–0159) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; or Lillian Deitzer at *Lillian_L_Deitzer@HUD.gov* or telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins or Ms Deitzer and at HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm.*

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information collection described below. This notice is soliciting comments from members of the public and affecting 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: Loan Guarantee Recovery Fund established pursuant to the Church Arson Prevention Act of 1996.

Approval Number: 2506–0159.

Form Numbers: HUD–40076–LGA, SF–424.

Description of the Need for the Information and Its Proposed Use: Section 4 of the Church Arson Prevention Act of 1996 authorizes the Secretary to guarantee loans made to certain nonprofit organizations whose properties have been damaged by an act or acts of arson or terrorism.

Frequency of Submission: On occasion, monthly.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting burden	34	10.76		3.82		1,400

Total Estimated Burden Hours: 1,400.

Status: Extension of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: March 31, 2005.

Wayne Eddins,

Departmental Paperwork, Reduction Act Officer, Office of the Chief Information Officer.

[FR Doc. E5–1578 Filed 4–5–05; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

American Indian Probate Reform Act of 2004

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The American Indian Probate Reform Act requires us to develop an informational notice about the Act and its provisions. The Act also requires us to publish this notice in the **Federal Register**. This notice fulfills these requirements.

FOR FUTHER INFORMATION CONTACT: Eufrona Snyder, Special Assistant-Trust Management, Office of Trust Service, Bureau of Indian Affairs, Department of the Interior, 1849 C Street, NW., Washington, DC 20240, telephone number 202–208–3614.

SUPPLEMENTARY INFORMATION: As required by the American Indian Probate Reform Act of 2004, we have developed this notice and are publishing it today to inform interested members of the public. This notice is the same notice which has been mailed by direct mail to Indians with interests in trust and restricted lands and through local newspapers in areas with significant Indian populations, reservation newspapers, and newspapers directed to an Indian audience. Copies of the notice will be available from the regional agencies of the Bureau of Indian Affairs and the Office of the Special Trustee.

Dated: March 25, 2005.

Michael D. Olsen,

Acting Principal Deputy Assistant Secretary—Indian Affairs.

Introduction and Overview

The American Indian Probate Reform Act (AIPRA) of 2004 was enacted on October 27, 2004. The Act amends the Indian Land Consolidation Act and amendments made in 2000 and this notice replaces the notice provided in 2001. This Act affects your ownership rights in trust or restricted land, unless the land is located in Alaska. Most of the provisions do not take effect for one (1) year.

AIPRA changes the way trust estates are distributed to your heirs after your death. This increases the importance and benefits of writing a will or doing an estate plan. AIPRA also improves your ability to consolidate your interests in trust or restricted land.

Section 1: Property Distribution, Wills, and Estate Planning

The Act creates a new nation-wide probate code that changes how your trust property will be distributed among your heirs if you die without a will. Other changes include amended definitions of ''Indian'' and ''eligible heirs'' for purposes of inheriting in trust. The changes also provide opportunities for Indians or the tribe to purchase your interest in trust or restricted land at probate. In order to give you time to plan, the inheritance changes take effect after one (1) year. To help you understand some of the most important changes, you need to know what happens if you do not have a will or an estate plan.

Should You Write a Will?

The new law protects your rights as a property owner to transfer your property by will. By writing a will, you can designate how your trust land will be transferred in trust to any Indian person or to your descendants even if they are not tribal members. You can control how your trust property is passed by creating an estate plan, such as a will or deed.

There are also new provisions on wills. If you have already written a will, you should review it to make sure the will says what you currently want.

Who Can Receive Your Property at Death in Trust?

Without a Will:

- If you do not write a will, your trust property will pass under the new federal probate code or approved tribal probate code, rather than under the state laws that currently govern Indian probate. Your trust land will continue to be inherited by your immediate family—first to your children or grandchildren or possibly great grandchildren, and if you have none, then to your parents or brothers and sisters. All of these people will be eligible to inherit your trust property as long as each meets the definition of Indian below, or are your descendants within two generations of an Indian, or they already are co-owners in the same parcel. Land not passing to one of the people above will then pass to the tribe where the land is located.
- If you have a spouse and other eligible heirs, your surviving spouse will inherit ⅓ of any money in your IIM account at the time of your death, and all of the money produced from your interest in trust or restricted land during your spouse's lifetime. Your other heirs get the remaining ⅔ of any money in your IIM account at the time of death, and the remaining ownership interest in the trust or restricted land. Your spouse may also continue to live in a family home located on allotted land.
- If your spouse but no other eligible heirs survive you, the spouse gets your IIM account, and during the spouse's lifetime, the money produced from your land interest. The spouse may also continue to live in a family home located on allotted land. The remaining ownership interest in land goes to the tribe where the land is located.
- If you do not write a will and your ownership interest is less than 5% of the total, your spouse may continue to live in the family home on the parcel and then the new probate law will limit inheritance to the oldest eligible child, and then oldest eligible grandchild or oldest eligible great-grandchild.

Additionally, the Department of the Interior may purchase interests in land that are less than 5% of the total, for fair market value during the probate proceeding without the consent of the heirs. However, this authority to purchase small interests without the heirs' consent *does not apply if the interest is passing through a valid will,* or if the heirs were living on the land. Spouses living on a parcel also are protected.

With a Will:

- By writing a will, your land can be transferred in trust to any Indian person, the tribe that has jurisdiction, or any Indian co-owners. You can also transfer your land in trust to any of your descendants (children, grandchildren, great grandchildren, and great-great grandchildren) even if they are not Indian. You can control how your trust property is passed by creating an estate plan, such as a will or deed. You can transfer your interests out of trust to anybody.
- Even if your spouse is not mentioned in a will, your spouse may inherit some of your trust property.

Who May Inherit Land in Trust Under AIPRA?

There is an amended definition of Indian that helps determine who can inherit an interest in land in trust, particularly where there is no will. Under AIPRA, an ''Indian'' is a person who:

1. Is a member of an Indian tribe, or
2. Is eligible to become a member of an Indian tribe; or
3. Was an owner of an interest in trust or restricted land on October 27, 2004; or
4. Meets the definition of ''Indian'' under the Indian Reorganization Act, or
5. In California, any person as in 1, 2, 3, and 4, or who owns trust or restricted land in California.

This will not affect your eligibility for other federal Indian programs.

Your heirs who are not Indian may be able to inherit in trust if they meet the statutory requirements for ''eligible heirs.'' If you have heirs who are non-Indian, be sure to seek information at the toll-free number below or at your local agency office.

The provisions of AIPRA are complex. Be sure to seek information for any questions you may have.

Section 2: Consolidating Ownership Interests

One of the main purposes of the Act is to preserve the trust status and reduce the number of small, fractionated interests in Indian lands. The Act does this by providing individuals and tribes with more opportunities to consolidate fractionated interests and by removing some restrictions on what tribes and individuals can do with their lands.

What Is the Purchase Option at Probate?

Certain people can purchase your interest in the parcel during probate. Your heirs, other co-owners, and the tribe where the land is located will be able to purchase your interest in the parcel. The purchase price must equal or exceed the fair market value. Your heirs would receive the money paid for your interest in the parcel instead of a share of your interest in the parcel. If your heirs are to receive 5% interest or more in the parcel, or if they live on the parcel, your heirs' consent to the purchase is required.

What Are Consolidation Agreements?

Heirs can decide how they want the trust estate distributed at the probate

hearing. For example, they may decide whether they wish to inherit their share, or sell it to other co-owners or the tribe where the land is located. Heirs may also give their share to another named Indian person instead of inheriting it.

How Can A Person Acquire Other Fractionated Interests?

The Act contains a number of provisions that are important to Indian landowners. Some examples are:

- Land consolidation options for landowners;
- Partition by sale of Indian lands;
- Continuation and expansion of the federal ''buy back'' program; and
- Greater flexibility for landowners to consolidate and acquire interests during the probate process.

How Can You Transfer An Interest In Property During Your Lifetime?

Please seek information from your trust officer, your local BIA office or the toll free number below for information on estate planning options during your lifetime such as:

- Negotiated sales,
- Gift deeds,
- Land exchanges, and other transactions.

For more information about this notice or the Act, call 1–888–678–6836 x 888.

[FR Doc. 05–6946 Filed 4–6–05; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–100–05–1310–DB]

Notice of Meeting of the Pinedale Anticline Working Group's Transportation Task Group

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (1976) and the Federal Advisory Committee Act (1972), the U.S. Department of the Interior, Bureau of Land Management (BLM) Pinedale Anticline Working Group (PAWG) Transportation Task Group (subcommittee) will meet in Pinedale, Wyoming, for a business meeting. Task Group meetings are open to the public.

DATES: A PAWG Transportation Task Group meeting is scheduled for May 3, 2005, from 1 p.m. until 5 p.m.

ADDRESSES: The meeting of the PAWG Transportation Task Group will be held in the Board Room of the Pinedale Library at 155 S. Tyler Ave., Pinedale, WY.

FOR FURTHER INFORMATION CONTACT: Bill Wadsworth, BLM/Transportation TG Liaison, Bureau of Land Management, Pinedale Field Office, 432 E. Mills St., PO Box 738, Pinedale, WY 82941; 307–367–5341.

SUPPLEMENTARY INFORMATION: The Pinedale Anticline Working Group (PAWG) was authorized and established with release of the Record of Decision (ROD) for the Pinedale Anticline Oil and Gas Exploration and Development Project on July 27, 2000. The PAWG advises the BLM on the development and implementation of monitoring plans and adaptive management decisions as development of the Pinedale Anticline Natural Gas Field proceeds for the life of the field.

The agenda for this meeting is to refine the transportation monitoring plan submitted to the PAWG. At a minimum, public comments will be heard just prior to adjournment of the meeting.

Dated: March 30, 2005.

Roger L. Bankert,

Associate Field Office Manager.

[FR Doc. 05–6851 Filed 4–6–05; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

March 29, 2005.

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 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Bureau of Labor Statistics (BLS), Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), 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: Bureau of Labor Statistics.

Type of Review: Extension of a currently approved collection.

Title: Producer Price Index Survey.

OMB Number: 1220–0008.

Frequency: Monthly and Annually.

Type of Response: Reporting.

Affected Public: Business of other for-profit.

Number of Respondents: 35,388.

Form	Total annual responses	Average time per response (hours)	Estimated total annual burden hours
BLS 1810A, A1, B, C, C1, and E	6,888	2	13,776
BLS 473P	1,260,000	.30	378,000
Totals	1,266,888		391,776

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: The Producer Price Index, one of the Nation's leading economic indicators, is used as a measure of price movements, as an indicator of inflationary trends, for inventory valuation, and as a measure of purchasing power of the dollar at the primary market level. It is also used for market and economic research and as a basis for escalation in long-term contracts and purchase agreements.

Agency: Bureau of Labor Statistics.

Type of Review: Extension of a currently approved collection.

Title: Quarterly Census of Employment and Wages (QCEW).

OMB Number: 1220–0012.

Frequency: Quarterly.

Type of Response: Reporting.

Affected Public: State, Local, or Tribal Government.

Number of Respondents: 53.

Annual Responses: 212.

Average Response Time: 5,180.

Annual Burden Hours: 1,098,240.

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: QCEW data, which are provided to BLS by State Workforce Agencies, are used by BLS as a sampling frame for its establishment surveys; for publishing of accurate current estimates of employment for the U.S., States, and metropolitan areas; and publishing quarterly census totals of local establishment counts, employment and wages. The Bureau of Economic Analysis uses the data to produce accurate personal income data in a timely matter for the U.S., States, and local areas. Finally, the data is critical to the Employment Training Administration to administer employment insurance programs.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–6918 Filed 4–6–05; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

March 24, 2005.

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 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov*.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment Standards Administration (ESA), Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), 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.

Type of Review: Extension of currently approved collection.

Title: Pre-Hearing Statement.

OMB Number: 1215–0085.

Form Number: LS–18.

Frequency: On occasion.

Type of Response: Reporting.

Affected Public: Business and other for-profit and Individuals or households.

Number of Respondents: 5,400.

Annual Reponses: 5,400.

Average Response Time: 10 minutes.

Total Annual Burden Hours: 918.

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $2,221.

Description: The Office of Workers' Compensation Programs administers the Longshore and Harbor Workers' Compensation Act (the Act). The Act provides benefits to workers injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. Title 20, CFR 702.317 provides for the referral of claims under the Longshore Act for formal hearings. The LS–18 is used to refer cases to the Office of the Administrative Law Judges for formal hearings under the Act.

Agency: Employment Standards Administration.

Type of Review: Extension of currently approved collection.

Title: Claim for Continuance of Compensation.

OMB Number: 1215–0154.

Form Number: CA–12.

Frequency: Annually.

Type of Response: Reporting.

Affected Public: Individuals or households.

Number of Respondents: 5,450.

Annual Reponses: 5,450.

Average Response Time: 5 minutes.

Total Annual Burden Hours: 454.

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $2,017.

Description: The Office of Workers' Compensation Programs (OWCP) administers the Federal Employees' Compensation Act (FECA), 5 U.S.C. 8133. FECA provides that eligible dependents of deceased employees receive compensation benefits on account of the employee's death. The OWCP monitors death benefits for current marital status, potential for dual benefits, and other criteria for qualifying as a dependent under the law. The CA–12 is sent annually to beneficiaries in death cases to ensure that their status has not changed and that they remain entitled to benefits.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–6921 Filed 4–6–05; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

March 30, 2005.

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 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), 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: Occupational Safety and Health Administration.

Type of Review: Extension of currently approved collection.

Title: Design of Cave-in Protection Systems.

OMB Number: 1218–0137.

Frequency: On occasion.

Type of Response: Recordkeeping.

Affected Public: Business or other for-profit.

Number of Respondents: 20,000.

Number of Annual Responses: 20,000.

Estimated Time Per Response: 2.08 hours.

Total Burden Hours: 20,222.

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $721,000.

Description: The requirements in 29 CFR 1926.652 for the design of cave-in protection systems are needed by employers in the construction industry and OSHA compliance officers to ensure that cave-in protection systems are designed, installed, and used in a manner to adequately protect employees.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension of currently approved collection.

Title: Methylene Chloride (29 CFR 1910.1052).

OMB Number: 1218–0179.

Frequency: On occasion; Quarterly; Semi-annually; and Annually.

Type of Response: Recordkeeping and Third party disclosure.

Affected Public: Business or other for-profit; Federal Government; and State, Local, or Tribal Government.

Number of Respondents: 88,623.

Number of Annual Responses: 274,090.

Estimated Time Per Response: Varies from 1 hour for administering a medical examination to 5 minutes to maintain an employee's medical or exposure record.

Total Burden Hours: 64,305.

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $15,942,530.

Description: The information-collection requirements specified in the Methylene Chloride Standard (29 CFR 1910.1052) protect employees from the adverse health effects that may result from their exposure to methylene chloride (MC). The requirements in the MC Standard include employee exposure monitoring, notifying employees of their MC exposures, administering medical examinations to employees, providing examining physicians with specific program and employee information, ensuring that employees receive a copy of their medical examination results, training employees on the hazards of MC, maintaining employees' exposure-monitoring and medical examination records for specific periods, and providing access to these records by OSHA, the National Institute of Occupational Safety and Health, the affected employees, and their authorized representatives.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–6922 Filed 4–6–05; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

March 30, 2005.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by contacting Ira Mills on 202–693–4122 (this is not a toll-free number) or e-mail: *mills-ira@dol.gov*.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ETA, Office of Management and Budget, Room 10235, Washington, DC 20503 (202–395–7316), within 30 days from the data 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 and Training Administration.

Type of Review: Extension.

Title: One-Stop Workforce Information Grant Plan and Annual Performance Report.

OMB Number: 1205–0417.

Affected Public: State Local or Tribal government; Federal Government.

Type of Response: Reporting.

Frequency: Annual.

Activity	Respondents	Responses per year	Total responses	Hours per response	Total burden hours
Annual Plan	54	1	54	42	2,268
Customer Satisfaction	54	1	54	292	15,768
Annual Report	54	1	54	39	2,106
Respondents Burden	54	1	54	204	11,016
Totals			216		31,158

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: The Department of Labor is requesting OMB approval to extend the collection of annual grant plan narratives and annual performance reports as requirements for receiving Workforce Information core products and services reimbursable grants.

Ira L. Mills,

Departmental Clearance Officer/Team Leader.

[FR Doc. 05–6923 Filed 4–6–05; 8:45 am]

BILLING CODE 4510–30–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency proposes to request extension of three currently approved information collections. The first is used by individuals applying for a research card which is needed to use original archival records in a National Archives and Records Administration facility. The second is used in issuing a building pass to National Archives and Records Administration volunteers and employees of NARA contractors so that they can enter NARA facilities to perform their duties. The third is used by individuals who wish to volunteer at the National Archives Building, the National Archives at College Park, regional records services facilities, and Presidential Libraries. The public is invited to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before June 6, 2005, to be assured of consideration.

ADDRESSES: Comments should be sent to: Paperwork Reduction Act Comments (NHP), Room 4400, National Archives and Records Administration, 8601 Adelphi Rd, College Park, MD 20740–6001; or faxed to 301–837–3213; or electronically mailed to *tamee.fechhelm@nara.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collection and supporting statement should be directed to Tamee Fechhelm at telephone number 301–837–1694, or fax number 301–837–3213.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collections are necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collections; (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 the use of information technology; and (e) whether small businesses are affected by these collections. The comments that are submitted will be summarized and included in the NARA request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this notice, NARA is soliciting comments concerning the following information collection:

1. *Title:* Researcher Application.

OMB Number: 3095–0016.

Agency Form Number: NA Form 14003.

Type of Review: Regular.

Affected Public: Individuals or households, Business or other for-profit, Not-for-profit institutions, Federal, State, local or tribal government.

Estimated Number of Respondents: 22,728.

Estimated Time Per Response: 8 minutes.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 3,030 hours.

Abstract: The information collection is prescribed by 36 CFR 1254.6. The collection is an application for a research card. Respondents are individuals who wish to use original archival records in a NARA facility. NARA uses the information to screen individuals, to identify which types of records they should use, and to allow further contact.

2. *Title:* Request for and Record of Pass.

OMB Number: 3095–0026.

Agency Form Number: NA Form 6006.

Type of Review: Regular.

Affected Public: Individuals or households, business or other for-profit organizations and institutions, and Federal government.

Estimated Number of Respondents: 2,000.

Estimated Time Per Response: 3 minutes.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 100 hours.

Abstract: The collection of information is necessary as a security measure to protect employees, information, and property in NARA facilities and to facilitate the issuance of passes. Use of the form is authorized by 44 U.S.C. 2104. Respondents who are contractors are given a building pass which expires at the end of each fiscal year; those who are volunteers are given a pass valid for 2 years. At the NARA College Park facility, individuals receive an access card with the pass that is electronically coded to permit access to secure zones ranging from a general nominal level to stricter access levels for classified records zones. The access card system is part of the security management system which meets the accreditation standards of the Government intelligence agencies for storage of classified information, and serves to comply with E.O. 12958.

3. *Title:* Volunteer Service Application Form.

OMB Number: 3095–0060.

Agency Form Number: NA Form 6045.

Type of Review: Regular.

Affected Public: Individuals or households.

Estimated Number of Respondents: 2,300.

Estimated Time Per Response: 15 minutes.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 575 hours.

Abstract: NARA uses volunteer resources to enhance its services to the public and to further its mission of providing ready access to essential evidence. Volunteers assist in outreach and public programs and provide technical and research support for administrative, archival, library, and curatorial staff. NARA needs a standard way to recruit volunteers and assess the qualifications of potential volunteers. The NA Form 6045, Volunteer Service Application Form, will be used by members of the public to signal their interest in being a NARA volunteer and to identify their qualifications for this work.

Dated: April 1, 2005.

Shelly L. Myers,

Deputy Chief Information Officer.

[FR Doc. 05–6899 Filed 4–6–05; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–3098]

Notice of Issuance of Construction Authorization to Duke Cogema Stone & Webster, Charlotte, NC

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance of construction authorization.

FOR FURTHER INFORMATION CONTACT: David Brown, Sr. Project Manager, Special Projects Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Rockville, MD, 20852. Telephone: (301) 415–5257; fax number: (301) 415–5370; e-mail: *DDB@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

Notice is hereby given that, pursuant to 10 CFR 70.23(a)(7) and (b), the Nuclear Regulatory Commission (the Commission) has issued Construction Authorization No. CAMOX–001 to Duke Cogema Stone & Webster (the applicant) for construction of a plutonium processing and fuel fabrication plant. The plant will be located on the Department of Energy's Savannah River Site near Aiken, South Carolina, and will be known as the Mixed Oxide Fuel Fabrication Facility.

The Commission has made appropriate findings as required by the Atomic Energy Act of 1954, as amended (the Act), the Commission's rules and regulations, and by the requirements of Section 102(2)(A) and (C) of the National Environmental Policy Act (NEPA), as set forth in Construction Authorization No. CAMOX–001 (CA).

II. Further Information

The CA is effective as of its date of issuance. For further details see Construction Authorization No. CAMOX–001 (ADAMS Accession No. ML050660392) and the Office of Nuclear Material Safety and Safeguards' Final Safety Evaluation Report (NUREG–1821) dated March 2005 (ADAMS Accession No. ML050660399). The Final Safety Evaluation Report relies, in part, on information provided in the applicant's construction authorization request dated October 31, 2002 (as subsequently revised). The results of the staff's environmental review are contained in NUREG–1767, ''Environmental Impact Statement on the Construction and Operation of a Proposed Mixed Oxide Fuel Fabrication Facility at the Savannah River Site, South Carolina,'' dated January 2005 (ML050240233, ML050240250). On October 25, 2004, the NRC suspended public access to the ADAMS online library and some other parts of its Web site to review documents and remove any that could reasonably be expected to aid a potential terrorist. Related to this effort, the NRC is withholding some records which are deemed to contain sensitive information under 10 CFR 2.390. Publicly available records may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agency-wide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room, and on the Internet at the NRC Web site, *http://www.nrc.gov/NRC/ADAMS/index.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC Public Document Room Reference staff by telephone at 1–800–397–4209, 301–415–4737, or by e-mail to pdr@nrc.gov.

Dated at Rockville, Maryland, this 1st day of April, 2005.

For the Nuclear Regulatory Commission.

Brian W. Smith,

Acting Branch Chief, Special Projects Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. E5–1596 Filed 4–6–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–3]

Notice of Issuance of Renewed Materials License SNM–2502; Progress Energy Carolinas, Incorporated; H. B. Robinson Steam Electric Plant, Unit 2 Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance of license renewal.

FOR FURTHER INFORMATION CONTACT: Christopher M. Regan, Senior Project Manager, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415–1179; fax number: (301) 415–8555; e-mail: *cmr1@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC or the Commission) has issued renewed Materials License SNM–2502 to Progress Energy Carolinas, Incorporated (PEC) for the receipt, possession, transfer, and storage of spent fuel at the H. B. Robinson Steam Electric Plant, Unit 2 (HBRSEP), Independent Spent Fuel Storage Installation (ISFSI), located in Darlington County, South Carolina. The renewed license authorizes operation of the HBRSEP ISFSI in accordance with the provisions of the renewed license and its Technical Specifications.

II. Background

By application dated February 27, 2004, PEC requested to renew the operating license for the HBRSEP ISFSI. PEC requested the renewal of the original ISFSI license for a renewal period of 20 years, and an exemption for an additional 20 years.

III. Finding

The application for the renewed license complies with the standards and requirements of the Atomic Energy Act of 1954 (the Act) , as amended, and the Commission's regulations. The Commission has made appropriate

findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter 1, which are set forth in the license. In addition, in accordance with 10 CFR 72.7, the Commission has determined that the exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest. Public notice of the proposed action and opportunity for hearing regarding the proposed issuance of the renewed license was published in the **Federal Register** on April 15, 2004 (69 FR 20073).

FOR FURTHER INFORMATION CONTACT: Supporting documentation is available for inspection at NRC's Public Electronic Reading Room at: *http://www.nrc.gov/reading-rm/ADAMS.html*. A copy of the license application, dated February 27, 2004, and the staff's Environmental Assessment, dated March 2005, can be found at this site using the Agency Document And Management System (ADAMS) accession numbers ML040690774 and ML050700137.

Dated in Rockville, Maryland, this 30th day of March, 2005.

For the Nuclear Regulatory Commission.

Christopher M. Regan,

Senior Project Manager, Licensing Section, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. E5–1595 Filed 4–6–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Workshop To Discuss What Is or Is Not Material to the Completion of Inspections, Tests, and Acceptance Criteria (ITAAC)

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of public workshop.

SUMMARY: The NRC needs to establish the basis for categorizing NRC inspection results during new reactor construction under 10 CFR part 52. In order to meet that goal, the NRC is holding a workshop to explore stakeholder views on what types of NRC inspection results could call into question the completion of the ITAAC for a particular certified reactor design.

SUPPLEMENTARY INFORMATION:

The Goal of the Workshop

The determination of whether a nuclear plant licensed under 10 CFR part 52 has been built in accordance with its design is dependent on the satisfactory completion by the licensee of all the related ITAAC. This workshop is for the NRC to understand stakeholder views on why various NRC inspection results may or may not be material to the successful completion of ITAAC. Being ''material to an ITAAC'' means the satisfactory completion of an ITAAC may be called into question. The labels and groupings previously used to describe NRC construction inspection results may no longer be applicable. The NRC believes it should listen to and understand the views of all stakeholders before reaching a decision on the need for any new groupings and labels to describe NRC construction inspection results. The NRC has made the examples to be discussed during the workshop available electronically at the Commission's Public Document Room in Rockville, Maryland or from the Publicly Available Records (PARS) component Agencywide Document Access and Management System (ADAMS) (Accession ML050870507). ADAMS can be accessed via the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* (the public electronic reading room). All participants are encouraged to review the examples before the workshop and come prepared to discuss their own points of view.

Some of the potential topics for discussion could include the following:

- Various interpretations of the examples.
- The groupings of the examples based on materiality to ITAAC completion.
- The need for additional examples in order to capture all possible groupings.
- What makes a particular example material to ITAAC.
- The possible actions of both the NRC and a licensee for each grouping.

Workshop Information

DATES: May 4, 2005, from 8:30 a.m. to 3:30 p.m.

Location: U.S. Nuclear Regulatory Commission, Two White Flint North Auditorium on Rockville Pike in Rockville, Maryland. All visitors should enter through the Two White Flint main entrance. No parking is available at the NRC headquarters. The NRC is located across from the White Flint Metro Station on the Red Line.

Registration: Individuals planning to attend the workshop are asked to pre-register for the workshop at e-mail address—*CIPWorkshop@NRC.gov.* Please provide the following information when pre-registering: Name; organization; country; and phone number or e-mail address.

Agenda: The workshop activities will consist of an introduction and discussion of anticipated workshop outcomes; assignment of participants into work teams; work team discussion of and deliberation on construction inspection examples for materiality to ITAAC; and group discussion of work team results.

FOR FURTHER INFORMATION CONTACT: Mary Ann M. Ashley, Team Leader, Construction Inspection Program, Inspection Program Branch, Mail Stop O–7H4, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001. Ms. Ashley can be reached at (301) 415–1073 or by e-mail at *mab@nrc.gov.*

Dated in Rockville, Maryland, this 30th day of March, 2005.

For the Nuclear Regulatory Commission.

Stuart A. Richards,

Chief, Inspection Program Branch, Division of Inspection Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. E5–1598 Filed 4–6–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Nuclear Waste; Notice of Meeting

The Advisory Committee on Nuclear Waste (ACNW) will hold its 159th meeting on April 18–19, 2005, Room T–2B3, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Wednesday, December 8, 2004 (69 FR 71084).

The schedule for this meeting is as follows:

Monday, April 18, 2005

10:30 a.m.–10:40 a.m.: Opening Statement (Open)—The ACNW Chairman will make opening remarks regarding the conduct of today's sessions.

10:40 a.m.–12 noon: Preparation of ACNW Reports (Open)—The Committee will discuss potential letter reports on Ground Water Recharge Model Abstraction and Validation, and Time-Period of Compliance for a Proposed High-Level Waste Geologic Repository. Other potential letter reports may be discussed.

1:30 p.m.–3:30 p.m.: NMSS Division Directors' Quarterly Program Update (Open)—The NMSS Division Directors will brief the Committee on recent activities of interest within their respective programs.

3:45 p.m.–4:45 p.m.: ACNW White Paper on Low-Level Radioactive Waste (Open)—The Committee will comment on the draft outline for the proposed White Paper. In addition, the Committee will discuss progress on specific sections of this White Paper, for example Section 1, ''Origins and History.''

4:45 p.m.–5:30 p.m.: Discussion of April 14–15, 2005, Visit to the Center for Nuclear Waste Regulatory Analyses (CNWRA) (Open)—An ACNW Subcommittee will report on the outcome of its recent visit to the CNWRA to review ongoing technical assistance work for NMSS' HLW programs.

Tuesday, April 19, 2005

8:30 a.m.–8:40 a.m.: Opening Remarks by the ACNW Chairman (Open)—The ACNW Chairman will begin the meeting with brief opening remarks, outline the topics to be discussed, and indicate items of interest.

8:40 a.m.–9:40 a.m.: National Source Tracking System (Open)—The Committee will receive a briefing by and hold discussions with representatives of the NMSS staff regarding the current rulemaking efforts regarding the National Source Tracking System.

9:40 a.m.–11:40 a.m.: Department of Energy (DOE) Repository Design (Open)—The Committee will be briefed by representatives from the U.S. Department of Energy on the status of the design of the proposed geologic repository at Yucca Mountain, Nevada.

1 p.m.–2 p.m.: Transportation Aspects of the Yucca Mountain Environmental Impact Statement (EIS) Update (Open)—The Committee will hear a briefing by and hold discussions with representatives of DOE regarding the updates to the Yucca Mountain final EIS in light of the Department's specification of preferred transportation method and route for radioactive waste to the Yucca Mountain site.

2 p.m.–3:30 p.m.: Electric Power Research Institute (EPRI) Topical Report on Future System States (Open)—The Committee will be briefed on the conclusions and recommendations from EPRI's recently published report on the treatment of future system states in long time-frame performance assessments.

3:45 p.m.–4:30 p.m.: Japan Waste Management Visit (Open)—The ACNW members will discuss final preparation for their May 14–21, 2005, trip to visit nuclear waste facilities and regulators in Japan.

4:30 p.m.–5:30 p.m.: Discussion of Possible Letters (Open)—The Committee will discuss prepared letters and determine whether letters would be written on topics discussed during the meeting.

5:30 p.m.–6 p.m.: Miscellaneous (Open)—The Committee will discuss matters related to the conduct of ACNW activities, and specific issues that were not completed during previous meetings, as time and availability of information permit. Discussions may include future Committee Meetings.

Wednesday and Thursday, April 20–21, 2005: NRC Decommissioning Workshop

The workshop is being held as part of the NRC staff's initiatives to continually improve the licensing process for decommissioning sites and terminating NRC licenses in accordance with 10 CFR part 20, subpart E. The ACNW will attend this workshop as observers. For more information on the workshop or to register on-line, visit: *http://www.nrc.gov/public-involve/conference-symposia/decommissioning.html.*

Procedures for the conduct of and participation in ACNW meetings were published in the **Federal Register** on October 18, 2004 (69 FR 61416). In accordance with these procedures, oral or written statements may be presented by members of the public. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Persons desiring to make oral statements should notify Ms. Sharon A. Steele (telephone (301) 415–6805), between 7:30 a.m. and 4 p.m. e.t., as far in advance as practicable so that appropriate arrangements can be made to schedule the necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during this meeting will be limited to selected portions of the meeting as determined by the ACNW Chairman. Information regarding the time to be set aside for taking pictures may be obtained by contacting the ACNW office prior to the meeting. In view of the possibility that the schedule for ACNW meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should notify Ms. Steele as to their particular needs.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted, therefore can be obtained by contacting Ms. Steele.

ACNW meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room (PDR) at *pdr@nrc.gov*, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/* (ACRS & ACNW Mtg schedules/agendas).

Video Teleconferencing service is available for observing open sessions of ACNW meetings. Those wishing to use this service for observing ACNW meetings should contact Mr. Theron Brown, ACNW Audiovisual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m. ET, at least 10 days before the meeting to ensure the availability of this service.

Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated: April 1, 2005.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. E5–1597 Filed 4–6–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

DATE: Week of April 4, 2005.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of April 4, 2005

Monday, April 4, 2005

12:30 p.m. Discussion of Intergovernmental Issues (Closed—Ex. 9).

*The schedule for commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Dave Gamberoni, (301) 415–1651.

* * * * *

ADDITIONAL INFORMATION: By a vote of 5–0 on April 1, the Commission

determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that ''Discussion of Intergovernmental Issues (Closed—Ex. 9)'' be held April 4, and on less than one week's notice to the public.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify the NRC's Disability Program Coordinator, August Spector, at 301–415–7080, TDD: 301–415–2100, or by e-mail at *aks@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: April 4, 2005.

Dave Gamberoni,

Office of the Secretary.

[FR Doc. 05–6995 Filed 4–5–05; 9:25 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission; Office of Filings and Information Services; Washington, DC 20549.

Extension:

Rule 17d–1; SEC File No. 270–505; OMB Control No. 3235–0562.

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 (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget (''OMB'') for extension and approval.

Section 17(d) of the Investment Company Act of 1940 (the ''Act'') prohibits first- and second-tier affiliates of a fund, the fund's principal underwriters, and affiliated persons of the fund's principal underwriters, acting as principal, to effect any transaction in which the fund or a company controlled by the fund is a joint or a joint and several participant in contravention of the Commission's rules. Rule 17d–1 (''Applications regarding joint enterprises or arrangements and certain profit-sharing plans'' [17 CFR 270.17d–1]) permit a fund to enter into a joint arrangement with a portfolio affiliate (an issuer of which a fund owns a position in excess of five percent of the voting securities), or an affiliated person of a portfolio affiliate, as long as certain other affiliated persons of the fund (*e.g.*, the fund's adviser, persons controlling the fund, and persons under common control with the fund) are not parties to the transaction and do not have a financial interest in a party to the transaction.

Rule 17d–1 provides that, in addition to the interests identified in the rule not to be ''financial interests,'' the term ''financial interest'' also does not include any interest that the fund's board of directors (including a majority of the directors who are not interested persons of the fund) finds to be not material. The rule requires that the minutes of the board's meeting record the basis for the board's finding.

The information collection requirements in rule 17d–1 are intended to ensure that Commission staff can review, in the course of its compliance and examination functions, the basis for a board of director's finding that the financial interest of a prohibited participant in a party to a transaction with a portfolio affiliate is not material.

Based on analysis of past filings, the Commission's staff estimates that 148 funds are affiliated persons of 668 issuers as a result of the fund's ownership or control of the issuer's voting securities, and that there are approximately 1,000 such affiliate relationships. Staff discussions with mutual fund representatives have suggested that no funds are currently relying on rule 17d–1 exemptions. We do not know definitively the reasons for this change in transactional behavior, but differing market conditions from year to year may offer some explanation for the current lack of fund interest in the exemptions under rule 17d–1. Accordingly, we estimate that annually there will be no joint transactions under rule 17d–1 that will result in a collection of information.

The Commission requests authorization to maintain an inventory of one burden hour to ease future renewals of rule 17d–1 collection of information analysis should reliance on the rule increase in the coming years.

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 R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: March 29, 2005.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1583 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission; Office of Filings and Information Services; Washington, DC 20549.

Extension:

Rule 12d3–1; SEC File No. 270–504; OMB Control No. 3235–0561.

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 (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget (''OMB'') for extension and approval.

Section 12(d)(3) of the Act generally prohibits registered investment companies (''funds''), and companies controlled by funds, from purchasing securities issued by a registered investment adviser, broker, dealer, or underwriter (''securities-related businesses''). Rule 12d3–1 (''Exemption of acquisitions of securities issued by persons engaged in securities related businesses'' [17 CFR 270.12d3–1]) permits a fund to invest up to five percent of its assets in securities of an issuer deriving more than fifteen percent of its gross revenues from securities-related businesses, but a fund may not rely on rule 12d3–1 to acquire securities of its own investment adviser or any affiliated person of its own investment adviser.

A fund may, however, rely on an exemption in rule 12d3–1 to acquire securities issued by its subadvisers in circumstances in which the subadviser would have little ability to take advantage of the fund, because it is not in a position to direct the fund's securities purchases. The exemption in rule 12d3–1(c)(3) is available if (i) the subadviser is not, and is not an affiliated person of, an investment adviser that provides advice with respect to the portion of the fund that is acquiring the securities, and (ii) the advisory contracts of the subadviser, and any subadviser that is advising the purchasing portion of the fund, prohibit them from consulting with each other concerning securities transactions of the fund, and limit their responsibility in providing advice to providing advice with respect to discrete portions of the fund's portfolio.

The Commission staff estimates that 3,028 portfolios of approximately 2,126 funds use the services of one or more subadvisers. Based on an analysis of investment company filings, the staff estimates that approximately 200 funds are registered annually. Assuming that the number of these funds that will use the services of subadvisers is proportionate to the number of funds that currently use the services of subadvisers, then we estimate that 46 new funds will enter into subadvisory agreements each year.[1] The Commission staff further estimates, based on analysis of investment company filings, that 10 extant funds will employ the services of subadvisers for the first time each year. Thus, the staff estimates that a total of 56 funds, with a total of 78 portfolios (respondents),[2] will enter into subadvisory agreements each year. Assuming that each of these funds enters into a subadvisory contract that permits it to rely on the exemptions in rule 12d3–1(c)(3),[3] we estimate that the rule's contract modification requirement will result in 117 burden hours annually.[4]

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 R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: March 28, 2005.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1585 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[1] The Commission staff estimates that approximately 23 percent of funds are advised by subadvisers.

[2] Based on existing statistics, we assume that each fund has 1.4 portfolios advised by a subadviser.

[3] Rules 12d3–1, 10f–3, 17a–10, and 17e–1 require virtually identical modifications to fund advisory contracts. The Commission staff assumes that funds would rely equally on the exemptions in these rules, and therefore the Commission has apportioned the burden hours associated with the required contract modifications equally among the four rules.

[4] This estimate is based on the following calculations: (78 portfolios × 6 hours = 468 burden hours for rules 12d3–1, 10f–3, 17a–10, and 17e–1; 468 total burden hours for all of the rules/four rules = 117 annual burden hours per rule.)

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 17a–10, SEC File No. 270–507, OMB Control No. 3235–0563.

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 (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget (''OMB'') for extension and approval.

Section 17(a) of the Investment Company Act of 1940 (the ''Act''), prohibits affiliated persons of a registered investment company (''fund'') from borrowing money or other property from, or selling or buying securities or other property to or from the fund, or any company that the fund controls. Rule 17a–10 permits (i) a subadviser of a fund to enter into transactions with funds the subadviser does not advise but which are affiliated persons of a fund that it does advise (*e.g.*, other funds in the fund complex), and (ii) a subadviser (and its affiliated persons) to enter into transactions and arrangements with funds the subadviser does advise, but only with respect to discrete portions of the subadvised fund for which the subadviser does not provide investment advice.

To qualify for the exemptions in rule 17a–10, the subadvisory relationship must be the sole reason why section 17(a) prohibits the transaction; and the advisory contracts of the subadviser entering into the transaction, and any subadviser that is advising the purchasing portion of the fund, must prohibit the subadvisers from consulting with each other concerning securities transactions of the fund, and limit their responsibility to providing advice with respect to discrete portions of the fund's portfolio.[1]

The Commission staff estimates that 3,028 portfolios of approximately 2,126 funds use the services of one or more subadvisers. Based on discussions with industry representatives, the staff estimates that it will require approximately 6 hours to draft and execute revised subadvisory contracts (5 staff attorney hours, 1 supervisory attorney hour), in order for funds and subadvisers to be able to rely on the exemptions in rule 17a–10. The staff assumes that all of these funds amended their advisory contracts following the adoption of rule 17a–10 in 2002 that conditioned certain exemptions upon these contractual alterations.[2]

[1] See 17 CFR 270.17a–10(a)(2).

[2] Rules 12d3–1, 10f–3, 17a–10, and 17e–1 require virtually identical modifications to fund advisory contracts. The Commission staff assumes that funds

Continued

Based on an analysis of investment company filings, the staff estimates that approximately 200 new funds are registered annually. Assuming that the number of these funds that will use the services of subadvisers is proportionate to the number of funds that currently use the services of subadvisers, then approximately 46 new funds will enter into subadvisory agreements each year.[3] The Commission staff further estimates, based on an analysis of investment company filings, that 10 extant funds will employ the services of subadvisers for the first time each year. Thus, the staff estimates that a total of 56 funds, with a total of 78 portfolios,[4] will enter into subadvisory agreements each year. Assuming that each of these funds enters into a contract that permits it to rely on the exemptions in rule 17a–10, we estimate that the rule's contract modification requirement will result in 117 burden hours annually.[5]

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 R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: March 29, 2005.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1586 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

would rely equally on the exemptions in these rules, and therefore the Commission has apportioned the burden hours associated with the required contract modifications equally among the four rules.

[3] Based on information in Commission filings, we estimate that 23 percent of funds are advised by subadvisers.

[4] Based on existing statistics, we assume that each fund has 1.4 portfolios advised by a subadviser.

[5] This estimate is based on the following calculations: (78 portfolios × 6 hours = 468 burden hours for rules 12d3–1, 10f–3, 17a–10, and 17e–1; 468 total burden hours for all of the rules/four rules = 117 annual burden hours per rule).

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 27d–1 and Form N–27D–1; SEC File No. 270–499; OMB Control No. 3235–0560; Rule 27d–2; SEC File No. 270–500; OMB Control No. 3235–0566.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 350l *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collections of information under the Investment Company Act of 1940 (''Act'') summarized below. The Commission plans to submit these collections of information to the Office of Management and Budget for approval.

Rule 27d–1 [17 CFR 270.27d–1] is entitled ''Reserve Requirements for Principal Underwriters and Depositors to Carry Out the Obligations to Refund Charges Required by Section 27(d) and Section 27(f) of the Act.'' Form N–27D–1 is entitled ''Accounting of Segregated Trust Account.'' Rule 27d–2 [17 CFR 270.27d–2] is entitled ''Insurance Company Undertaking in Lieu of Segregated Trust Account.'' Rule 27d–1 requires the depositor or principal underwriter for an issuer to deposit funds into a segregated trust account to provide assurance of its ability to fulfill its refund obligations under sections 27(d) and 27(f). The rule sets forth minimum reserve amounts and guidelines for the management and disbursement of the assets in the account. A single account may be used for the periodic payment plans of multiple investment companies. Rule 27d–1(j) directs depositors and principal underwriters to make an accounting of their segregated trust accounts on Form N–27D–1, which is intended to facilitate the Commission's oversight of compliance with the reserve requirements set forth in rule 27d–1. The form requires depositors and principal underwriters to report deposits to a segregated trust account, including those made pursuant to paragraphs (c) and (e) of the rule. Withdrawals pursuant to paragraph (f) of the rule also must be reported. In addition, the form solicits information regarding the minimum amount required to be maintained under paragraphs (d) and (e) of rule 27d–1. Depositors and principal underwriters must file the form once a year on or before January 31 of the year following the year for which information is presented.

Instead of relying on rule 27d–1 and filing Form N–27D–1, depositors or principal underwriters for the issuers of periodic payment plans may rely on the exemption afforded by rule 27d–2. In order to comply with the rule, (i) the depositor or principal underwriter must secure from an insurance company a written guarantee of the refund requirements, (ii) the insurance company must satisfy certain financial criteria, and (iii) the depositor or principal underwriter must file as an exhibit to the issuer's registration statement, a copy of the written undertaking, an annual statement that the insurance company has met the requisite financial criteria on a monthly basis, and an annual audited balance sheet.

Rules 27d–1 and 27d–2, which were explicitly authorized by statute, provide assurance that depositors and principal underwriters of issuers have access to sufficient cash to meet the demands of certificate holders who reconsider their decisions to invest in a periodic payment plan. The information collection requirements in rules 27d–1 and 27d–2 enable the Commission to monitor compliance with reserve rules.

Commission staff estimates that there are four issuers of periodic payment plan certificates. The depositor or principal underwriter of each of these issuers must file Form N–27D–1 annually or comply with the requirements in rule 27d–2. On average, the Commission receives two Form N–27D–1 filings annually. The staff estimates that a staff accountant spends 8 hours and an accounting manager spends 3 hours preparing the form. Therefore, the total annual hour burden associated with rule 27d–1 and Form N–27d–1 is estimated to be 22 hours.[1] The staff estimates that two depositors or principal underwriters rely on rule 27d–2 and that each of these respondents makes three responses annually. We estimate that each depositor or underwriter expends approximately two hours per year obtaining a written guarantee from an insurance company or negotiating changes to coverage with the insurance company and five hours per year filing the two required documents from the insurance company on EDGAR. Thus, we estimate that the

[1] This estimate is based on the following calculation: 2 funds × (8 hours of staff accountant time + 3 hours of accounting manager time) = 22 hours.

annual burden is approximately 14 hours.[2]

The staff believes that rules 27d–1 and 27d–2 and Form N–27D–1 do not impose any cost burdens other than those arising from the hour burdens discussed above.

The estimates of average burden hours and costs are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.[3]

Complying with the collection of information requirements of rule 27d–1 is mandatory for depositors or principal underwriters of issuers of periodic payment plans unless they comply with the requirements in rule 27d–2. The information provided pursuant to rules 27d–1 and 27d–2 is public and, therefore, will not be kept confidential. 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.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission'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 R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: March 29, 2005.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1588 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[2] This estimate is based on the following calculation: 2 funds × (2 hours negotiating coverage + 5 hours filing necessary proof of adequate coverage) = 14 hours.

[3] These estimates are based on telephone interviews between the Commission staff and representatives of depositors or principle underwriters of periodic payment plan issuers.

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 17e–1; SEC File No. 270–224; OMB Control No. 3235–0217.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17e–1 [17 CFR 270.17e–1] under the Investment Company Act of 1940 (the ''Act'') is entitled ''Brokerage Transactions on a Securities Exchange.'' The rule governs the remuneration that a broker affiliated with a registered investment company (''fund'') may receive in connection with securities transactions by the fund. The rule requires a fund's board of directors to establish, and review as necessary, procedures reasonably designed to provide that the remuneration to an affiliated broker is a fair amount compared to that received by other brokers in connection with transactions in similar securities during a comparable period of time. Each quarter, the board must determine that all transactions with affiliated brokers during the preceding quarter complied with the procedures established under the rule. Rule 17e–1 also requires the fund to (i) maintain permanently a written copy of the procedures adopted by the board for complying with the requirements of the rule; and (ii) maintain for a period of six years a written record of each transaction subject to the rule, setting forth: The amount and source of the commission, fee or other remuneration received; the identity of the broker; the terms of the transaction; and the materials used to determine that the transactions were effected in compliance with the procedures adopted by the board. The Commission's examination staff uses these records to evaluate transactions between funds and their affiliated brokers for compliance with the rule.

The Commission staff estimates that 3,028 portfolios of approximately 2,126 funds use the services of one or more subadvisers. Based on discussions with industry representatives, the staff estimates that it will require approximately 6 hours to draft and execute revised subadvisory contracts (5 staff attorney hours, 1 supervisory attorney hour), in order for funds and subadvisers to be able to rely on the exemptions in rule 17e–1. The staff assumes that all of these funds amended their advisory contracts when rule 17e–1 was amended in 2002 by conditioning certain exemptions upon such contractual alterations.[1]

Based on an analysis of fund filings, the staff estimates that approximately 200 new funds are registered annually. Assuming that the number of these funds that will use the services of subadvisers is proportionate to the number of funds that currently use the services of subadvisers, then approximately 46 new funds will enter into subadvisory agreements each year.[2] The Commission staff further estimates, based on analysis of fund filings, that 10 extant funds will employ the services of subadvisers for the first time each year. Thus, the staff estimates that a total of 56 funds, with a total of 78 portfolios,[3] will enter into subadvisory agreements each year. Assuming that each of these funds enters into a contract that permits it to rely on the exemptions in rule 17e–1, we estimate that the rule's contract modification requirement will result in 117 burden hours annually.[4]

Based on an analysis of fund filings, the staff estimates that approximately 300 funds use at least one affiliated broker. Based on conversations with fund representatives, the staff estimates that rule 17e–1's exemption would free approximately 40 percent of transactions that occur under rule 17e–1 from the rule's recordkeeping and review requirements. This would leave approximately 180 funds (300 funds × .6 = 180) still subject to the rule's recordkeeping and review requirements. The staff estimates that each of these funds spends 57 hours per year hours at a cost of approximately $3,780 per year complying with rule 17e–1's requirements that (i) the fund retain

[1] Rules 12d3–1, 10f–3, 17a–10, and 17e–1 require virtually identical modifications to fund advisory contracts. The Commission staff assumes that funds would rely equally on the exemptions in these rules, and therefore the burden hours associated with the required contract modifications should be apportioned equally among the four rules.

[2] Based on information in Commission filings, we estimate that 23 percent of funds are advised by subadvisers.

[3] Based on existing statistics, we assume that each fund has 1.4 portfolios advised by a subadviser.

[4] This estimate is based on the following calculations: (78 portfolios × 6 hours = 468 burden hours for rules 12d3–1, 10f–3, 17a–10, and 17e–1; 468 total burden hours for all of the rules/four rules = 117 annual burden hours per rule.)

records of transactions entered into pursuant to the rule, and (ii) the fund's directors review those transactions quarterly.[5] We estimate, therefore, that all funds relying on this exemption incur yearly hourly burdens of 10,260 burden.[6] Therefore, the annual aggregate burden hour associated with rule 17e–1 is 10,377.[7]

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study. 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.

Written comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collections of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burdens of the collections 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 R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: March 28, 2005.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1589 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[5] In calculating the total annual cost of complying with amended rule 17e–1, the Commission staff assumes that the entire burden would be attributable to professionals with an average hourly wage rate of $66.31 per hour. Unless stated otherwise, all hourly rates in this Supporting Statement are derived from the average annual salaries reported for employees outside of New York City in Securities Industry Association, *Management and Professional Earnings in the Securities Industry* (2003) and Securities Industry Association, *Office Salaries in the Securities Industry* (2003).

[6] This estimate is based on the following calculation: (180 funds × 57 hours = 10,260).

[7] This estimate is based on the following calculation: (117 hours + 10,260 hours = 10,377).

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 17a–6, SEC File No. 270–506, OMB Control No. 3235–0564.

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 (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget (''OMB'') for extension and approval.

Section 17(a) of the Investment Company Act of 1940 (the ''Act''), prohibits affiliated persons of a registered investment company (''fund'') from borrowing money or other property from, or selling or buying securities or other property to or from the fund, or any company that the fund controls. Rule 17a–6 permits a fund and its ''portfolio affiliates'' (an issuer of which a fund owns more than five percent of the voting securities) to engage in principal transactions with if no prohibited participants (e.g., directors, officers, employees, or investment advisers of the fund contain persons controlling and under common control with the fund, and their affiliates) are parties to the transaction or have a direct or indirect financial interest in the transaction. Rule 17a–6 specifies certain interests that are not ''financial interests.'' The rule also provides that the term ''financial interest'' does not include any interest that the fund's board of directors (including a majority of the directors who are not interested persons of the fund) finds to be not material, as long as the board records the basis for the findings in its meeting minutes.

The information collection requirements in rule 17a–6 are intended to ensure that Commission staff can review, in the course of its compliance and examination functions, the basis for a board of director's finding that the financial interest of a prohibited participant in a party to a transaction with a portfolio affiliate is not material.

Based on analysis of past filings, the Commission's staff estimates that 148 funds are affiliated persons of 668 issuers as a result of the fund's ownership or control of the issuer's voting securities, and that there are approximately 1,000 such affiliate relationships. Staff discussions with mutual fund representatives have suggested that no funds currently rely on rule 17a–6 exemptions. We do not know definitively the reasons for this change in transactional behavior, but differing market conditions from year to year may offer some explanation for the current lack of fund interest in the exemptions under rule 17a–6. Accordingly, we estimate that annually there will be no principal transactions under rule 17a–6 that will result in a collection of information.

The Commission requests authorization to maintain an inventory of one burden hour to ease future renewals of rule 17a–6's collection of information analysis should reliance on rule 17a–6 increase in the coming years.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act. The estimate is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Complying with this collection of information requirement is necessary to obtain the benefit of relying on rule 17a–6. 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 control number.

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 R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: March 28, 2005.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1590 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27955]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

April 1, 2005.

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 under the Act. 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 amendment(s) is/are available for public inspection through the Commission's Branch 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 April 26, 2005, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, 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 the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts 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 April 26, 2005, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Cinergy Corp.

[70–10287]

Cinergy Corp., (''Cinergy''), 139 East Fourth Street, Cincinnati, Ohio 45202, a registered holding company has filed an application-declaration (''Application'') under sections 6(a), 7, 9(a), 10 and 11(b)(1) of the Act and rule 54 under the Act.

By order dated October 23, 2002 in File No. 70–10015, HCAR No. 27581 (''2002 Order''), the Commission authorized Cinergy to invest up to $500 million through March 31, 2005 in new or existing non-utility companies (''IS Subsidiaries'') that derive or would derive substantially all of their operating revenues from the sale of Infrastructure Services (as hereinafter defined) both within and outside the United States, while reserving jurisdiction over investments by Cinergy in IS Subsidiaries that would provide Infrastructure Services outside the United States.

As defined in the 2002 Order, and for purposes of the Application, ''Infrastructure Services'' include design, construction (as defined in rule 80(c) under the Act), retrofit and maintenance of utility transmission and distribution systems; substation construction; installation and maintenance of natural gas pipelines and laterals, water and sewer pipelines, and underground and overhead telecommunications networks; and installation and servicing of meter reading devices and related communications networks, including fiber optic cable; provided, however, that Infrastructure Services would under no circumstances include the acquisition or ownership of ''utility assets'' within the meaning of section 2(a)(18) of the Act.

Cinergy now requests authority to invest, directly or indirectly through one or more subsidiaries, up to $100 million (including existing investments, the ''Investment Cap'') from time to time through December 31, 2008 (''Authorization Period''), in new or IS Subsidiaries that derive or would derive substantially all of their operating revenues from the sale of Infrastructure Services both within and outside the United States. The Investment Cap would include Cinergy's existing investments in IS Subsidiaries on the date of any order issued by the Commission's in regard to the Application.[1] Cinergy requests that the Commission reserve jurisdiction, pending completion of the record, over Cinergy's proposal to invest in any IS Subsidiary that derives or will derive a substantial portion of its operating revenues from the sale of Infrastructure Services outside the United States. Cinergy states that the requested authority is necessary to enable Cinergy to continue to operate and develop the Infrastructure Services businesses previously authorized by the Commission in the 2002 Order.

Currently, Cinergy has four IS Subsidiaries: (i) Cinergy Supply Network, Inc., a Delaware corporation (''CSN''), which does not engage in an active business but is solely a holding company for Cinergy's other IS Subsidiaries:[2] (ii) Reliant Services, LLC (''Reliant''), an Indiana limited liability company owned jointly and equally by CSN and a subsidiary of Vectren Corporation. Reliant provides line locating and meter reading services to utilities and through its wholly-owned indirect subsidiary, Miller Pipeline Corporation, installs, repairs and maintains underground pipelines used in natural gas, water and sewer systems. Reliant operates throughout the United States with its customer base primarily concentrated in the Midwest. (iii) MP Acquisition Corp., an Indiana corporation (''MP''), is a direct wholly-owned subsidiary of Reliant that engages in no active business but rather is solely a holding company for Miller Pipeline Corporation; (iv) Miller Pipeline Corporation, an Indiana corporation (''Miller Pipeline'') and a direct wholly-owned subsidiary of MP that installs, repairs and maintains underground pipelines used in natural gas, water and sewer systems. Miller Pipeline operates throughout the United States with its customer base primarily concentrated in the Midwest.

Investments in any IS Subsidiary may take the form of an acquisition, directly or indirectly, of the stock or other equity securities of a new subsidiary or of an existing company and any subsequent purchases of additional equity securities and any loans or cash capital contributions to any such company. In addition, any guarantee provided by Cinergy in respect of any payment or performance obligation of any IS Subsidiary would be counted against the Investment Cap. Cinergy will fund investments in IS Subsidiaries using available cash or the proceeds of financings, as authorized in HCAR No. 27190 (June 23, 2000) or any supplemental or superseding financing order issued to Cinergy during the Authorization Period.

Cinergy states that it will not seek recovery through higher rates to its utility subsidiaries' customers for any losses Cinergy may sustain, or any inadequate returns it may realize, in respect of its investments in IS Subsidiaries, and that any Infrastructure Services performed by any IS Subsidiaries, directly or indirectly, for any associate or affiliate utility companies (as those terms are defined in the Act) would be conducted at cost and otherwise in accordance with the service agreements approved by the Commission in HCAR No. 27016, (May 4, 1999).

[1] Cinergy states that at December 31, 2004 it had invested approximately $30 million in IS Subsidiaries.

[2] CSN has one subsidiary, Fiber Link, LLC, an Indiana limited liability company, that is not an IS Subsidiary but rather is an ETC as certified by the Federal Communication Commission. Fiber Link holds conduit inventory for sale to the telecommunications industry.

Cleco Corp.

[70–10268]

Cleco Corporation (''Cleco Corp.''), 2030 Donahue Ferry Road, Pineville, LA, a Louisiana corporation and a holding company exempt under section 3(a)(1) of the Act, has filed an application under sections 9(a)(2) and 10 to retain its ownership interest in Perryville Energy Partners, LLC (''Perryville''), upon Perryville's loss of status as an exempt wholesale generator (''EWG'') under the Act.

Cleco Corp. is the parent company of Cleco Power LLC (''Cleco Power''), a Louisiana limited liability public-utility company that provides electric utility service in central and southeastern Louisiana. Cleco Corp. also is the indirect owner, through its subsidiary companies Cleco Midstream Resources LLC and Perryville Energy Holdings LLC of Perryville, which owns a 718-megawatt generating facility as well as interconnection facilities used to connect the facility to the transmission system of Entergy Louisiana (''Entergy LA''). Perryville has entered into an agreement to sell the generating facility to Entergy LA (although it will retain ownership of the interconnection facilities). Following the sale, Perryville will no longer own generating facilities, will cease to qualify as an EWG, and will become a public-utility company, as defined in section 2(a)(5) of the Act.

For the Commission by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1601 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Homeland Security Network, Inc.; Order of Suspension of Trading

April 5, 2005.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Homeland Security Network, Inc. (''HSYN'') because the company is delinquent in its periodic filing obligations under section 13(a) of the Securities Exchange Act of 1934 and because of possible manipulative conduct occurring in the market for the company's stock.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to section 12(k) of the Securities Exchange Act of 1934, that trading in the above-listed company is suspended for the period from 9:30 a.m. e.d.t., on April 5, 2005, through 11:59 p.m. e.d.t., on April 18, 2005.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 05–7025 Filed 4–5–05; 11:35 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51460; File No. SR–Amex–2005–007]

Self-Regulatory Organizations; American Stock Exchange LLC; Order Granting Approval of Proposed Rule Change and Amendment No. 1 Thereto To Require Specialists To Use and Maintain a Back-Up Automatic Quote System in ANTE Classes

March 31, 2005.

On January 12, 2005, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''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 amend Amex Rule 950–ANTE(l), Commentary .02(a) to require specialists to use and maintain a back-up automatic quote system in ANTE classes, and to incorporate violations of this requirement in the Exchange's minor rule violation plan (''Plan''). The proposed rule change was published for comment in the **Federal Register** on February 23, 2005.[3] The Commission received no comments on the proposal. On March 15, 2005, the Exchange filed Amendment No. 1 to the proposed rule change.[4] This order approves the proposed rule change, as amended.

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,[5] and, in particular, the requirements of Section 6 of the Act [6] and the rules and regulations thereunder. The Commission finds specifically that the proposed rule change, as amended, is consistent with Section 6(b)(5) of the Act [7] because it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also finds that the Exchange's Plan is consistent with Section 6(b)(6) of the Act,[8] which require that the rules of an exchange enforce compliance and provide appropriate discipline for violations of Commission and Exchange rules.

The Commission believes that requiring Amex specialists to use and maintain an Exchange-provided automatic quote system as a back-up to the Exchange-approved proprietary automatic quote system in ANTE classes should help to assure an orderly market. In addition, the Commission believes that including this requirement in the Exchange's Plan should strengthen the ability of the Exchange to carry out its oversight and enforcement responsibilities as a self-regulatory organization (''SRO''). In approving this proposed rule change, as amended, the Commission in no way minimizes the importance of compliance with Amex Rule 950—ANTE(l), Commentary .02(a) and all other rules subject to the imposition of fines under the Exchange's Plan. The Commission believes that the violation of any SRO's rules, as well as Commission rules, is a serious matter. However, the Exchange's Plan provides a reasonable means of addressing rule violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. The Commission expects that the Amex will continue to conduct surveillance with due diligence and make a determination based on its findings, whether fines of more or less than the recommended amount are appropriate for violations under the Plan, on a case-by-case basis, or a violation requires formal disciplinary action.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 51209 (February 15, 2005), 70 FR 8859.

[4] *See* Partial Amendment dated March 15, 2005 (''Amendment No. 1''). In Amendment No. 1, the Exchange made technical corrections to the proposed rule text. Accordingly, this Amendment is not subject to notice and comment.

[5] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78f(b)(6).

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[9] that the proposed rule change (SR–Amex–2005–007), as amended, be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1580 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51459; File No. SR–CBOE–2005–27]

Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change by the Chicago Board Options Exchange, Incorporated Relating to the Hybrid Opening System

March 31, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 24, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would amend the Hybrid Opening System (''HOSS'') procedures and the rule relating to the obligations of electronic designated primary market makers (''e-DPMs''). The text of the proposed rule change is available on the CBOE's Web site (*http://www.cboe.com*), at the CBOE's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE 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

1. Purpose

The Exchange is proposing to amend its rules relating to HOSS procedures and the rules relating to e-DPMs to require all e-DPMs to submit opening quotes during the HOSS opening rotation for every series in each Hybrid class to which any e-DPM is allocated. Currently, CBOE rules only require DPMs to submit opening quotes in option classes listed and traded on the Exchange. The Exchange believes that requiring e-DPMs to submit opening quotes along with DPMs would enhance the opening process for Hybrid option classes by providing greater liquidity during opening rotations, which would in turn lessen the possibility that a Hybrid option class might be unable to open.

To illustrate, under current CBOE rules, only a DPM is required to submit opening quotes in a series[3] and, if the DPM's quoted size at the open is below the total size of the market orders on the other side of the market and no other quotes are on the open, there is a market order imbalance and, under CBOE rules, HOSS will not open that series.[4] If all e-DPMs are now required to add size to the opening quote for each series in the option classes allocated to e-DPMs, the incidence of market order imbalances is likely to decrease.

As such, HOSS rules[5] and the rules relating to e-DPM and DPM obligations, respectively,[6] will be amended to require both e-DPMs and DPMs to enter opening quotes in accordance with HOSS rules in 100% of the series of each class allocated to that DPM or e-DPM.[7]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rule 6.2B(a).

[4] *See* Rule 6.2B(e)(iii).

[5] Rule 6.2B.

[6] DPM obligations are provided under Rule 8.85(a) and e-DPM obligations are provided under Rule 8.93.

[7] Under current CBOE rules, DPMs already are required to submit opening quotes in all of its allocated classes, but this rule filing proposes to adopt rule language that will apply uniformly to both DPMs and e-DPMs.

2. Statutory Basis

By enhancing HOSS opening procedures and making an e-DPM's HOSS obligations consistent with those of a DPM's, the Exchange believes that this proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and further the objectives of Section 6(b)(5)[9] in particular, in that it should promote just and equitable principles of trade, serve to remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

This proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

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 CBOE 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, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form *(http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2005–27 on the subject line.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

Paper Comments

• Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–CBOE–2005–27. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site *(http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2005–27 and should be submitted on or before April 28, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1582 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51463; File No. SR–CBOE–2005–19]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Proposed Rule Change and Amendment No. 1 Thereto Relating to an Interpretation of Paragraph (b) of Article Fifth of Its Certificate of Incorporation and an Amendment to Rule 3.16(b)

March 31, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on March 7, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. On March 28, 2005, the Exchange submitted Amendment No. 1 to the proposed rule change.[2] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of an interpretation of paragraph (b) of Article Fifth of the Certificate of Incorporation of the CBOE pertaining to the right of the 1,402 Full Members of the Board of Trade of the City of Chicago, Inc. (''CBOT'') to become members of CBOE without having to purchase a CBOE membership (paragraph (b) of Article Fifth of CBOE's Certificate of Incorporation is referred to as ''Article Fifth(b),'' and the right of CBOT Full Members to become members of CBOE as described therein is referred to as the ''Exercise Right''). This interpretation of the Exercise Right is embodied in an Agreement dated August 7, 2001, (''2001 Agreement'') between CBOE and the CBOT as modified by a Letter Agreement among CBOE, CBOT Holdings, Inc. (''CBOT Holdings'') and CBOT dated October 7, 2004 (the ''October 2004 Letter Agreement''), and it is reflected in a related amendment to CBOE Rule 3.16.

The 2001 Agreement as modified by the October 2004 Letter Agreement represents the agreement of the parties concerning the nature and scope of the Exercise Right following the consummation of a proposed restructuring of CBOT and in light of the expansion of the CBOT's electronic trading system. The 2001 Agreement as modified incorporates CBOE's interpretation concerning the operation of Article Fifth(b) in light of these changed circumstances at CBOT. That interpretation, together with a proposed amendment to Rule 3.16, constitutes the proposed rule change that is the subject of this filing.

In a Letter Agreement among CBOE, CBOT Holdings and CBOT dated February 14, 2005 (the ''February 2005 Letter Agreement''), the parties confirmed that the proposed restructuring of the CBOT as described in Amendment 13 to the registration statement filed by CBOT Holdings and CBOT on Form S–4 under the Securities Act of 1933 as amended at that time, which was the last substantive amendment to the registration statement before it was declared effective by the Commission on that date, constitutes the CBOT restructuring for purposes of the 2001 Agreement and CBOE's interpretation of Article Fifth(b) embodied therein. The 2001 Agreement as modified and clarified by the October 2004 Letter Agreement and the February 2005 Letter Agreement is referred to herein as the ''2001 Agreement as amended.'' The text of the 2001 Agreement is attached as Exhibit 3a to the CBOE's Form 19b–4, the text of the October 7, 2004 Letter Agreement is attached as Exhibit 3b to the CBOE's Form 19b–4, the text of the February 14, 2005 Letter Agreement is attached as Exhibit 3c to the CBOE's Form 19b–4, and the opinion letter of CBOE's special Delaware counsel is attached as Exhibit 3d to the CBOE's Form 19b–4. The text of the proposed rule change, including the above-referenced Exhibits and Amendment No. 1, is available on CBOE's Web site (*http://www.cboe.org/Legal/SubmittedSECFilings.aspx*), at the CBOE's Office of the Secretary, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] Due to a pending motion to reconsider the Commission's approval of SR–CBOE–2004–16, which was submitted on March 7, 2005, Amendment No. 1 removed certain language from the text of CBOE Rule 3.16(b) that was included with the original filing to reflect the stay of effectiveness of the text added by SR–CBOE–2004–16 pending a final Commission determination of the motion to reconsider. Accordingly, Amendment No. 1 revised the proposed rule change to reflect the text of CBOE Rule 3.16 as currently in effect, without the language added to the Rule by SR–CBOE–2004–16, and as it is proposed to be modified by the current rule filing. Amendment No. 1 also adds Exhibit 3d to the filing, which consists of an opinion letter received by CBOE from its special Delaware counsel that pertains to the proposed rule change.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE 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

1. Purpose

The purpose of the proposed rule change is to provide an interpretation of the rules of CBOE as set forth in paragraph (b) of Article Fifth(b) concerning the effect on the Exercise Right of a proposed restructuring of the CBOT and the expansion of electronic trading on the CBOT and the CBOE. The source of the Exercise Right is Article Fifth(b), which provides in part that ''every present and future member of [CBOT] who applies for membership in the [CBOE] and who otherwise qualifies shall, so long as he remains a member of said Board of Trade, be entitled to be a member of the [CBOE] notwithstanding any such limitation on the number of members and without the necessity of acquiring such membership for consideration or value from the [CBOE], its members or elsewhere.'' This filing does not propose to amend Article Fifth(b), but only to interpret how it should apply in circumstances that were not envisioned at the time Article Fifth(b) was adopted and therefore were not addressed in the language of that Article.

This is not the first time Article Fifth(b) had to be interpreted by CBOE in response to unanticipated changed circumstances at CBOT. CBOE previously interpreted that Article in accordance with an agreement between CBOE and CBOT dated September 1, 1992, (the ''1992 Agreement''), parts of which are incorporated in CBOE Rule 3.16(b).[3] The interpretation embodied in the 1992 Agreement served to resolve a dispute between CBOE and CBOT concerning the effect on the Exercise Right of action taken or proposed to be taken by CBOT at that time to unbundle certain of the trading rights held by CBOT members, to issue transferable evening trading permits to its members, and to allow CBOT members to ''delegate'' (*i.e.*, lease) the trading rights associated with their memberships. In CBOE's view, these actions had distorted and could further distort the traditional integration of access and ownership that was embodied in the concept of exchange membership as it existed when the Exercise Right was created.

To preserve what CBOE considered to be the original intent of the Exercise Right in light of these changed circumstances, Article Fifth(b) was interpreted in the 1992 Agreement so that only an individual who is an ''Eligible CBOT Full Member'' or an ''Eligible CBOT Full Member Delegate'' would be considered to be a member of the CBOT within the meaning of Article Fifth(b). The 1992 Agreement defined an ''Eligible CBOT Full Member'' to mean ''an individual who at the time is the holder of one of the One Thousand Four Hundred Two (1,402) existing CBOT Full Memberships (''CBOT Full Memberships'') and who is in possession of all trading rights and privileges appurtenant to such CBOT Full Membership.'' The term ''Eligible CBOT Full Member Delegate'' was defined in the 1992 Agreement to mean ''the individual to whom a CBOT Full Membership is delegated (leased) and who is in possession of all trading rights and privileges appurtenant to such CBOT Full Membership.'' The 1992 Agreement also provided that in the event of any division of the trading rights and privileges appurtenant to a CBOT Full Membership or any division of the CBOT Full Membership itself, a CBOT member retained the right to exercise only if he held all of the parts into which his membership may have been divided and all of the trading rights and privileges appurtenant thereto. As a result of the 1992 Agreement, the number of potential ''exerciser'' members of CBOE has been limited to the 1,402 Full Members of CBOT or their delegates (lessees), but not both in respect of the same CBOT membership.

CBOE next interpreted Article Fifth(b) in response to amendments to CBOT's rules that purported to adopt abbreviated membership approval procedures applicable to persons who sought to become CBOT Full Members only in order to be able to utilize the Exercise Right to become members of CBOE. Since persons who attempted to become CBOT members pursuant to these abbreviated procedures would not have any trading rights at CBOT, they would fail to satisfy the requirement of Article Fifth(b) as interpreted in the 1992 Agreement that to become a member of CBOE pursuant to the Exercise Right, a Full Member of CBOT must be in possession of all trading rights and privileges appurtenant to a CBOT Full Membership. CBOE clarified that these new procedures would not satisfy the requirements of the Exercise Right in an interpretation of Article Fifth(b) that was filed with and approved by the Commission in SR-CBOE–2002–41.[4]

More recently, Article Fifth(b) again had to be interpreted by CBOE in response to changes to CBOT's rules that authorized CBOT to make available to its full members, upon their request, a separately transferable interest representing that component of CBOT full membership representing the Exercise Right. This interpretation was embodied in an Agreement between CBOE and CBOT dated December 17, 2003, (''2003 Agreement'') and in related revisions to CBOE Rule 3.16. The interpretation of Article Fifth(b) embodied in the 2003 Agreement was filed with the Commission in SR–CBOE–2004–16, and was approved by the Commission by authority delegated to the Division of Market Regulation on July 15, 2004.[5] Upon receipt of a petition for review of the approval by delegated authority filed by a CBOE member, that approval was automatically stayed pending review by the full Commission.[6] On February 25, 2005, the prior approval of this proposed rule change by delegated authority was set aside, and instead this proposed rule change was approved by the Commission.[7]

Just as when CBOE had to interpret Article Fifth(b) in 1992 and in 2004 in response to changed circumstances at CBOT, CBOE believes CBOT's current proposal to implement a restructuring of that exchange again makes it necessary to interpret how Article Fifth(b) will apply under these changed circumstances. The proposed restructuring of CBOT, which is subject to a vote of the CBOT membership, was

[3] The interpretation of Article Fifth(b) embodied in the 1992 Agreement and an amendment to Rule 3.16 referring to the 1992 Agreement were approved by the Commission in Securities Exchange Act Release No. 32430. *See* Securities Exchange Act Release No. 32430 (June 8, 1993), 58 FR 32969 (June 14, 1993) (File No. SR–CBOE–92–42).

[4] *See* Securities Exchange Act Release No. 46719 (October 25, 2002), 67 FR 66689 (November 1, 2002).

[5] *See* Securities Exchange Act Release No. 50028 (July 15, 2004), 69 FR 43644 (July 21, 2004).

[6] The stay of that approval was announced in Securities Exchange Act Release No. 50464 dated September 29, 2004.

[7] *See* Securities Exchange Act Release No. 51252 (February 25, 2005), 70 FR 10442 (March 3, 2005).

originally described in a registration statement filed in 2001 by CBOT under the Securities Act of 1933 as a series of transactions that were designed to (1) demutualize CBOT by converting it from a not-for-profit membership corporation to a for-profit stock corporation and distributing shares of common stock of the for-profit CBOT to its members; (2) modernize the CBOT's corporate governance structure by substantially eliminating the membership petition process, streamlining its board of directors and making other changes to improve the efficiency of its corporate decision-making process; and (3) reorganize the CBOT's electronic trading business into a new wholly-owned subsidiary of CBOT that would trade electronically all of the products theretofore traded in CBOT's open-outcry market, including agricultural products not previously traded electronically.[8] In connection with the restructuring as then proposed, each member of CBOT would have received a predetermined number of shares of Class A common stock representing equity in the new for-profit corporation, and a single share of one of five series of Class B common stock representing an additional equity interest in the new corporation and, subject to satisfaction of applicable membership and eligibility requirements, trading rights and privileges corresponding to those associated with one of the five current classes of membership in the existing not-for-profit CBOT. When all of the steps of the restructuring of CBOT as originally proposed were fully implemented, CBOT would no longer have been a membership corporation but instead would have become a stock corporation with its former members as its stockholders. CBOT's electronic trading system, which was to have been operated as an open-access system by a wholly-owned subsidiary of CBOT, would have traded all CBOT products side-by-side with their being traded on the existing open-outcry trading floor (as long as that market continued to operate).

CBOE believes these changes in the structure of CBOT would have had the potential to impact the Exercise Right in ways that were not contemplated when that right came into existence. Just as in 1992 when other changes at CBOT not anticipated at the time the Exercise Right was created raised questions concerning their effect on the Exercise Right, CBOT's proposed restructuring once again made it necessary for CBOE to interpret Article Fifth(b) in response to the changes that were now being proposed. To this end, over a period of several months in 2001 the CBOE and CBOT engaged in a series of discussions to see whether agreement could be reached concerning the nature and scope of the Exercise right following the proposed restructuring of CBOT, and how this might be reflected in an interpretation by CBOE of Article Fifth(b). The 2001 Agreement was the result of those discussions, and embodied an interpretation of the Exercise Right by CBOE that, subject to the terms and conditions of that Agreement, would allow CBOT Full Members and Full Member Delegates to be able to exercise following the effectiveness of the proposed restructuring of CBOT as described by CBOT at the time the 2001 Agreement was entered into on August 7, 2001. The 2001 Agreement made this interpretation of the Exercise Right by CBOE contingent upon certain obligations imposed on CBOT, including the obligation to take steps to preserve the value of CBOT memberships and thereby prevent the restructuring from having a dilutive effect on the value of CBOE memberships by encouraging mass exercise or by making it easier for CBOT members or their delegates to trade concurrently as CBOT members and as exerciser members of CBOE.

Later in 2001, following the signing of the 2001 Agreement, CBOT informed CBOE that it wished to make certain revisions to its proposed restructuring. Among these were to make CBOT a wholly-owned for-profit subsidiary of a new holding company, CBOT Holdings, Inc., a Delaware stock, for-profit corporation (''CBOT Holdings''). CBOT Holdings would be owned by its common stockholders, who would have all voting rights and equity ownership rights in the corporation. In the revised restructuring, each member of CBOT would have received a predetermined number of shares of common stock of CBOT Holdings, with each of the 1,402 CBOT Full Members receiving 25,000 shares of CBOT Holdings common stock. In addition, Class B memberships, representing trading rights on the CBOT subsidiary, would have been issued in five different series to the five different categories of current members of CBOT, with each of the 1,402 CBOT Full Members receiving one Series B–1 membership in CBOT representing the trading rights of a Full Member in the CBOT market. In addition, 1,402 Class C memberships, representing the Exercise Right (when held together with the other interests issued to CBOT Full Members in the restructuring), would have been issued to the 1,402 current CBOT Full Members. As then proposed, Series B–1 memberships and Class C memberships would have been freely transferable. To be consistent with the provision of Article Fifth(b) as interpreted in the 1992 Agreement that the Exercise Right itself could not be transferred separate and apart from a transfer of the related CBOT Full Membership, although Class C memberships would have been freely transferable, the holder of a Class C membership would not have been entitled to utilize the Exercise Right unless the holder also held all of the other rights and privileges of a CBOT Full Member (namely, the shares of CBOT Holdings common stock and the Series B–1 membership issued to CBOT Full Members in the restructuring).

In addition, under the restructuring of CBOT as then revised, Class B members of CBOT would have had limited voting rights to approve changes that could adversely affect certain specified ''core'' trading rights of such members. Also, in the restructuring as then revised, the electronic trading business of CBOT would continue to have been operated by a wholly-owned subsidiary of CBOT (a second-tier subsidiary of CBOT Holdings) in much the same manner as was contemplated in the restructuring as originally proposed.

On October 24, 2001, CBOE, CBOT Holdings and CBOT entered into a letter agreement (the ''October 2001 Letter Agreement'') that modified the 2001 Agreement to take into account these revisions to CBOT's proposed restructuring. The October 2001 Letter Agreement reflected a further interpretation of the Exercise Right by CBOE intended to make it clear that, subject to the terms and conditions of the October 2001 Letter Agreement as well as of the 2001 Agreement, the Exercise Right would continue to be available to CBOT's Full Members and Full Member Delegates following the revised restructuring. The October 2001 Letter Agreement also made it clear that under the proposed holding company structure, CBOT and CBOT Holdings would remain bound by the obligations of CBOT under the 2001 Agreement.

Some time after the execution of the October 2001 Letter Agreement, CBOT again informed CBOE that it intended to make some additional revisions and refinements to its proposed restructuring. Among other things, CBOT intended to eliminate the free transferability of Series B–1 memberships that were to be issued to

[8] Registration Statement on Form S–4, Registration No. 333–54370, initially filed by CBOT on January 22, 2001.

its Full Members in the restructuring. Instead, CBOT proposed to impose a complete restriction on the transfer of Series B–1 memberships, except that a Series B–1 membership could be transferred together with a transfer of all of the 25,000 shares of CBOT Holdings common stock associated with the Series B–1 membership, and except that the CBOT Board of Directors would be authorized to remove or reduce the restriction on the transferability of Series B–1 memberships if it determined such action to be appropriate. In response, CBOE, CBOT Holdings and CBOT entered into a letter agreement dated September 13, 2002 (the ''September 2002 Letter Agreement'') as a further addendum to the 2001 Agreement. The September 2002 Letter Agreement reflected a further interpretation of the Exercise Right by CBOE to make it clear that, subject to the terms and conditions of the September 2002 Letter Agreement as well as of the October 2001 Letter Agreement and the 2001 Agreement, the Exercise Right would continue to be available to CBOT's Full Members and Full Member Delegates notwithstanding the restriction on transferability of Series B–1 memberships. The September 2002 Letter Agreement also clarified the intent of the parties to the effect that in order to be an ''Eligible CBOT Full Member'' or an ''Eligible CBOT Full Member Delegate'' eligible to exercise pursuant to the interpretation embodied in the 2001 Agreement, a person must be in possession of ''all trading rights and privileges appurtenant to such CBOT Full Membership'' as that phrase is defined in the 1992 Agreement.

More recently, CBOT further revised its proposed restructuring to reflect, among other things, the settlement of the litigation brought by certain members of CBOT that had challenged the proposed allocation of equity in a restructured CBOT. Consistent with the settlement, in the restructuring as now proposed, each Full Member of CBOT will receive 27,338 shares of Class A common stock of CBOT Holdings in three different series, together with one Class B, Series B–1 membership in the CBOT subsidiary. The issuance of a transferable Class C membership in the CBOT subsidiary representing the Exercise Right has been eliminated, because, as described above, in 2004 CBOT amended its rules to provide for the issuance of a transferable ''Exercise Right Privilege'' to any of its Full Members requesting the same.[9] Since these Exercise Right Privileges are intended to serve the same purpose that was to have been served by Class C memberships, and since the rules of CBOT governing the issuance and transfer of Exercise Right Privileges will remain in effect following the effectiveness of the proposed restructuring, there is no longer any need for CBOT to provide for the issuance of Class C memberships in the restructuring.[10]

Other recent changes in the proposed restructuring of CBOT are intended to permit CBOT Holdings to facilitate the creation of public markets in its equity securities and to engage in capital-raising transactions and other securities issuances. Before it can authorize any such transactions, however, the CBOT Holdings board of directors must seek and obtain the approval of a majority of the stockholders of CBOT Holdings to do so (referred to as the ''second approval''), which would follow the initial approval of the CBOT membership to implement the steps of the CBOT restructuring up to the point where the second approval is needed. Still other changes concern the transfer restrictions that will apply to CBOT Holdings common stock issued to CBOT members. The transfer of these shares separate from a transfer of the associated Series B–1 CBOT membership will continue to be restricted, as will the transfer of the Series B–1 memberships separate from the transfer of all of the 27,338 shares of Class A common stock associated with them. It is now provided that the transfer restrictions on shares of Class A common stock will be lifted in stages following any underwritten public offering of these shares. In addition, following the second approval certain additional permitted transfers will be allowed as exceptions to these transfer restrictions. Restrictions on the transfer of Series B–1 memberships and on certain limited transfers of shares of Class A common stock will also be lifted following the ''second approval.'' Finally, the proposed restructuring reflects certain changes to the governance of CBOT Holdings and its CBOT subsidiary, including changes to the size and composition of the boards of directors of both corporations in connection with any underwritten public offering of CBOT Holdings Class A common stock, as well as changes to the voting rights of CBOT members.

On October 7, 2004, CBOE, CBOT Holdings and CBOT entered into the October 2004 Letter Agreement as a further amendment to the 2001 Agreement in order to incorporate in that Agreement and in CBOE's interpretation of the Exercise Right embodied therein the recent changes made by CBOT to its proposed restructuring. The October 2004 Letter Agreement also incorporates the terms of the October 2001 and September 2002 Letter Agreements and provides that it supersedes those two agreements. Finally, in a Letter Agreement among CBOE, CBOT Holdings and CBOT dated February 14, 2005 (the ''February 2005 Letter Agreement''), the parties confirmed that the proposed restructuring of the CBOT as described in the registration statement filed by CBOT Holdings and CBOT on Form S–4 under the Securities Act of 1933 as amended at that time, which was shortly before it was declared effective by the Commission, constitutes the CBOT restructuring for purposes of the 2001 Agreement and CBOE's interpretation of Article Fifth(b) embodied therein. The interpretation of Article Fifth(b) embodied in the 2001 Agreement as modified and clarified by the October 2004 Letter Agreement and the February 2005 Letter Agreement (referred to herein as the ''2001 Agreement as amended'') is intended to confirm to the CBOT and its Full Members that if CBOT is restructured as proposed, the 1,402 Full Members of the CBOT following the restructuring will continue to be able to utilize the Exercise Right to become members of CBOE in accordance with and subject to the terms and conditions of that interpretation.

The interpretation by CBOE of the Exercise Right embodied in the 2001 Agreement as amended does not displace the interpretation reflected in the 1992 Agreement, except where there are inconsistencies between the interpretation embodied in the modified 2001 Agreement and the interpretation embodied in the 1992 Agreement, the interpretation embodied in the modified 2001 Agreement controls. Neither does it displace CBOE's interpretation of the Exercise Right concerning abbreviated membership approval procedures at CBOT that was filed with and approved

[9] As was previously the case for Class C memberships as described in the text above, in order to be consistent with the nontransferability of the Exercise Right itself separate from a transfer of the related CBOT Full Membership, the holder of an Exercise Right Privilege may not utilize the Exercise Right it represents unless the holder also holds all of the other rights and privileges of a CBOT Full Member (which, following the restructuring of CBOT, will include the 27,338 shares of Class A common stock and the Class B, Series B–1 membership issued to each CBOT Full Member in the restructuring).

[10] CBOE has interpreted Article Fifth(b) in response to CBOT's recent rule change providing for the issuance of transferable Exercise Right Privileges in accordance with an agreement between CBOE and CBOT dated December 17, 2003. *See supra* note 5 and accompanying text.

by the Commission in SR–CBOE–2002–41, or CBOE's interpretation concerning the effect on the Exercise Right of CBOT rule changes pertaining to the issuance of Exercise Right Privileges that was filed with and approved by the Commission in SR–CBOE–2004–16.[11] Because existing CBOE Rule 3.16 refers to certain terms that were previously defined in the 1992 Agreement and are now further defined in the modified 2001 Agreement, the proposed rule change also includes an amendment to that Rule to make it conform to the definitions in both the 1992 Agreement and the modified 2001 Agreement.

A principal feature of the interpretation embodied in the modified 2001 Agreement is to define who will be an ''Eligible CBOT Full Member'' and ''Eligible CBOT Full Member Delegate'' entitled to exercise after CBOT has completed its proposed restructuring. These definitions are intended to apply upon consummation of the proposed CBOT restructuring as specifically described in Amendment No. 13 to CBOT Holdings' Registration Statement on form S–4 (Registration No. 333–72184), and any subsequent amendments to that registration statement consented to by CBOE, and in the absence of any other material changes to the structure or ownership of CBOT or to the trading rights and privileges appurtenant to a CBOT Full Membership not contemplated in the restructuring as so described.

As noted above, in the currently proposed restructuring of CBOT, each of the 1,402 CBOT Full Members, who are the only persons currently entitled to the Exercise Right, will receive 27,338 shares of Class A Common Stock of CBOT Holdings representing equity ownership in that corporation and one Series B–1 membership in CBOT representing the trading rights of a CBOT Full Member and specified voting rights in respect of CBOT. Consistent with the interpretation of the Exercise Right embodied in the 1992 Agreement to the effect that in the event of any split or other division of CBOT Full Membership into two or more parts, a CBOT Full Member must hold all of the parts into which his membership may have been divided and all trading rights and privileges appurtenant thereto in order to be able to exercise, the interpretation of the Exercise Right embodied in the modified 2001 Agreement conditions the right of an individual to become a CBOE member by exercise upon that individual's being the owner or delegate of all of the parts distributed in respect of his membership in the restructuring (*i.e.*, the 27,338 Class A shares of common stock of CBOT Holdings and the Series B–1 membership), as well as an Exercise Right Privilege. These interests may be separately bought and sold and bundled and rebundled for purposes of qualifying the owner as eligible to exercise, subject to the restriction on transferability of Class A Common Stock and Series B–1 memberships referred to above. Antidilution adjustments are provided for in the case of certain issuances of additional shares of Class A Common Stock of CBOT Holdings, and the CBOT has agreed that no Series B–1 Memberships beyond the 1,402 issued in the restructuring will ever be issued.

CBOE's interpretation of the Exercise Right embodied in the 2001 Agreement as amended also addresses CBOE's concerns regarding the expansion of electronic trading of CBOT products. CBOE believes that expanded electronic trading on CBOT carries with it with the potential for providing open access to the CBOT market over the electronic platform on substantially the same terms to members and nonmembers alike. This raises the possibility that CBOT members will no longer need the trading rights provided by their memberships in order to be able to trade CBOT products, in which event they would be free to sell or delegate their CBOT memberships to persons who would utilize CBOT memberships only to obtain the Exercise Right, or they would themselves utilize their CBOT membership to become exerciser members, while retaining the right to trade on CBOT on the same terms as members of that exchange. Likewise, CBOE believes that expanded electronic trading of CBOT products could facilitate the ability of CBOT members or their delegates to trade on CBOT as members and on CBOE as exercise members concurrently, since physical presence on the CBOT trading floor would no longer be required to trade CBOT products that are available on the electronic system.

For these reasons, CBOE believes that expanded electronic trading on CBOT could result in a mass exercise by CBOT Full Members to an extent never contemplated at the time the Exercise Right was first established. When the Exercise Right was first established, the only way a CBOT Full Member who was also a member of CBOE could trade as a member of both exchanges was to physically move from one exchange's trading floor to another. Although the proximity of the two trading floors made this at least theoretically possible, few CBOT Full Members have ever attempted to trade on both floors in this way. In CBOE's view, this is because a CBOT member who is also a CBOE member would find it difficult to fulfill his obligations to both exchanges, as well as to manage the positions resulting from his trading, if he frequently had to be absent from one exchange's trading floor because of a need to be on the other exchange's floor. For this reason, although the Exercise Right has always been available to all 1,402 CBOT Full Members, CBOE believes it was inherent in the nature of exchange trading at the time Article Fifth(b) was adopted that only a fraction of CBOT Full Members would be expected to use that right to become members of CBOE. Confirming this, during the entire time the Exercise Right has been in effect the percentage of CBOT Full Members who exercised has averaged 33.12%, and has never exceeded 52.85%. During the year ended December 31, 2004, the percentage of CBOT Full Members who exercised ranged from a high of 29.24% to a low of 25.53%.

Neither the restructuring and demutualization of CBOT nor the development of electronic trading was contemplated at the time the Exercise Right was first established, nor were they addressed in the 1992 Agreement. On the other hand, CBOE believes both have the potential to increase the number of exercise members of CBOE by changing the nature of CBOT full membership in ways different than were intended when the Exercise Right was established. In order to permit the Exercise Right to remain available to CBOT Full Members and Full Member Delegates following the proposed restructuring of CBOT in a manner consistent with what CBOE believes was its original intent, CBOE (with CBOT's concurrence) proposes to interpret its rules governing the Exercise Right (*i.e.*, Article Fifth(b) and the interpretation thereof embodied in the 1992 Agreement) that takes these unforeseen circumstances into account.

CBOE's interpretation of the Exercise Right embodied in the 2001 Agreement as amended is based upon specified agreements made by CBOT Holdings and CBOT. These include the agreement of CBOT and CBOT Holdings to take various measures to promote the value of CBOT membership while at the same time to limit the ability of CBOT members and their delegates to trade as members on CBOT and CBOE concurrently, in order to reduce the likelihood of a mass exercise under circumstances that CBOE believes were not contemplated when the Exercise Right was established. These measures include restricting the ability of

[11] *See supra* notes 4–7 and accompanying text.

exercising CBOT members to have preferred member access to the CBOT's electronic trading platform while they are present on the CBOE trading floor or are logged on to the CBOE electronic platform. If either of these circumstances applies, the exercising members may access CBOT's electronic platform only in the capacity of nonmember customers. Similarly, CBOT agreed that any CBOT Full Member Delegates who have exercised may trade on CBOT's electronic platform only as customers.

The 2001 Agreement as amended also reflects the agreement of CBOT to modify its rules effective not later than December 1, 2004, to preclude any Full Member of CBOT who is also an exerciser member of CBOE from trading on the trading floor of CBOT as a member of CBOT at any time when the member is logged on to CBOE's electronic trading platform.[12] This latter restriction does not apply to a CBOT Full Member who owns more than one CBOT membership, at least one of which has not been delegated or, in the case of a CBOT Full Membership, used to acquire a CBOE membership by exercise. Finally, the 2001 Agreement as amended provides that if a CBOT Full Member delegates his only CBOT Full Membership to a delegate who exercises, the CBOT Full Member has no right to exercise and may trade on CBOE only as a customer.

The revised terms of the proposed restructuring of CBOT increase the likelihood that following the restructuring of CBOT, subject to the ''second approval'' of the stockholders of CBOT Holdings referred to above, there may be additional issuances of shares of CBOT Holdings Class A Common Stock. In order to prevent the value of the 27,338 shares of CBOT Holdings Class A common stock issued to CBOT Full Members in the restructuring from being diluted as a result of certain below-market issuances to CBOT Full Members, CBOT has agreed that, subject to limited exceptions, no such shares will be issued to CBOT Full Members unless a recognized, independent investment bank or valuation firm has rendered an opinion that the consideration to be received by CBOT Holdings in connection with any such additional issuance is fair to the issuer from a financial point of view, or unless the shares are issued for a consideration that is not less than the consideration received by CBOT Holdings in connection with any concurrent or related issuance for a bona fide business purpose to a person who is not a CBOT Full Member, or unless the consideration is not less that the average of the closing prices of CBOT Holdings Class A Common Stock as reported in the Consolidated Quotation System.

In order to make these restrictions on exercising members and delegates effective for their intended purpose, the 2001 Agreement as amended provides that the application of CBOE's interpretation of the exercise right to the CBOT's holding company structure is conditioned on CBOT and CBOT Holdings meeting obligations to maintain meaningful fee preferences for the members and delegates of CBOT as compared with the fees payable by nonmember customers, and to maintain other incentives to support the value of CBOT Full Membership. In the original 2001 Agreement, these were the direct obligations of CBOT. In the 2001 Agreement as amended, CBOT Holdings is obligated to cause CBOT, as its subsidiary, to comply fully with its obligations under the 2001 Agreement, and not to take any action, directly or indirectly, that if taken by CBOT itself would amount to a violation of the terms of the 2001 Agreement, or that would cause the various incentives to promote the continued value of CBOT membership, including member and delegate fee preferences and pit closing provisions and seat ownership requirements for CBOT clearing firms as described in the 2001 Agreement, to no longer be meaningful for the purpose stated in the 2001 Agreement.

The 2001 Agreement as amended provides that if disagreements arise between CBOE and CBOT or CBOT Holdings as to whether meaningful fee preferences and other incentives are being maintained, the matter will be referred to arbitration. The arbitrators are authorized to determine whether meaningful member and delegate fee preferences remain in effect, and if not, to specify a remedy for CBOT's or CBOT Holdings' failure to maintain them and to specify how they must be restored. The arbitrators are also authorized to prescribe the consequences of any failure by the CBOT or by CBOT Holdings to take any action required under the remedy specified by the arbitrators within 30 days of the arbitrators' decision.

To facilitate administration of the 2001 Agreement as amended, each party has agreed to provide to the other information regarding the status of members, including exercisers, on a current and continuing basis. CBOE represents that the CBOT has also agreed to amend its rules to implement the provisions of the 2001 Agreement as amended.

2. Statutory Basis

CBOE represents that the interpretation of the Exercise Right embodied in the 2001 Agreement as amended and the conforming amendment to CBOE Rule 3.16 that together constitute the proposed rule change are consistent with and further the objectives of the Act, as amended, and Section 6(b)(5) of the Act[13] in particular, in that they constitute an interpretation of and an amendment to the rules of the Exchange that are designed to promote just and equitable principles of trade, to perfect the mechanisms of a free and open market, and to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Although no written comments were solicited or received with respect to the proposed rule change in its present form, comments were received from some members in respect of the prior filing of the interpretation of Article Fifth(b) embodied in the 2001 Agreement that has since been withdrawn, and on August 30, 2001, 10 members of the CBOE filed suit in the Circuit Court of Cook County, Illinois seeking a temporary restraining order and preliminary injunction against the CBOE and the CBOT that would prevent CBOE from implementing the 2001 Agreement.[14] The allegations made by these commenters and by the plaintiffs in the dismissed lawsuit raised essentially the same procedural issue, which involved characterizing the 2001 Agreement not as an interpretation of Article Fifth(b), but as an amendment to that Article. Since by its terms Article Fifth(b) may be amended only with the approval of 80% of the exerciser members of CBOE and 80% of the non-exerciser members of CBOE, these commenters and the plaintiffs in the lawsuit took the position that the 2001 Agreement was invalid.

[12] CBOE represents that the CBOT has already implemented this modification of its rules.

[13] 15 U.S.C. 78f(b)(5).

[14] On September 17, 2001, the Court granted CBOE's and CBOT's motions to dismiss this lawsuit.

Since this same procedural issue may again be raised in comments on the proposed rule change, CBOE will repeat here the substance of what it previously said when this issue was raised in the context of the prior filing of the interpretation of Article Fifth(b) embodied in the 2001 Agreement.

CBOE believes any allegation that the 2001 Agreement or the interpretation of Article Fifth(b) embodied therein reflects an amendment of Article Fifth(b), and not an interpretation of that Article, is entirely without merit. The interpretation embodied in the 2001 Agreement does not change either the language or intended meaning of Article Fifth(b), but instead provides an interpretation of that Article to deal with circumstances involving the proposed restructuring of CBOT that were not contemplated or addressed in that Article or in any prior interpretations of that Article.

Exactly the same kind of interpretation of Article Fifth(b) was embodied in the 1992 Agreement and in the 2003 Agreement and was the subject of SR–CBOE–2002–41. Each of these prior interpretations addressed circumstances that were not contemplated when Article Fifth(b) was adopted, and were not addressed in the terms of that Article. Because CBOE had no choice but to interpret Article Fifth(b) in response to these changed circumstances, and because these interpretations did not amend the terms of that Article, none of these prior interpretations was submitted to an 80% class vote of the CBOE membership as would have had to be done if they had been treated as an amendment to that Article. They were, however, filed by CBOE and approved by the Commission as interpretations of an existing rule constituting a rule change under Section 19(b) of the Act and Rule 19b–4 thereunder.[15]

Just as issues resulting from unanticipated changes at CBOT were addressed in 1992, CBOE believes the proposed restructuring of CBOT, in which the existing rights of CBOT Full Members will be changed into rights of stockholders in a new holding company and into trading and limited voting rights in a reorganized for profit subsidiary of the holding company, raises unanticipated issues concerning who if anyone should be viewed as a Full Member of CBOT entitled to the Exercise Right following the restructuring. CBOE believes these issues can be resolved only by CBOE's interpreting how Article Fifth(b) will apply under these changed circumstance. Such an interpretation is embodied in the 2001 Agreement as amended, and it, together with a conforming amendment to Rule 3.16, constitutes the proposed rule change filed hereby. Neither this interpretation of Article Fifth(b) nor the proposed change to Rule 3.16 makes any changes to the text of Article Fifth(b) nor are they in any way inconsistent with that Article. Instead, they simply interpret Article Fifth(b) so it may operate as intended in circumstances that CBOE believes were not contemplated at the time that Article was drafted or was previously interpreted.

If CBOE were not able to interpret Article Fifth(b) under unanticipated changed circumstances without satisfying the 80% class vote requirements that apply in the case of an amendment to that Article, CBOE would be placed on the horns of a dilemma. If an interpretation did not achieve the 80% approval of each class of voting members, the interpretation could not be enforced. However, CBOE would still need to know how the Exercise Right should apply under the changed circumstances. But under the view that any interpretation CBOE might adopt in such circumstances must be treated as an amendment to Article Fifth(b), CBOE could be paralyzed because conceivably no interpretation would receive the necessary vote. In other words, where CBOE has no choice but to interpret Article Fifth(b) in response to unanticipated changed circumstances and where its interpretation is entirely consistent with that Article, CBOE must be able to make such an interpretation without having to satisfy the requirements that would apply if Article Fifth(b) were being amended.

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 Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2005–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–CBOE–2005–19. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 also will be available for inspection and copying at the principal office of the CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2005–19 and should be submitted on or before April 28, 2005.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[16]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1587 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[15] *See supra* notes 3–7.

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51462; File No. SR–CBOE–2005–20]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Proposed Rule Change and Amendment No. 1 Thereto Relating to an Interpretation of Paragraph (b) of Article Fifth of Its Certificate of Incorporation and an Amendment to Rule 3.16(b)

March 31, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on March 9, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. On March 28, 2005, the Exchange submitted Amendment No. 1 to the proposed rule change.[2] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of an interpretation of paragraph (b) of Article Fifth of the Certificate of Incorporation of the CBOE pertaining to the right of the 1,402 Full Members of the Board of Trade of the City of Chicago, Inc. (the ''CBOT'') to become members of the CBOE without having to purchase a CBOE membership (''Exercise Right''). This interpretation of the Exercise Right is embodied in an Agreement dated October 7, 2004 (''2004 Agreement'') between the CBOE and the CBOT and in a related proposed amendment to CBOE Rule 3.16. The 2004 Agreement reflects the agreement of the CBOE and the CBOT concerning the nature and scope of the Exercise Right in light of the expanded operation of the CBOT's electronic trading system. The text of the 2004 Agreement is attached as Exhibit 3 to the CBOE's Form 19b–4, and the opinion letter of CBOE's special Delaware counsel is attached as Exhibit 3b to the CBOE's Form 19b–4. The text of the proposed rule change, including the above-referenced Exhibits and Amendment No. 1, is available on CBOE's Web site [*http://www.cboe.org/Legal/SubmittedSECFilings.aspx*], at the CBOE's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE 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

1. Purpose

The purpose of the proposed rule change is to provide an interpretation of the rules of the CBOE as set forth in paragraph (b) of Article Fifth of the CBOE Certificate of Incorporation (''Article Fifth(b)'') concerning the effect on the Exercise Right of the expansion of CBOT's electronic trading platform. The source of the Exercise Right is Article Fifth(b), which provides in part that ''every present and future member of [CBOT] who applies for membership in the [CBOE] and who otherwise qualifies shall, so long as he remains a member of said Board of Trade, be entitled to be a member of the [CBOE] notwithstanding any such limitation on the number of members and without the necessity of acquiring such membership for consideration or value from the [CBOE], its members or elsewhere.'' This filing does not propose to amend Article Fifth(b), but only to interpret how it should apply in circumstances that CBOE believes were not envisioned at the time Article Fifth(b) was adopted and therefore were not addressed in the language of that Article.

Expanded electronic trading on CBOT carries with it with the potential for providing open access to the CBOT market over the electronic platform on substantially the same terms to members and nonmembers alike. This raises the possibility that CBOT members will no longer need the trading rights provided by their memberships in order to be able to trade CBOT products, in which event they would be free to sell or delegate their CBOT memberships to persons who would exercise them to become CBOE members, or to become CBOE exerciser members themselves, while still retaining the right to trade on CBOT's open access electronic platform. Accordingly, expanded electronic trading of CBOT products could facilitate the ability of CBOT members or their delegates to trade on CBOT as members and on CBOE as exercise members concurrently, since physical presence on the CBOT trading floor would not be required to trade CBOT products that are available in the electronic system.

For these reasons, CBOE believes expanded electronic trading on CBOT could result in a mass exercise by CBOT Full Members to an extent never contemplated at the time the Exercise Right was first established. When the Exercise Right was first established, the only way a CBOT Full Member who was also a member of CBOE could trade as a member of both exchanges was to physically move from one exchange's trading floor to another. Although the proximity of the two trading floors made this theoretically possible, few CBOT Full Members have ever attempted to trade on both floors in this way. CBOE believes a principal reason for this is because a CBOT member who is also a CBOE member would find it difficult to fulfill his obligations to both exchanges, as well as to manage the positions resulting from his trading, if he frequently had to be absent from one exchange's trading floor because of a need to be on the other exchange's floor. Therefore, although the Exercise Right has always been available to all 1,402 CBOT Full Members, it was inherent in the nature of exchange trading at the time Article Fifth(b) was adopted that only a fraction of CBOT Full Members would be expected to use that right to become members of CBOE. This is confirmed by the fact that during the entire time the Exercise Right has been in effect the percentage of CBOT Full Members who have exercised has averaged 33.12%, and has never exceeded 52.85%. During the year ended December 31, 2004, the percentage of CBOT Full Members who

[1] 15 U.S.C. 78s(b)(1).

[2] Due to a pending motion to reconsider the Commission's approval of SR–CBOE–2004–16, which was submitted on March 7, 2005, Amendment No. 1 removed certain language from the text of CBOE Rule 3.16(b) that was included with the original filing to reflect the stay of effectiveness of the text added by SR–CBOE–2004–16 pending a final Commission determination of the motion to reconsider. Accordingly, Amendment No. 1 revised the proposed rule change to reflect the text of CBOE Rule 3.16 as currently in effect, without the language added to the Rule by SR–CBOE–2004–16, and as it is proposed to be modified by the current rule filing. Amendment No. 1 also adds Exhibit 3b to the filing, which consists of an opinion letter received by CBOE from its special Delaware counsel that pertains to the proposed rule change.

exercised ranged from a high of 29.24% to a low of 25.53%.

In order to permit the Exercise Right to remain available to CBOT Full Members in a manner consistent with what CBOE believes was its original intent, CBOE (with CBOT's concurrence) proposes to interpret Article Fifth(b) to take into account the development and expansion of electronic trading that were not anticipated at the time that Article was adopted, and thus are not addressed in the language of that Article.

In 2001, concurrently with announcing the planned expansion of electronic trading in its market, CBOT also announced a proposed strategic restructuring of that exchange that would have changed CBOT from a non-profit membership corporation to a for-profit stock corporation to be owned by its former members as stockholders (subsequently revised to make CBOT a for-profit subsidiary of a for-profit holding company to be owned by the former members). CBOE believed that the proposal to restructure CBOT was also not anticipated when Article Fifth(b) was adopted, and that it created a separate need for CBOE to interpret how Article Fifth(b) would apply when former members of CBOT became stockholders of a new holding company.

For these reasons, in early 2001 CBOE entered into discussions with CBOT in an effort to reach agreement regarding how CBOE would interpret Article Fifth(b) in response to both of these developments at CBOT. These discussions resulted in an agreement between CBOE and CBOT, entered into as of August 1, 2001 (the ''2001 Agreement''), that embodied CBOE's interpretation of Article Fifth(b) in response to both developments. That interpretation, as subsequently modified to reflect several revisions to CBOT's proposed restructuring, was filed by CBOE as a proposed rule change under Rule 19b–4 of the Act in SR–CBOE–2002–01.

Prior to and during the time SR–CBOE–2002–01 was on file at the Commission, CBOT's proposed restructuring was the subject of litigation between CBOT and certain of its members. Although this litigation did not involve CBOE and was not related to the Exercise Right, CBOT's proposed restructuring was delayed while the litigation was pending. For this reason, at CBOE's request, the Commission deferred acting on SR–CBOE–2002–01, and on April 6, 2004, when it remained uncertain when CBOT would be able to go forward with its restructuring, CBOE formally withdrew that filing. Recently, following the settlement on September 20, 2004, of the litigation that had delayed the CBOT's proposed restructuring and the effectiveness on February 14, 2005, of the registration statement of CBOT Holdings, Inc. needed to permit the members of the CBOT to vote on the proposed restructuring, on March 7, 2005, CBOE refiled the interpretation of Article Fifth(b) embodied in the 2001 Agreement.[3]

Although the interpretation embodied in the 2001 Agreement addresses the expansion of electronic trading as well as the proposed restructuring of the CBOT, that interpretation can become effective, subject to Commission approval, only upon the effectiveness of the CBOT's restructuring. Because expanded electronic trading may have an impact on the Exercise Right as described above independent of whether the restructuring of the CBOT becomes effective, CBOE believes it must interpret Article Fifth(b) to address the expansion of electronic trading at CBOT in a way that is not conditioned on the effectiveness of the proposed restructuring of CBOT. For this reason, in late 2004 CBOE and CBOT entered into discussions in an attempt to reach agreement on an interpretation of Article Fifth(b) by CBOE that would be solely in response to expanded electronic trading and would be completely independent of the restructuring of CBOT. As a result of these discussions, CBOE and CBOT entered into the 2004 Agreement. The interpretation of Article Fifth(b) embodied in the 2004 Agreement, together with a related amendment to CBOE Rule 3.16(b), constitutes the proposed rule change that is the subject of this filing.

The interpretation of Article Fifth(b) embodied in the 2004 Agreement mirrors that aspect of the interpretation embodied in the 2001 Agreement that addressed the expansion of electronic trading to the effect that the Exercise Right would continue to be available to CBOT Full Members notwithstanding the development of electronic trading and related changes to trading hours and access policies that may be made by either exchange, if certain conditions are satisfied. Included among these conditions is the agreement of CBOT to take various measures to promote the value of CBOT membership while at the same time to limit the ability of CBOT members and their delegates to trade as members on CBOT and CBOE concurrently, in order to reduce the likelihood of a mass exercise under circumstances that CBOE believes were not contemplated when the Exercise Right was established. These measures include restricting the ability of exercising CBOT members to have preferred member access to the CBOT's electronic trading platform while they are present on the CBOE trading floor or are logged on to the CBOE electronic platform. If either of these circumstances applies, the exercising members may access CBOT's electronic platform only in the capacity of nonmember customers. Similarly, CBOT agreed that any CBOT Full Member Delegates who have exercised may trade on CBOT's electronic platform only as customers. Finally, the 2004 Agreement provides that if a CBOT Full Member delegates his only CBOT Full Membership to a delegate who exercises, the CBOT Full Member has no right to exercise and may trade on CBOE only as a customer.

Like the 2001 Agreement, the 2004 Agreement includes the agreement of CBOT to modify its rules effective not later than December 1, 2004, to preclude any Full Member or Full Member Delegate of CBOT who is also an exercise member of CBOE from trading as a member on the trading floor of CBOT at any time when the member is logged on to CBOE's electronic trading platform. (The CBOE represents that the CBOT has adopted such a rule.) This latter restriction does not apply to a CBOT Full Member who owns more than one CBOT membership, at least one of which has not been delegated or, in the case of a CBOT Full Membership, used to acquire a CBOE membership by exercise. Finally, the 2004 Agreement provides that if a CBOT Full Member delegates his only CBOT Full Membership to a delegate who exercises, the CBOT Full Member has no right to exercise and may trade on CBOE only as a customer.

In order to make these restrictions on exercising members and delegates effective for their intended purpose, the 2004 Agreement, like the 2001 Agreement, provides that the application of CBOE's interpretation of the exercise right embodied therein is conditioned on CBOT's maintaining meaningful fee preferences for the members and delegates of CBOT as compared with the fees payable by nonmember customers, and maintaining other incentives to support the value of CBOT Full Membership. The 2004 Agreement provides that if disagreements arise between CBOE and CBOT as to whether meaningful fee preferences and other incentives are being maintained, the matter will be

[3] *See* Securities Exchange Act Release No. 51463 (March 31, 2005) providing notice of File No. SR–CBOE–2005–19.

referred to arbitration. The arbitrators are authorized to determine whether meaningful member and delegate fee preferences are being maintained, and if not, to specify a remedy for CBOT's failure to maintain them and to specify how they must be restored. The arbitrators are also authorized to prescribe the consequences of any failure by the CBOT to take any action required under the remedy specified by the arbitrators within 30 days of the arbitrators' decision. The CBOE represents that the CBOT has agreed to amend its rules to implement the provisions of the 2004 Agreement.

This interpretation of Article Fifth(b) does not displace other interpretations of Article Fifth(b) previously adopted by CBOE and approved by the Commission to address other unanticipated changed circumstances. These consist of the interpretation embodied in an agreement between CBOE and CBOT dated as of September 1, 1992, filed in SR–CBOE–92–42, an interpretation filed in SR–CBOE–2002–41, and an interpretation embodied in an agreement between CBOE and CBOT dated as of December 17, 2003, filed in SR–CBOE–2004–16.[4] Because existing CBOE Rule 3.16 refers to all of the interpretations of Article Fifth(b), the proposed rule change also includes an amendment to that Rule to add a reference to this latest interpretation.

2. Statutory Basis

The CBOE represents that the interpretation of the Exercise Right embodied in the 2004 Agreement and the conforming amendment to CBOE Rule 3.16 that together constitute the proposed rule change are consistent with and further the objectives of the Act, as amended, and Section 6(b)(5) of the Act[5] in particular, in that they constitute an interpretation of and an amendment to the rules of the Exchange that are designed to promote just and equitable principles of trade, to perfect the mechanisms of a free and open market, and to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change. Comments were received from some members in respect of the prior filing of the interpretation of Article Fifth(b) embodied in the 2001 Agreement, and on August 30, 2001, ten members of the CBOE filed suit in the Circuit Court of Cook County, Illinois seeking a temporary restraining order and preliminary injunction against the CBOE and the CBOT that would prevent CBOE from implementing the 2001 Agreement.[6] The allegations made by these commenters and by the plaintiffs in the dismissed lawsuit raised essentially the same procedural issue, which involved characterizing the 2001 Agreement not as an interpretation of Article Fifth(b), but as an amendment to that Article. Since, by its terms, Article Fifth(b) may be amended only with the approval of 80% of the exerciser members of CBOE and 80% of the non-exerciser members of CBOE, these commenters and the plaintiffs in the lawsuit took the position that the 2001 Agreement was invalid.[7]

Although none of these allegations was directed toward the 2004 Agreement and the interpretation of Article Fifth(b) embodied therein that is the subject of this proposed rule change, the same procedural issue could be raised in response to the proposed rule change. Accordingly, CBOE will repeat here the substance of what it said when this issue was previously raised.

CBOE believes any allegation that the 2004 Agreement reflects an amendment of Article Fifth(b), and not an interpretation of that Article, is entirely without merit. The 2004 Agreement does not change either the language or intended meaning of Article Fifth(b), but instead provides an interpretation of that Article to deal with circumstances brought about by the expansion of electronic trading on CBOT that were not contemplated or addressed in the language of that Article or in any of CBOE's prior interpretations of that Article.

Exactly the same kind of interpretation of Article Fifth(b) was embodied in the 1992 Agreement and the 2003 Agreement and was the subject of SR–CBOE–2002–41. Each of these three prior interpretations addressed circumstances that were not contemplated when Article Fifth(b) was adopted, and were not addressed in the terms of that Article. Because CBOE had no choice but to interpret Article Fifth(b) in response to these changed circumstances, and because these interpretations did not amend the terms of that Article, none of these prior interpretations was submitted to an 80% class vote of the CBOE membership as would have had to be done if they had been treated as amendments to that Article. They were, however, filed by CBOE and approved by the Commission as interpretations of an existing rule constituting a rule change under Section 19(b) of the Act and Rule 19b–4 thereunder.[8]

CBOE believes the expansion of electronic trading on CBOT, absent appropriate safeguards, raises the potential for a mass exercise by most or all of the 1,402 Full Members of CBOT in a manner that would be inconsistent with how the Exercise Right was expected to operate at the time it was adopted. To prevent this from happening, CBOE believes it is again necessary for it to interpret how Article Fifth(b) will apply in light of this unanticipated changed circumstance as it has done before when faced with different changed circumstances at CBOT. Such an interpretation of the Exercise Right by CBOE is embodied in the 2004 Agreement, and it, together with a conforming amendment to Rule 3.16, constitutes the proposed rule change filed hereby. CBOE represents that neither this interpretation of Article Fifth(b) nor the proposed change to Rule 3.16 makes any changes to the text of Article Fifth(b), nor are they in any way inconsistent with the language of that Article. Instead, they simply interpret Article Fifth(b) so it may operate as intended in circumstances that CBOE believes were not contemplated at the time that Article was drafted or was previously interpreted.

CBOE represents that if it is not able to interpret Article Fifth(b) under unanticipated changed circumstances without satisfying the 80% class vote requirements that apply in the case of an amendment to that Article, CBOE would be placed on the horns of a

[4] *See* Securities Exchange Act Release No. 32430 (June 8, 1993), 58 FR 32969 (June 14, 1993) (File No. SR–CBOE–1992–42); Securities Exchange Act Release No. 46719 (October 25, 2002), 67 FR 66689 (November 1, 2002) (File No. SR–CBOE–2002–41); and Securities Exchange Act Release No. 51252 (February 25, 2005), 70 FR 10442 (File No. SR–CBOE–2004–16). A motion for reconsideration of the Commission's order approving SR–CBOE–2004–16 was filed on March 7, 2005 and is currently pending before the Commission.

[5] 15 U.S.C. 78f(b)(5).

[6] On September 17, 2001, the Court granted CBOE's and CBOT's motions to dismiss this lawsuit.

[7] Similar allegations were made in the petition for Commission review of the approval by delegated authority of SR–CBOE–2004–16. *See supra* note 4.

[8] *See supra* note 4.

dilemma. If an interpretation did not achieve the 80% approval of each class of voting members, the interpretation could not be enforced. However, CBOE would still need to know how the Exercise Right should apply under the changed circumstances. But under the view that any interpretation CBOE might adopt in such circumstances must be treated as an amendment to Article Fifth(b), CBOE could be paralyzed because conceivably no interpretation would receive the necessary vote. In other words, where CBOE has no choice but to interpret Article Fifth(b) in response to changed circumstances and where its interpretation is entirely consistent with the language of Article Fifth(b), CBOE must be able to make such an interpretation without having to satisfy the requirements that would apply if Article Fifth(b) were being amended.

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 Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2005–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–CBOE–2005–20. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 also will be available for inspection and copying at the principal office of the CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2005–20 and should be submitted on or before April 28, 2005.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1591 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51468; File No. SR–CBOE–2005–18]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto by the Chicago Board Options Exchange, Incorporated Relating to a Fee Cap for Options Dividend Spread Transactions

April 1, 2005.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 2, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I, II, and III below, which items have been prepared by CBOE. On March 17, 2005, CBOE filed Amendment No. 1 to the proposed rule change.[3] CBOE designated the proposed rule change, as amended, as establishing or changing a due, fee, or other charge imposed by CBOE under section 19(b)(3)(A)(ii) of the Act,[4] and Rule 19b–4(f)(2) thereunder,[5] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fee Schedule to modify its fee cap on dividend spread transactions and to update the symbol for the Nasdaq-100 Index Tracking Stock. The text of the proposed rule change is available on CBOE's Web site *(http://www.cboe.com),* at the Office of the Secretary, CBOE, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The CBOE 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

1. Purpose

In July 2004, the Exchange implemented a program under which market-maker, firm and broker-dealer transaction fees associated with ''dividend spread'' transactions are

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 replaced and superseded the proposed rule change in its entirety. Telephone conversation between Jaime Galvan, Assistant Secretary, CBOE, and Steve L. Kuan, Attorney, Division of Market Regulation, Commission, on March 30, 2005. In Amendment No. 1, CBOE clarified that the effective date of the Fee Schedule is March 2, 2005, the date CBOE initially filed the proposed rule change. Further, CBOE proposed that the fee cap on dividend spread transactions operate on a pilot basis until September 1, 2005.

[4] 15 U.S.C. 78s(b)(3)(A)(ii).

[5] 17 CFR 240.19b–4(f)(2).

capped at $2,000 per dividend spread transaction.[6] CBOE defines a dividend spread as any trade done to achieve a dividend arbitrage between any two deep-in-the-money options. This program is similar to fee cap programs adopted by other exchanges.[7]

The Exchange proposes to amend its Fee Schedule to enhance its dividend spread fee cap program. Specifically, the Exchange proposes to cap market-maker, firm, and broker-dealer transaction fees at $2,000 for all dividend spread transactions executed on the same trading day in the same options class. The Exchange proposes to implement the enhanced fee cap program as a pilot program that will expire on September 1, 2005. The Exchange believes that enhancing the fee cap to accommodate these transactions will attract additional liquidity.

As is done under the current program, the Exchange will rebate transaction fees for qualifying transactions. Members who wish to benefit from the fee cap will be required to submit to the Exchange a rebate request form with supporting documentation (*e.g.*, clearing firm transaction data).

In addition, the Exchange proposes to update the Fee Schedule in various places to reflect the symbol change, from QQQ to QQQQ, that accompanied the transfer of the listing of the Nasdaq–100 Index Tracking Stock from the American Stock Exchange to the Nasdaq Stock Market.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, is consistent with section 6(b) of the Act[8], in general, and furthers the objectives of section 6(b)(4) of the Act,[9] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among CBOE members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change, as amended, will impose any burden on competition that is not necessary or appropriate in furtherance of purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change, as amended.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act[10] and subparagraph (f)(2) of Rule 19b–4 thereunder[11] because it establishes or changes a due, fee, or other charge imposed by the Exchange. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[12]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form *(http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2005–18 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–CBOE–2005–18. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site *(http://www.sec.gov/rules/sro.shtml).* 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 also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2005–18 and should be submitted on or before April 28, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E5–1600 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[6] *See* Securities Exchange Act Release No. 50175 (August 10, 2004), 69 FR 51129 (August 17, 2004) (SR–CBOE–2004–38).

[7] *See* Securities Exchange Act Release Nos. 48363 (August 19, 2003), 68 FR 51625 (August 27, 2003) (SR–PCX–2003–39); 48983 (December 23, 2003), 68 FR 75703 (December 31, 2003) (SR–Phlx–2003–80); and 49358 (March 3, 2004), 69 FR 11469 (March 10, 2004) (SR–Amex–2004–09).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(2).

[12] For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change under section 19(b)(3)(C) of the Act, the Commission considers that period to have commenced on March 17, 2005, the date the Exchange filed Amendment No. 1 to the proposed rule change. *See* 15 U.S.C. 78s(b)(3)(C)

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51465; File No. SR–CHX–2005–04]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment Nos. 1 and 2 Thereto by the Chicago Stock Exchange, Inc. To Clarify That Specialists May Not Charge Commissions With Respect to the Execution of CHXpress Orders

April 1, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 1, 2005, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On March 21, 2005, the Exchange filed Amendment No. 1 to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the proposed rule change.[3] On March 30, 2005, the Exchange filed Amendment No. 2 to the proposed rule change.[4] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules to clarify that a specialist is not permitted to charge a commission on the execution of CHXpress™ orders. The text of the proposed rule change is included below. Italics indicate new text; brackets indicate deletions.

ARTICLE XX

Regular Trading Sessions

* * * * *

Guaranteed Execution System and Midwest Automated Execution System

Rule 37. (a) No change to text.

(b) No change to text.

(1)–(10) No change to text.

(11) CHXpress Orders. This section applies to the execution and display of orders through CHXpress, an automated functionality offered by the Exchange. All other rules of the Exchange are applicable, unless expressly superseded by this section.

* * * * *

(H) A CHX specialist may not charge a commission for execution of a CHXpress order.

* * * * *

ARTICLE XXX

Specialists

* * * * *

Precedence to Orders in Book

RULE 2. The specialist, co-specialist and relief specialist shall at all times give precedence to orders in the book for purchase or sale of securities over the orders which originate with him or it as a dealer, provided, his or its orders and those of his or its customer are market orders, or limited orders at the same price. Notwithstanding the foregoing, whenever a specialist, co-specialist or relief specialist elects to accept a professional order for the book which is not required to be accepted by such specialist, co-specialist or relief specialist pursuant to the rules and polices of the Exchange, such specialist, co-specialist or relief specialist is not required to relinquish precedence to such order over the orders which originate with him or it as dealer, provided (a) his or its orders and those of his or its customer are limited orders at the same price and (b) the specialist, co-specialist or relief specialist is displaying his or its order, including its size, through the quotation system. [No specialist, co-specialist or relief specialist may charge a Participant a commission in any transaction in which he or it is a principal.]

** * * Interpretations and Policies*

.005 No specialist, co-specialist or relief specialist may charge a Participant a commission in any transaction in which such specialist, co-specialist or relief specialist is a principal, or for execution of any CHXpress order.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange 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

1. Purpose

The Exchange is rolling out a new, automated functionality for the handling of CHXpress orders. According to the Exchange, the CHXpress functionality is designed to provide additional opportunities for the Exchange's participants to seek and receive liquidity through automated executions of orders at the Exchange.[5] With a few exceptions, CHXpress orders will be executed immediately and automatically against same or better-priced orders in the specialist's book, or against the specialist's quote (when CHXpress is available).[6] If a CHXpress order cannot be immediately executed, it will be placed in the specialist's book for display or later execution.[7] A CHX specialist may not cancel or place a CHXpress order on hold or otherwise prevent the order-sending firm from canceling the order. In addition, CHX specialists do not provide CHXpress orders with the execution guarantees that might otherwise be available to agency limit orders.[8] Specifically, these orders are not eligible for automated price improvement, or execution based on quotes in the national market system or prints in the primary market for a security. CHX specialists also would not be required to seek liquidity for CHXpress orders in other markets.

Through this filing, the Exchange seeks to clarify that a CHX specialist would not be permitted to charge a commission in connection with the execution of a CHXpress order. The Exchange believes that this clarification is appropriate for several reasons. First, as noted above, the handling of these orders within the Exchange's systems is entirely automatic—orders can execute automatically and be displayed automatically. Moreover, CHX specialists would not provide CHXpress orders with the execution guarantees that might otherwise be available to agency limit orders. Specifically, these orders would not be eligible for automated price improvement, or execution based on quotes in the national market system or prints in the primary market for a security. A CHX specialist also would not act as agent for the orders in other markets.

2. Statutory Basis

The Exchange believes the proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[9] The Exchange believes the proposal is consistent with Section 6(b)(5) of the Act,[10] in that the

[3] *See* Form 19b–4, dated March 20, 2005 (''Amendment No. 1''), which replaced the original filing in its entirety.

[4] *See* Form 19b–4, dated March 30, 2005 (''Amendment No. 2''), which corrected an inadvertent reference to filing pursuant to Section 19(b)(3)(A) instead of Section 19(b)(2).

[5] *See* Securities Exchange Act Release No. 50481 (Sept. 30, 2004); 69 FR 60197 (Oct. 7, 2004) (SR–CHX–2004–12).

[6] If the execution of a CHXpress order would cause an improper trade-through of another ITS market, the CHXpress order would be automatically cancelled. If trading in an issue has been halted, all CHXpress orders in that issue would be automatically cancelled. *See* CHX Article XX, Rule 37(b)(11)(C).

[7] A CHXpress order will be instantaneously and automatically displayed when it constitutes the best bid or offer in the CHX book. *See* CHX Article XX, Rule 37(b)(11)(D). CHXpress orders, like all other orders at the Exchange, will not be eligible for automated display if that display would improperly lock or cross another ITS market. A CHXpress order that would improperly lock or cross the NBBO will be cancelled. Because CHXpress orders will be automatically displayed, there is no mechanism to allow them to be excluded from the CHX's quote.

[8] *See* CHX Article XX, Rule 37(b)(11)(E)–(F).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

proposal is designed to promote just and equitable principles of trade, to remove impediments, and to perfect the mechanism of, a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

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 Exchange consents, the Commission will:

(A) By order approve the 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, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–CHX–2005–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–CHX–2005–04. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CHX–2005–04 and should be submitted on or before April 28, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1584 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51456: File No. SR–NSX–2004–07]

Self-Regulatory Organizations; National Stock Exchange; Order Approving Proposed Rule Change Relating to Non-Member Give-Ups

March 31, 2005.

On August 31, 2004, the National Stock Exchange^{SM} (''NSX^{SM}'') submitted to the Securities and Exchange Commission (''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 relating to non-member give-ups. On December 3, 2004, the NSX^{SM} filed Amendment No. 1 to the proposed rule change. The Commission published the proposed rule change, as amended for comment in the **Federal Register** on December 29, 2004.[3] The Commission did not receive any comments on the proposed rule change.

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange.[4] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[5] which requires, among other things, that the rules of the NSX^{SM} be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The Commission believes that permitting NSX^{SM} members to give-up non-NSX^{SM} members' clearing numbers for purposes of clearing and settling trades should add transparency to trading on the NSX^{SM} and should eliminate unnecessary steps in clearing and settling these trades. The proposed rule requires that the NSX^{SM} member clearing firm accept financial responsibility for all transactions with non-members. It further requires non-members to enter into a contract consenting to the disciplinary jurisdiction of the NSX^{SM}. This requirement should provide an adequate level of control by the NSX^{SM} over non-members engaging in transactions on the NSX^{SM}.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[6] that the proposed rule change (SR–NSX–20004–07) be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1579 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 50898 (December 21, 2004), 69 FR 78028.

[4] In approving the proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51464; File No. SR–NYSE–2005–20]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the New York Stock Exchange, Inc. To Extend for Additional Four Months Its Pilot Program Permitting a Floor Broker To Use an Exchange Authorized and Provided Portable Telephone on the Exchange Floor

March 31, 2005.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 11, 2005, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I and II below, which items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange seeks to extend its pilot program that amends NYSE Rule 36 (Communication Between Exchange and Members' Offices) to allow a Floor broker's use of an Exchange authorized and provided portable telephone on the Exchange Floor upon approval by the Exchange (''Pilot'') for an additional four months, until July 31, 2005. The last extension of the Pilot was in effect on a four-month pilot basis expiring on March 31, 2005.[3] The text of the proposed rule change is available on the Exchange's Web site (*http://www.nyse.com*), at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The Exchange 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

1. Purpose

The Commission originally approved the Pilot to be implemented as a six-month pilot[4] beginning no later than June 23, 2003.[5] Since the inception of the Pilot, the Exchange has extended the Pilot three times, with the current Pilot expiring on March 31, 2005.[6] The Exchange represents that no regulatory actions or administrative or technical problems, other than routine telephone maintenance issues, have resulted from the Pilot over the past few months.[7] Therefore, the Exchange seeks to extend the Pilot for an additional four months, until July 31, 2005.

NYSE Rule 36 governs the establishment of telephone or electronic communications between the Exchange's Trading Floor and any other location. Prior to the Pilot, NYSE Rule 36.20 prohibited the use of portable telephone communications between the Trading Floor and any off-Floor location, and the only way that voice communication could be conducted by Floor brokers between the Trading Floor and an off-Floor location was by means of a telephone located at a broker's booth. These communications often involved a customer calling a broker at the booth for ''market look'' information. Prior to the Pilot, a broker could not use a portable phone at the point of sale in the trading crowd to speak with a person located off the Floor.

The Exchange proposes to extend the Pilot for an additional four months, expiring on July 31, 2005. The Pilot would amend NYSE Rule 36 to permit a Floor broker to use an Exchange authorized and issued portable telephone on the Floor. Thus, with the approval of the Exchange, a Floor broker would be permitted to engage in direct voice communication from the point of sale to an off-Floor location, such as a member firm's trading desk or the office of one of the broker's customers. Such communications would permit the broker to accept orders consistent with Exchange rules, provide status and oral execution reports as to orders previously received, as well as ''market look'' observations as have historically been routinely transmitted from a broker's booth location. Use of a portable telephone on the Exchange Floor other than one authorized and issued by the Exchange would continue to be prohibited.

Furthermore, both incoming and outgoing calls would continue to be allowed, provided the requirements of all other Exchange rules have been met. Under NYSE Rule 123(e), a broker would not be permitted to represent and execute any order received as a result of such voice communication unless the order was first properly recorded by the member and entered into the Exchange's Front End Systemic Capture (''FESC'') electronic database.[8] In addition, Exchange rules require that any Floor broker receiving orders from the public over portable phones must be properly qualified to engage in such direct access business under NYSE Rules 342 and 345, among others.[9]

Furthermore, orders in Investment Company Units (as defined in Section 703.16 of Listed Company Manual), also known as Exchange-Traded Funds (''ETFs'''), would also be subject to the same FESC requirements as orders in any other security listed on the Exchange.[10] As a result, the Pilot would

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 50777 (December 1, 2004), 69 FR 71090 (December 8, 2004) (SR–NYSE–2004–67).

[4] *See* Securities Exchange Act Release No. 47671 (April 11, 2003), 68 FR 19048 (April 17, 2003) (SR–NYSE–2002–11) (''Original Order'').

[5] *See* Securities Exchange Act Release No. 47992 (June 5, 2003), 68 FR 35047 (June 11, 2003) (SR–NYSE–2003–19) (delaying the implementation date for portable phones from on or about May 1, 2003 to no later than June 23, 2003).

[6] *See* Securities Exchange Act Release Nos. 48919 (December 12, 2003), 68 FR 70853 (December 19, 2003) (SR–NYSE–2003–38) (extending the Pilot for an additional six months ending on June 16, 2004); 49954 (July 1, 2004), 69 FR 41323 (July 8, 2004) (SR–NYSE–2004–30) (extending the Pilot for an additional five months ending on November 30, 2004); and 50777, *supra* note 3.

[7] The Commission notes that the Exchange currently has not been receiving incoming telephone numbers from the telephone records of the Exchange authorized and provided portable telephones since the inception of the Pilot. Telephone conversation between Jeffrey Rosenstrock, Senior Special Counsel, NYSE, and Cyndi N. Rodriguez, Special Counsel, Division of Market Regulation (''Division''), Commission, dated March 31, 2005.

[8] *See* Securities Exchange Act Release No. 43689 (December 7, 2000), 65 FR 79145 (December 18, 2000) (SR–NYSE–98–25). *See also* Securities Exchange Act Release No. 44943 (October 16, 2001), 66 FR 53820 (October 24, 2001) (SR–NYSE–2001–39) (discussing certain exceptions to FESC, such as orders to offset an error or a bona fide arbitrage, which may be entered within 60 seconds after a trade is executed).

[9] *See* Information Memos 01–41 (November 21, 2001), 01–18 (July 11, 2001) (available on *http://www.nyse.com/regulation.html*) and 91–25 (July 8, 1991) for more information regarding Exchange requirements for conducting a public business on the Exchange Floor.

[10] Previously, under an exception to NYSE Rule 123(e), orders in ETFs could first be executed and then entered into FESC. However, in SR–NYSE–

continue to allow for the use of portable phones for orders in ETFs.[11]

The Exchange believes that an extension of the Pilot for an additional four months would enable the Exchange to provide more direct, efficient access to its trading crowds and customers, increase the speed of transmittal of orders and the execution of trades, and provide an enhanced level of service to customers in an increasingly competitive environment.[12] By enabling customers to speak directly to a Floor broker in a trading crowd on an Exchange authorized and issued portable telephone, the Exchange believes that the proposed rule change would expedite and make more direct the free flow of information which, prior to the Pilot, had to be transmitted somewhat more circuitously via the broker's booth.

In addition, NYSE Rule 36.20, both prior to the Pilot, and as proposed to be amended, would not apply to specialists who are prohibited from speaking from the post to upstairs trading desks or customers. The Exchange notes that specialists are subject to separate restrictions in NYSE Rule 36 on their ability to engage in voice communications from the specialist post to an off-Floor location.[13]

The Exchange represents that no regulatory actions or administrative or technical problems, other than routine telephone maintenance issues, have resulted from the Pilot since its inception.[14] The Exchange believes that the Pilot appears to be successful in that there is a reasonable degree of usage of portable phones, but as noted above, no regulatory, administrative, or other technical problems associated with their usage. The Exchange believes that the Pilot appears to facilitate communication on the Floor without any corresponding drawbacks. Therefore, the Exchange believes it is appropriate to extend the Pilot for an additional four months.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act[15] in general, and further the objectives of section 6(b)(5) of the Act[16] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that the amendment to NYSE Rule 36 would support the mechanism of free and open markets by providing for increased means by which communications to and from the Floor of the Exchange could take place.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to section 19(b)(3)(A) of the Act[17] and Rule 19b–4(f)(6) thereunder.[18] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The Exchange requests that the Commission waive the five-day pre-filing period and 30-day operative period under Rule 19b–4(f)(6)(iii).[19] The Exchange believes that the continuation of the Pilot is in the public interest as it will avoid inconvenience and interruption to the public. The Commission has waived the five-day pre-filing requirement for this proposed rule change. In addition, the Commission believes that it is consistent with the protection of investors and the public interest to waive the 30-day operative delay and make this proposed rule change immediately effective upon filing on March 11, 2005.[20] The Commission believes that the waiver of the 30-day operative delay will allow the Exchange to continue, without interruption, the existing operation of its Pilot until July 31, 2005.

The Commission notes that proper surveillance is an essential component of any telephone access policy to an Exchange Trading Floor. Surveillance procedures should help to ensure that Floor brokers who are interacting with the public on portable phones are authorized to do so, as NYSE Rule 36 requires,[21] and that orders are being handled in compliance with NYSE rules. The Commission expects the Exchange to actively review these procedures and address any potential concerns that have arisen during the extension of the Pilot. In this regard, the Commission notes that the Exchange should address whether telephone records, including incoming telephone records, are adequate for surveillance purposes.

The Commission also requests that the Exchange report any problems, surveillance, or enforcement matters associated with the Floor brokers' use of an Exchange authorized and provided portable telephone on the Floor. As stated in the Original Order, the NYSE should also address whether additional

2003–09, the Exchange eliminated the exception to NYSE Rule 123(e) for ETFs, and, as part of its proposal in SR–NYSE–2002–11, allowed the use of portable phones for orders in ETFs. *See* Securities Exchange Act Release No. 47667 (April 11, 2003), 68 FR 19063 (April 17, 2003). NYSE Rule 123(e) provides that all orders in any security traded on the Exchange be entered into FESC before they can be represented in the Exchange's auction market.

[11] Telephone conversation between Jeffrey Rosenstrock, Senior Special Counsel, NYSE, and Cyndi N. Rodriguez, Special Counsel, Division, Commission, dated March 31, 2005.

[12] *See, e.g.*, Securities Exchange Act Release Nos. 43493 (October 30, 2000), 65 FR 67022 (November 8, 2000) (SR–CBOE–00–04) (expanding the Chicago Board Options Exchange, Inc.'s existing policy and rules governing the use of telephones at equity option trading posts by allowing for the receipt of orders over outside telephone lines from any source, directly at equity trading posts) and 43836 (January 11, 2001), 66 FR 6727 (January 22, 2001) (SR–PCX–00–33) (discussing and approving the Pacific Exchange, Inc.'s proposal to remove current prohibitions against Floor brokers' use of cellular or cordless phones to make calls to persons located off the trading floor).

[13] *See* Securities Exchange Act Release No. 46560 (September 26, 2002), 67 FR 62088 (October 3, 2002) (SR–NYSE–00–31) (discussing restrictions on specialists' communications from the post).

[14] The Exchange provided pilot program results that were noticed in SR–NYSE–2004–67, *supra* note 3. The Commission expects the Exchange to provide updated figures to the Commission during the extension of the Pilot.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6).

[19] 17 CFR 240.19b–4(f)(6)(iii).

[20] For purposes only of waiving the 30-day operative delay of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[21] *See* note 9 *supra* and accompanying text for other NYSE requirements that Floor brokers be properly qualified before doing public customer business.

surveillance would be needed because of the derivative nature of the ETFs. Furthermore, in any future additional filings on the Pilot, the Commission would expect that the NYSE submit information documenting the usage of the phones, any problems that have occurred, including, among other things, any regulatory actions or concerns, and any advantages or disadvantages that have resulted.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2005–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NYSE–2005–20. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2005–20 and should be submitted on or before April 28, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E5–1599 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51454; File No. SR–ODD–2005–01]

Self-Regulatory Organizations; the Options Clearing Corporation; Order Granting Approval of Proposed Supplement to the Options Disclosure Document Regarding Volatility Options

March 30, 2005.

On March 29, 2005, the Options Clearing Corporation (''OCC'') submitted to the Securities and Exchange Commission (''Commission''), pursuant to Rule 9b–1 under the Securities Exchange Act of 1934 (''Act''),[1] five definitive copies of the supplement to its options disclosure document (''ODD'') to accommodate trading of options on any index intended to measure the predicted volatility of the daily returns of a stock index.[2]

The ODD currently contains general disclosures on the characteristics and risks of trading standardized options. Recently, an options exchange amended its rules to permit trading of volatility options.[3] This proposed supplement accommodates this change by amending the ODD to provide disclosure relating to indexes intended to measure the predicted volatility of the daily returns of a stock index (''volatility indexes'') and options on such volatility indexes (''volatility options'').[4]

Specifically, the proposed supplement amends existing general disclosure regarding the characteristics of indexes to include a description of the characteristics of volatility indexes. In addition, the proposed supplement adds a new section titled ''Volatility Indexes.'' This new section is being added to the ODD to discuss in detail the characteristics of volatility indexes and volatility options.[5] Finally, the proposed supplement amends the section of the ODD titled ''Special Risks of Index Options'' to include disclosure relating to the risks associated with the purchase and sale of volatility options.[6]

The Commission has reviewed the proposed supplement and finds that it complies with Rule 9b–1 under the Act.[7] The proposed supplement is intended to be read in conjunction with the more general ODD, which, as described above, discusses the characteristics and risks of options generally.

Rule 9b–1(b)(2)(i) under the Act[8] provides that an options market must file five copies of an amendment or supplement to the ODD with the Commission at least 30 days prior to the date definitive copies are furnished to customers, unless the Commission determines otherwise, having due regard to the adequacy of information disclosed and the public interest and protection of investors.[9] In addition, five definitive copies shall be filed with the Commission not later than the date the amendment or supplement, or the amended options disclosure document, is furnished to customers. The Commission has reviewed the proposed supplement, and finds, having due regard to the adequacy of the information disclosed, it is consistent with the protection of investors and in the public interest to allow the distribution of this document as of the date of this order.

It is therefore ordered, pursuant to Rule 9b–1 under the Act,[10] that the proposed supplement (SR–ODD–2005–01), which provides disclosure relating to volatility indexes and volatility options, is approved. The Commission has also determined that definitive

---

[22] 17 CFR 200.30–3(a)(12).

[1] 17 CFR 240.9b–1.

[2] *See* letter from James R. McDaniel, Sidley Austin Brown & Wood LLP, to Sharon Lawson, Senior Special Counsel, Division of Market Regulation, Commission, dated March 23, 2005 (''OCC letter'').

[3] *See* Securities Exchange Act Release Nos. 49563 (April 14, 2004), 69 FR 21589 (April 21, 2004) (approving File No. SR–CBOE–2003–40), and 49698 (May 13, 2004), 69 FR 29152 (May 20, 2004) (approving File No. SR–CBOE–2004–09).

[4] *See* OCC Letter, *supra* note 2.

[5] The Commission notes that the ODD will take existing disclosure on stock indexes and options on stock indexes and move it to a new, separate section titled ''Stock Indexes.''

[6] The Commission notes that OCC must continue to ensure that the ODD is in compliance with the requirements of Rule 9b–1(b)(2)(i) under the Act, 17 CFR 240.9b–1(b)(2)(i), including when future changes relating to volatility indexes or volatility options are made. In addition, the Commission notes that any changes to the rules of the exchanges concerning volatility indexes or volatility options would need to be submitted to the Commission under Section 19(b) of the Act. 15 U.S.C. 78s(b).

[7] 17 CFR 240.9b–1.

[8] 17 CFR 240.9b–1(b)(2)(i).

[9] This provision is intended to permit the Commission either to accelerate or extend the time period in which definitive copies of a disclosure document may be distributed to the public.

[10] 17 CFR 240.9b–1.

copies can be furnished to customers as of the date of this order.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1581 Filed 4–6–05; 8:45 am]

BILLING CODE 8010–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before May 9, 2005. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: Agency Clearance Officer, Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and *David_Rostker@omb.eop.gov* or fax at 202–395–7285, Office of Management and Budget, Office of Information and Regulatory Affairs.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, *Jacqueline.white@sba.gov* (202) 205–7044.

SUPPLEMENTARY INFORMATION:

Title: Lenders Transcript of Account.

Form No: SBA Form 1149.

Frequency: On occasion.

Description of Respondents: SBA Lenders.

Responses: 3,600.

Annual Burden: 3,600.

Jacqueline K. White,

Chief, Administrative Information Branch.

[FR Doc. 05–6897 Filed 4–6–05; 8:45 am]

BILLING CODE 8025–01–P

[11] 17 CFR 200.30–3(a)(39).

DEPARTMENT OF STATE

[Public Notice 5042]

Bureau of Educational and Cultural Affairs; English Language Fellow Program for Academic Year 2006–2007

ACTION: This announcement amends the Request for Grant Proposals (RFGP) in support of Funding Opportunity Number ECA/A/L–06–01, ''English Language Fellow Program for Academic Year 2006–2007'' published in the **Federal Register** on March 10, 2005.

SUMMARY: Pending the availability of FY–2006 funds, the office anticipates revisions to the original program design as follows:

(1) Under Award Information, Section II: Approximate total funding available may increase from $6,000,000 to $6,800,000. Proposals should be based on a level of $6.8 million. The Bureau still intends to make one award under this competition.

(2) Stipend levels as outlined in the Proposal Objectives, Goals and Implementation (POGI) document for this RFGP have been increased as follows:

- Fellows: from $18,500 to $25,000
- Senior Fellows: from $25,500 to $35,000

(3) All other terms and conditions contained in the original RFGP published on March 10, 2005 remain the same.

Additional Information: Interested U.S. organizations should contact Catherine Williamson at (202) 619–5878 for additional information.

The English Language Fellow Program was announced in the **Federal Register**, Volume 70, Number 46, on March 10, 2005.

Dated: April 4, 2005.

C. Miller Crouch,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 05–7045 Filed 4–6–05; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 5040]

Bureau of Educational and Cultural Affairs (ECA) Request for Grant Proposals: Serbia and Montenegro High School Exchange Program

Announcement Type: New Grant.

Funding Opportunity Number: ECA/PE/C/PY–05–57.

Catalog of Federal Domestic Assistance Number: 00.000.

Key Dates: Application Deadline: June 2, 2005.

Executive Summary: The Office of Citizen Exchanges' Youth Programs Division announces an open competition for a new program for high school students from Serbia and Montenegro. Public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3) may submit proposals to recruit and select high school students aged 15–17 from Serbia and Montenegro, place them with host families and schools for an academic semester or year of study in the United States, provide activities that will enable the students to learn about civic responsibility, community activism, democracy, and American society, as well as to educate Americans about their country and culture, and to support alumni in projects at home.

I. Funding Opportunity Description:

Authority

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Pub. L. 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is ''to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations* * *and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world.'' The funding authority for the program above is provided through legislation. The funding authority for the Serbia and Southeast Europe projects is provided through Support for East European Democracy (SEED) legislation.

Purpose

The goals of the program are to develop a sense of civic responsibility and commitment to community development among youth; to foster relationships among youth from different ethnic, religious, and national groups; to assist the successor generation of Serbia and Montenegro in developing the qualities it will need to lead in their aspirations for transformation in the 21st century; and to promote mutual understanding between the people of the United States

and the people of Serbia and Montenegro.

With these goals in mind, the Bureau of Educational and Cultural Affairs (ECA) is sponsoring this program to provide scholarships for secondary school students from Serbia and Montenegro to spend up to one academic year in the United States, living with U.S. host families and attending high school. Programmatic activities will introduce students to the principles of civic education, civil society, rule of law, community service, and youth leadership as they are practiced in the United States. Upon the students' return to Serbia and Montenegro, the program will continue to support the students with follow-on and alumni activities as they apply their experiences in the United States to their lives at home.

Applicants should identify specific objectives that will demonstrate progress toward the goals stated above through the program. These will be the basis of an evaluation designed to measure the program's success. Please see Section IV.3d.3. on program monitoring and evaluation.

Guidelines

Applicants should be able to implement the program components both in the United States and in Serbia and Montenegro (SAM). The organization must have an established office in Serbia and Montenegro and must be able to dedicate to this program key staff who possess a thorough understanding of the secondary school student J Exchange Visitor Program regulations.

Most student participants will arrive in their host communities during the month of August and remain for 10 or 11 months until their departure during the period of mid-May to early July. A modest start-up semester program will be offered the first year.

Proposed funding would support approximately 15 participants for a semester program in 2006 (January–June), and between 85 and 110 for each of the following two academic years (2006–07 and 2007–08). Approximately 25% of the total number should be recruited from the Republic of Montenegro; the rest should be recruited from all regions of the Republic of Serbia, excluding Kosovo.

Given the small number of participants in the semester program and the abbreviated timeframe, recruitment for this component should be focused on a few cities, to be determined in consultation with the embassy, rather than nationwide. Applicants should provide a Fall 2005 recruitment planning schedule for both the 2006 semester program and the 2006–07 academic year program.

The students will enroll in a U.S. high school and live with an American family, in many ways living like a typical American teenager and developing an understanding of U.S. life and culture. In addition to these firsthand experiences, students will participate in activities specifically designed to teach them about community life, citizen participation in a democracy, and U.S. culture during the exchange period. The focus of many of the students' enhancement activities while in the United States will include principles of civil society, community service, and leadership through focused training and facilitation. Participants will have the opportunity to give presentations on their country and culture in community forums.

Upon the students' return to Serbia and Montenegro, the program will continue to support them as they apply their experiences in the United States to their lives at home. The ability of the grant recipient to track and engage alumni is a critical factor in the success of the program. Appropriate financial and organizational support for the follow-on component for alumni is as important as the U.S. exchange.

II. Award Information

Type of Award: Grant Agreement.

Fiscal Year Funds: 2005.

Approximate Total Funding: $2,543,750.

Approximate Number of Awards: One.

Approximate Average Award: $2,543,750.

Anticipated Award Date: Proposed start date is August 2005.

Anticipated Project Completion Date: December 2008 (flexible).

Additional Information: Pending successful implementation of this program and the availability of funds in subsequent fiscal years, it is ECA's intent to renew this grant for two additional fiscal years, before openly competing it again.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3).

III.2. Cost Sharing or Matching Funds

There is no minimum or maximum percentage required for this competition. However, the Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

When cost sharing is offered, it is understood and agreed that the applicant must provide the amount of cost sharing as stipulated in its proposal and later included in an approved grant agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, you must maintain written records to support all costs which are claimed as your contribution, as well as costs to be paid by the Federal government. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110, (Revised), Subpart C.23—Cost Sharing and Matching. In the event you do not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced in like proportion.

III.3. Other Eligibility Requirements

Bureau grant guidelines require that organizations with less than four years experience in conducting international exchanges be limited to $60,000 in Bureau funding. ECA anticipates awarding one grant, in an amount up to $2,543,750 to support program and administrative costs required to implement this exchange program. Therefore, organizations with less than four years experience in conducting international exchanges are ineligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

IV. Application and Submission Information

Note: Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

IV.1. Contact Information To Request an Application Package

Please contact the Youth Programs Division, Office of Citizen Exchanges (ECA/PE/C/PY), U.S. Department of State, SA–44, 301 4th Street, SW., Room 568, Washington, DC 20547, telephone: (202) 203–7505, fax: (202) 203-7529; e-mail: *LantzCS@state.gov* to request a Solicitation Package. Please refer to the Funding Opportunity Number ECA/PE/C/PY–05–57 located at the top of this announcement when making your request.

The Solicitation Package contains the Proposal Submission Instruction (PSI) document which consists of required application forms, and standard guidelines for proposal preparation. It also contains the Project Objectives, Goals and Implementation (POGI) document, which provides specific information, award criteria and budget instructions tailored to this competition.

Please specify Program Officer Carolyn Lantz and refer to the Funding Opportunity Number located at the top of this announcement on all other inquiries and correspondence. Contact information is at the end of this announcement.

IV.2. To Download a Solicitation Package Via Internet

The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/education/rfgps/menu.htm.* Please read all information before downloading.

IV.3. Content and Form of Submission

Applicants must follow all instructions in the Solicitation Package. The original and seven copies of the application should be sent per the instructions under IV.3e. ''Submission Dates and Times'' section below.

IV.3a. You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the U.S. Government. This number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Please ensure that your DUNS number is included in the appropriate box of the SF–424 which is part of the formal application package.

IV.3b. All proposals must contain an executive summary, proposal narrative and budget.

Please Refer to the Solicitation Package. It contains the mandatory Proposal Submission Instructions (PSI) document and the Project Objectives, Goals and Implementation (POGI) document for additional formatting and technical requirements.

IV.3c. You must have nonprofit status with the IRS at the time of application. If your organization is a private nonprofit which has not received a grant or cooperative agreement from ECA in the past three years, or if your organization received nonprofit status from the IRS within the past four years, you must submit the necessary documentation to verify nonprofit status as directed in the PSI document. Failure to do so will cause your proposal to be declared technically ineligible.

IV.3d. Please take into consideration the following information when preparing your proposal narrative:

IV.3d.1 *Adherence to All Regulations Governing the J Visa.* The Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs is the official program sponsor of the exchange program covered by this RFGP, and an employee of the Bureau will be the ''Responsible Officer'' for the program under the terms of 22 CFR part 62, which covers the administration of the Exchange Visitor Program (J visa program). Under the terms of 22 CFR part 62, organizations receiving grants under this RFGP will be third parties ''cooperating with or assisting the sponsor in the conduct of the sponsor's program.'' The actions of grantee program organizations shall be ''imputed to the sponsor in evaluating the sponsor's compliance with'' 22 CFR part 62. Therefore, the Bureau expects that any organization receiving a grant under this competition will render all assistance necessary to enable the Bureau to fully comply with 22 CFR part 62 *et seq.*

The Bureau of Educational and Cultural Affairs places great emphasis on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by grantee program organizations and program participants to all regulations governing the J visa program status. Therefore, proposals should *explicitly state in writing* that the applicant is prepared to assist the Bureau in meeting all requirements governing the administration of Exchange Visitor Programs as set forth in 22 CFR part 62. If your organization has experience as a designated Exchange Visitor Program Sponsor, the applicant should discuss their record of compliance with 22 CFR part 62 *et seq.*, including the oversight of their Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, record-keeping, reporting and other requirements.

The Office of Citizen Exchanges of ECA will be responsible for issuing DS–2019 forms to participants in this program.

A copy of the complete regulations governing the administration of Exchange Visitor (J visa) programs is available at *http://exchanges.state.gov* or from:

United States Department of State, Office of Exchange Coordination and Designation, ECA/EC/ECD—SA–44, Room 734, 301 4th Street, SW., Washington, DC 20547, Telephone: (202) 401–9810, FAX: (202) 401–9809.

IV.3d.2. *Diversity, Freedom and Democracy Guidelines.* Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. ''Diversity'' should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and disabilities. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into your proposal. Public Law 104–319 provides that ''in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy,'' the Bureau ''shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries.'' Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

IV.3d.3. *Program Monitoring and Evaluation.* Proposals must include a plan to monitor and evaluate the project's success, both as the activities unfold and at the end of the program. The Bureau recommends that your proposal include a draft survey questionnaire or other technique plus a description of a methodology to use to link outcomes to original project objectives. The Bureau expects that the grantee will track participants or partners and be able to respond to key evaluation questions, including satisfaction with the program, learning as a result of the program, changes in behavior as a result of the program, and effects of the program on institutions (institutions in which participants work or partner institutions). The evaluation plan should include indicators that measure gains in mutual understanding as well as substantive knowledge.

Successful monitoring and evaluation depend heavily on setting clear goals and outcomes at the outset of a program. Your evaluation plan should include a

description of your project's objectives, your anticipated project outcomes, and how and when you intend to measure these outcomes (performance indicators). The more that outcomes are ''smart'' (specific, measurable, attainable, results-oriented, and placed in a reasonable time frame), the easier it will be to conduct the evaluation. You should also show how your project objectives link to the goals of the program described in this RFGP.

Your monitoring and evaluation plan should clearly distinguish between program *outputs* and *outcomes. Outputs* are products and services delivered, often stated as an amount. Output information is important to show the scope or size of project activities, but it cannot substitute for information about progress towards outcomes or the results achieved.

Examples of outputs include the number of people trained or the number of seminars conducted. *Outcomes,* in contrast, represent specific results a project is intended to achieve and is usually measured as an extent of change. Findings on outputs and outcomes should both be reported, but the focus should be on outcomes.

We encourage you to assess the following four levels of outcomes, as they relate to the program goals set out in the RFGP (listed here in increasing order of importance):

1. *Participant satisfaction* with the program and exchange experience.
2. *Participant learning,* such as increased knowledge, aptitude, skills, and changed understanding and attitude. Learning includes both substantive (subject-specific) learning and mutual understanding.
3. *Participant behavior,* concrete actions to apply knowledge in work or community; greater participation and responsibility in civic organizations; interpretation and explanation of experiences and new knowledge gained; continued contacts between participants, community members, and others.
4. *Institutional changes,* such as increased collaboration and partnerships, policy reforms, new programming, and organizational improvements.

Please note: Consideration should be given to the appropriate timing of data collection for each level of outcome. For example, satisfaction is usually captured as a short-term outcome, whereas behavior and institutional changes are normally considered longer-term outcomes.

Overall, the quality of your monitoring and evaluation plan will be judged on how well it (1) Specifies intended outcomes; (2) gives clear descriptions of how each outcome will be measured; (3) identifies when particular outcomes will be measured; and (4) provides a clear description of the data collection strategies for each outcome (*i.e.*, surveys, interviews, or focus groups). (Please note that evaluation plans that deal only with the first level of outcomes [satisfaction] will be deemed less competitive under the present evaluation criteria.)

Grantees will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

IV.3e. *Budget.* Please take the following information into consideration when preparing your budget:

IV.3e.1. Applicants must submit a comprehensive budget for the entire program. Awards may not exceed $2,543,750. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification.

Please refer to the Solicitation Package (both the POGI and the PSI) for complete budget guidelines and formatting instructions.

IV.3f. *Submission Dates and Times: Application Deadline Date:* Thursday, June 2, 2005.

Explanation of Deadlines: Due to heightened security measures, proposal submissions must be sent via a nationally recognized overnight delivery service (*i.e.*, DHL, Federal Express, UPS, Airborne Express, or U.S. Postal Service Express Overnight Mail, etc.) and be shipped no later than the above deadline. The delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. Proposals shipped on or before the above deadline but received at ECA more than seven days after the deadline will be ineligible for further consideration under this competition. Proposals shipped after the established deadlines are ineligible for consideration under this competition. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor/confirm delivery to ECA via the Internet. ECA will *not* notify you upon receipt of application. Delivery of proposal packages *may not* be made via local courier service or in person for this competition. Faxed documents will not be accepted at any time. Only proposals submitted as stated above will be considered. Applications may not be submitted electronically at this time.

Applicants must follow all instructions in the Solicitation Package.

Important note: When preparing your submission please make sure to include one extra copy of the completed SF–424 form and place it in an envelope addressed to ''ECA/EX/PM''.

The original, one fully-tabbed copy, and six copies of the application with Tabs A–E (for a total of eight copies) should be sent to: U.S. Department of State, SA–44, Bureau of Educational and Cultural Affairs, Ref.: ECA/PE/C/PY–05–57, Program Management, ECA/EX/PM, Room 534, 301 4th Street, SW., Washington, DC 20547.

Along with the Project Title, all applicants must enter the above Reference Number in Box 11 on the SF–424 contained in the mandatory Proposal Submission Instructions (PSI) of the solicitation document.

IV.3g. *Intergovernmental Review of Applications:* Executive Order 12372 does not apply to this program.

IV.3h. With the submission of the proposal package, please also submit the Executive Summary, Proposal Narrative, and Budget sections of the proposal as e-mail attachments in Microsoft Word and/or Excel to the program officer at *LantzCS@state.gov*. The Bureau will provide these files electronically to the Office of Public Affairs at the U.S. Embassy in Belgrade for its review.

V. Application Review Information

V.1. Review Process

The Bureau will review all proposals for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office, as well as the Public Diplomacy section overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards (grants) resides with the Bureau's Grants Officer.

Technically eligible applications will be competitively reviewed according to the criteria stated in the Project Objectives, Goals, and Implementation (POGI) document.

VI. Award Administration Information

VI.1a. Award Notices

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures. Successful applicants will receive an Assistance Award Document (AAD) from the Bureau's Grants Office. The AAD and the original grant proposal with subsequent modifications (if applicable) shall be the only binding authorizing document between the recipient and the U.S. Government. The AAD will be signed by an authorized Grants Officer, and mailed to the recipient's responsible officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review from the ECA program office coordinating this competition.

VI.2. Administrative and National Policy Requirements

Terms and Conditions for the Administration of ECA agreements include the following:

Office of Management and Budget Circular A–122, ''Cost Principles for Nonprofit Organizations.''

Office of Management and Budget Circular A–21, ''Cost Principles for Educational Institutions.''

OMB Circular A–87, ''Cost Principles for State, Local and Indian Governments''.

OMB Circular No. A–110 (Revised), Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations.

OMB Circular No. A–102, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.

OMB Circular No. A–133, Audits of States, Local Government, and Non-profit Organizations

Please reference the following Web sites for additional information: *http://www.whitehouse.gov/omb/grants*, *http://exchanges.state.gov/education/grantsdiv/terms.htm#articleI*.

VI.3. Reporting Requirements

You must provide ECA with a hard copy original plus two copies of the following reports:

(1) Quarterly program and financial reports;

(2) A final program and financial report no more than 90 days after the expiration of the award.

Grantees will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. Please refer to Application and Submission Instructions (IV.3.d.3) above for Program Monitoring and Evaluation information.

All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

All reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document.

VI.4. Program Data Requirements

Organizations awarded grants will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau as required. As a minimum, the data must include the following:

(1) Name, address, contact information and biographic sketch of all persons who travel internationally on funds provided by the grant or who benefit from the grant funding but do not travel.

(2) Itineraries of international and domestic travel, providing dates of travel and cities in which any exchange experiences take place. Final schedules for in-country and U.S. activities must be received by the ECA Program Officer at least three work days prior to the official opening of the activity.

VII. Agency Contacts

For questions about this announcement, contact: Carolyn Lantz, Program Officer, Youth Programs Division, Office of Citizen Exchanges (ECA/PE/C/PY), U.S. Department of State, SA–44, 301 4th Street, SW., Room 568, Washington, DC 20547, telephone: (202) 203–7505, fax: (202) 203–7529, e-mail: *LantzCS@state.gov*.

All correspondence with the Bureau concerning this RFGP should reference the above title and number ECA/PE/C/PY–05–57.

Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

VIII. Other Information

Notice

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

Dated: March 31, 2005.

C. Miller Crouch,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 05–6937 Filed 4–6–05; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Agency Information Collection Activities; Request for Comments; Clearance of a New Information Collection; Freight Planning Noteworthy Practices

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA has forwarded the new information collection request described in this notice to the Office of Management and Budget (OMB) for review and approval. We published a **Federal Register** notice with a 60-day public comment period on this information collection on August 10, 2004 (69 FR 48556). We are required to publish this notice in the Federal Register by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by May 9, 2005.

FOR FURTHER INFORMATION CONTACT: Ms. Eloise Freeman-Powell, (202) 366–2068, Office of Planning, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001. Office hours are from 8 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Freight Planning Noteworthy Practices.

Background: The FHWA plans to update its Freight Planning Web site by adding a new feature that will collect information and photographs about

freight planning activities from the FHWA's public sector partners. This information will be reviewed by the FHWA on a monthly basis to determine which project will be posted on the Web site as an informational and educational tool for the FHWA's public sector audiences that are engaged in freight planning activities and/or are beginning to develop their freight planning activities. State Departments of Transportation, metropolitan planning organizations, and local government agencies will provide a description of case studies on freight planning and implementation, which can include plans or projects, or both.

Respondents: State Departments of Transportation, metropolitan planning organizations, and local government agencies.

Estimated Total Annual Burden: It is estimated that each State Department of Transportation, metropolitan planning organization, and local government agency will spend about one hour to prepare and to provide their freight plans or projects to the FHWA. The estimated total annual burden is 60 hours.

Frequency: On-going basis.

ADDRESSES: You may send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: DOT Desk Officer. You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit *http://dms.dot.gov*.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: March 21, 2005.

James R. Kabel,

Chief, Management Programs, and Analysis Division.

[FR Doc. 05–6951 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Over-the-Road Bus Accessibility Program Grants

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of availability of fiscal year 2005 funds: solicitation of grant applications.

SUMMARY: The U.S. Department of Transportation (DOT) Federal Transit Administration (FTA) announces the availability of funds in fiscal year (FY) 2005 for the Over-the-Road Bus (OTRB) Accessibility Program, authorized by section 3038 of the Transportation Equity Act for the 21st Century (TEA–21). The OTRB Accessibility Program makes funds available to private operators of over-the-road buses to finance the incremental capital and training costs of complying with DOT's over-the-road bus accessibility final rule, 49 CFR part 37, published in a **Federal Register** notice on September 28, 1998 (63 FR 51670). The authorizing legislation calls for national solicitation of applications, with grantees to be selected on a competitive basis. Federal transit funds are available to intercity fixed-route providers and other OTRB providers at up to 90 percent of the project cost.

In FY 2005, $5,208,000 was appropriated for intercity fixed-route service providers and $1,686,400 was appropriated for other over-the-road bus service providers.

This announcement is available on the Internet on the FTA Web site at: *http://www.fta.dot.gov.* FTA will announce final selections on the Web site and in the **Federal Register**. A synopsis of this announcement will be posted in the FIND module of the government-wide electronic grants Web site at *http://www.grants.gov.* Applications may be submitted to FTA in hard copy or electronically through the GRANTS.GOV APPLY function.

DATES: Complete applications for Over-the-Road Bus (OTRB) Program grants must be submitted to the appropriate FTA regional office (see Appendix C) by June 6, 2005, or submitted electronically through the GRANTS.GOV Web site by the same date. Anyone intending to apply electronically should initiate the process of registering on the GRANTS.GOV site immediately to ensure completion of registration before the deadline for submission. FTA will announce grant selections when the competitive selection process is complete.

FOR FURTHER INFORMATION CONTACT: The appropriate FTA Regional Administrator (Appendix C) for application-specific information and issues. For general program information, contact Blenda Younger, Office of Program Management, (202) 366–2053, e-mail: *blenda.younger@fta.dot.gov.* A TDD is available at 1–800–877–8339 (TDD/FIRS).

Overview Information

Federal Agency Name: Department of Transportation, Federal Transit Administration (FTA).

Funding Opportunity Title: Capital and Training Assistance Program for over-the-road bus accessibility.

Announcement Type: Initial announcement: notice of availability of fiscal year 2005 funds: solicitation of grant applications.

Catalog of Federal Domestic Assistance (CFDA) Number: 20.518. Capital and Training Assistance Program for over-the-road bus accessibility.

DATES: Complete applications for Over-the-Road Bus (OTRB) Program grants must be submitted to the appropriate FTA regional office (*see* Appendix C) by June 6, 2005, or submitted electronically through the GRANTS.GOV Web site by the same date. Anyone intending to apply electronically should initiate the process of registering on the GRANTS.GOV site immediately to ensure completion of registration before the deadline for submission. FTA will announce grant selections when the competitive selection process is complete.

SUPPLEMENTARY INFORMATION

Table of Contents

I. Funding Opportunity Description
II. Award Information
III. Eligibility Information
IV. Application and Submission Information
V. Application Review Information
VI. Award Administration Information
VII. Agency Contacts
Appendix A Over-the-Road Bus Accessibility Program Application
Appendix B Federal Fiscal Year 2005 Certifications and Assurances for the Federal Transit Administration Over-the-Road Bus Accessibility Grants
Appendix C FTA Regional Offices

I. Funding Opportunity Description

A. Authority

The program is authorized under Section 3038 of the Transportation Equity Act for the 21st Century (TEA–21) as extended by the Surface Transportation Extension Act of 2004, Part V (Pub. L 108–310, September 30, 2004).

B. Background

Over-the-road buses are used in intercity fixed-route service as well as other services, such as commuter, charter, and tour bus services. These services are an important element of the U.S. transportation system. TEA–21 authorized FTA's Over-the-road Bus Accessibility Program to assist over-the-road bus operators in complying with the Department's Over-the-Road Bus Accessibility rule, ''Transportation for Individuals with Disabilities'' (49 CFR Part 37) published in a **Federal Register** notice on September 28, 1998 (63 FR 51670).

Summary of DOT's Over-the-Road Bus Accessibility Rule

Deadlines for Acquiring Accessible Vehicles. Under the over-the-road bus accessibility rule, all new buses obtained by large (Class I carriers, *i.e.*, those with gross annual operating revenues of $5.3 million or more), fixed-route carriers after October 30, 2000 must be accessible, with wheelchair lifts and tie-downs that allow passengers to ride in their own wheelchairs. The rule requires 50 percent of the fixed-route carriers' fleets to be accessible by 2006, and 100 percent of the vehicles in their fleets to be accessible by 2012. The buses acquired by small (gross operating revenues of less than $5.3 million annually) fixed-route providers after October 29, 2001 also are required to be lift-equipped, although they do not have a deadline for total fleet accessibility. Small providers also can provide equivalent service in lieu of obtaining accessible buses. Starting in 2001, charter and tour companies have to provide service in an accessible bus on 48 hours' advance notice. Fixed-route companies must also provide this kind of service on an interim basis until their fleets are completely accessible.

Deadlines for Delivering Accessible Service. The rules for delivering accessible motorcoach service went into effect October 29, 2001 for large fixed-route, charter, tour and other demand-responsive motorcoach companies. The rules went into effect for small operators on October 28, 2002. After these dates, companies must provide service in an accessible coach to a passenger who requests it and gives 48 hours' advance notice. Small companies may provide equivalent service, instead of acquiring accessible coaches. This equivalent service may be provided in an alternate vehicle (*e.g.*, a van), provided that the service allows passengers to travel in their own wheelchairs.

Specifications describing the design features that an over-the-road bus must have to be readily accessible to and usable by persons who use wheelchairs or other mobility aids required by the ''Americans with Disabilities Act Accessibility Guidelines for Transportation Vehicles: Over-the-Road Buses'' rule (36 CFR part 1192) were published in another **Federal Register** notice on September 28, 1998.

C. Purpose

Improving mobility and shaping America's future by ensuring that the transportation system is accessible, integrated, and efficient, and offers flexibility of choices is a key strategic goal of the Department of Transportation. Over-the-road Bus Accessibility projects will improve mobility for individuals with disabilities by providing financial assistance to help make vehicles accessible and training to ensure that drivers and others understand how to use accessibility features as well as how to treat patrons with disabilities.

D. Vehicle and Service Definitions

An ''over-the-road bus'' is a bus characterized by an elevated passenger deck located over a baggage compartment.

Intercity, fixed-route over-the-road bus service is regularly scheduled bus service for the general public, using an over-the-road bus that: operates with limited stops over fixed routes connecting two or more urban areas not in close proximity or connecting one or more rural communities with an urban area not in close proximity; has the capacity for transporting baggage carried by passengers; and makes meaningful connections with scheduled intercity bus service to more distant points.

Other over-the-road bus service means any other transportation using over-the-road buses, including local fixed-route service, commuter service, and charter or tour service (including tour or excursion service that includes features in addition to bus transportation such as meals, lodging, admission to points of interest or special attractions). While some commuter service may also serve the needs of some intercity fixed-route passengers, the statute includes commuter service in the definition of ''other'' service. Commuter service providers should apply for these funds, even though the services designed to meet the needs of commuters may also provide service to intercity fixed-route passengers on an incidental basis. If a service provider can document that more than 50 percent of its passengers are using the service as intercity fixed-route service, the provider may apply for the funds designated for intercity fixed-route operators.

II. Award Information

Federal transit funds are available to intercity fixed-route providers and other OTRB providers at up to 90 percent of the project cost. In FY 2005, $5,208,000 was appropriated for intercity fixed-route service providers and $1,686,400 was appropriated for other over-the-road bus service providers. Successful applicants will be awarded grants. Typical grants under this program range from $20,000 to $291,000.

III. Eligibility Information

1. Eligible Applicants

Grants will be made directly to operators of over-the-road buses. Intercity, fixed-route over-the-road bus service providers may apply for the $5,208,000 that FTA expects will be available to intercity fixed-route providers in FY 2005. Other over-the-road bus service providers, including operators of local fixed-route service, commuter service, and charter or tour service may apply for the $1,686,400 available in FY 2005 for these providers. OTRB operators who provide both intercity, fixed-route service and another type of service, such as commuter, charter or tour, may apply for both categories of funds with a single application. Private for-profit operators of over-the-road buses are eligible to be direct applicants for this program. This is a departure from most other FTA programs for which the direct applicant must be a state or local public body.

Eligible Projects

Projects to finance the incremental capital and training costs of complying with DOT's over-the-road bus accessibility rule (49 CFR part 37) are eligible for funding. Incremental capital costs eligible for funding include adding lifts, tie-downs, moveable seats, doors and all labor costs associated with work on the vehicle needed to make vehicles accessible. Retrofitting vehicles with such accessibility components is also an eligible expense. Please see Buy America section for further determination of eligibility.

FTA may award funds for costs already incurred by the applicants. Any

new wheelchair accessible vehicles delivered since June 8, 1998, the date that the Transportation Equity Act for the 21st Century was effective, are eligible for funding under the program. Vehicles of any age that have been retrofitted with lifts and other accessibility components since June 8, 1998 are also eligible for funding.

Eligible training costs are those required by the final accessibility rule as described in 49 CFR 37.209. These activities include training in proper operation and maintenance of accessibility features and equipment, boarding assistance, securement of mobility aids, sensitive and appropriate interaction with passengers with disabilities, and handling and storage of mobility devices. The costs associated with developing training materials or providing training for local providers of over-the-road bus services for these purposes are eligible expenses.

FTA will not fund the incremental costs of acquiring used wheelchair accessible OTRBs, as it may be impossible to verify whether or not FTA funds were already used to make the vehicles accessible. Also, it would be difficult to place a value on the accessibility features based upon the depreciated value of the vehicle. FTA wishes to increase the number of wheelchair accessible over-the-road buses available to persons with disabilities throughout the country, and the purchase of used accessible vehicles, whether or not they were previously funded by FTA, does not further this objective.

FTA has sponsored the development of accessibility training materials for public transit operators. FTA-funded Project Action is a national technical assistance program to promote cooperation between the disability community and the transportation industry. Project Action provides training, resources and technical assistance to thousands of disability organizations, consumers with disabilities, and transportation operators. It maintains a resource center with the most up-to-date information on transportation accessibility. Project Action may be contacted at: Project Action, 700 Thirteenth Street NW., Suite 200, Washington, DC 20590, Phone: 1–800–659–6428, Internet address: *http://www.projectaction.org/.*

2. Cost Sharing or Matching

Federal transit funds are available to intercity fixed-route providers and other OTRB providers at up to 90 percent of the project cost. A 10 percent match is required.

IV. Application and Submission Information

1. Address To Request Application Package

This announcement includes all of the information that you need to apply. It is available on the Internet on the FTA Web site at *http://www.fta.dot.gov.* FTA will announce final selections on the Web site and in the **Federal Register**. A synopsis of this announcement will be posted in the FIND module of the government-wide electronic grants Web site at *http://www.grants.gov.*

2. Content and Form of Application Submission

Guidelines for Preparing Grant Application

FTA is conducting a national solicitation for applications under the OTRB Accessibility program. Grant awards will be made on a competitive basis. The application should provide information on all items for which you are requesting funding in FY 2005. If you use another company's previous application as a guide, remember to modify all elements as appropriate to reflect your company's situation. The application must include a project narrative in the format provided in Appendix A, in addition to Standard Form 424, ''Application for Federal Assistance''.

Application Content

• Applicant Information

This addresses basic identifying information, including:

a. Company name.

b. Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number.

c. Contact information for notification of project selection: Contact name, address, fax and phone number.

d. Description of services provided by company, including areas served.

e. For fixed-route carriers, whether you are a large (Class I, with gross annual operating revenues of $5.3 million or more) or small (gross operating revenues of less than $5.3 million annually) carrier.

f. Existing fleet and employee information, including number of over-the-road buses used for intercity fixed-route service and other service and number of employees.

g. If you provide both intercity fixed-route service and another type of service, such as commuter, charter or tour service, please provide an estimate of the proportion of your service that is intercity.

h. Description of your technical, legal, and financial capacity to implement the proposed project. Include evidence that you currently possess appropriate operating authority—*e.g.* DOT number if you operate interstate or identifier assigned by state if you do not operate interstate service.

• Project Information

Every application must:

a. Provide the Federal amount requested for each purpose for which funds are sought in the format in Appendix A.

b. If requesting funding for intercity service, document how intercity fixed-route service meets the definition of intercity fixed-route service, including how service makes meaningful connections with scheduled intercity bus service to more distant points.

c. Document that intercity service is included in Russell's Official National Motor Coach Guide.

d. Document matching funds, including amount and source.

e. Describe project, including components to be funded, *i.e.*, lifts, tie-downs, moveable seats, etc., and/or training.

f. Provide project time-line, including significant milestones such as date or contract for purchase of vehicle(s), and actual or expected delivery date of vehicles.

g. Address each of the five statutory evaluation criteria described in V.

• Labor Information

a. Identify any labor organizations that may represent your employees and all labor organizations that represent the employees of any transit providers in the service area of the project. For each local of a nationally affiliated union, the applicant must provide the name of the national organization and the number or other designation of the local union. (For example, Amalgamated Transit Union local 1258.) Since DOL makes its referral to the national union's headquarters, there is no need to provide a means of contacting the local organization.

b. For each independent labor organization (*i.e.*, a union that is not affiliated with a national or international organization) the local information will be necessary (name of organization, address, contact person, phone, fax numbers).

c. Where a labor organization represents transit employees in the service area of the project, DOL must refer the proposed protective arrangements to each union and to each recipient. For this reason, please provide DOL with a contact person, address, telephone number and fax number for your company and associated union information.

3. Submission Dates and Times

Complete applications for OTRB Accessibility Program grants must be submitted to the appropriate FTA regional office (see Appendix C) June 6, 2005 or submitted electronically through the GRANTS.GOV Web site by the same date. Applicants planning to apply electronically are encouraged to begin the process of registration on the GRANTS.GOV site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. FTA will announce grant selections when the competitive selection process is complete.

4. Intergovernmental Review

This program is not generally subject to Executive Order (EO) 12372, ''Intergovernmental Review of Federal Programs.'' For more information, contact the State's Single Point of Contact (SPOC) to find out about and comply with the State's process under EO 12372. The names and addresses of the SPOCs are listed in the Office of Management and Budget's Home page at *http://www.whitehouse.gov/omb/grants/spoc.html.*

5. Funding Restrictions

Only applications from eligible recipients for eligible activities will be considered for funding (*see* Section III). Due to funding limitations, applicants that are selected for funding may receive less than the amount requested.

6. Other Submission Requirements

Applicants should submit 3 copies of their project proposal application, consistent with the application format provided at Appendix A, to the appropriate regional office or apply electronically through the governmentwide electronic grant application portal at *http://www.grants.gov.*

V. Application Review Information

1. Project Evaluation Criteria—Projects Will Be Evaluated According to the Following Criteria:

A. The identified need for over-the-road bus accessibility for persons with disabilities in the areas served by the applicant. (20 points)

B. The extent to which the applicant demonstrated innovative strategies and financial commitment to providing access to over-the-road buses to persons with disabilities. (20 points)

C. The extent to which the over-the-road bus operator acquired equipment required by DOT's over-the-road bus accessibility rule prior to the required time-frame in the rule. (20 points)

D. The extent to which financing the costs of complying with DOT's rule presents a financial hardship for the applicant. (20 points)

E. The impact of accessibility requirements on the continuation of over-the-road bus service with particular consideration of the impact of the requirements on service to rural areas and for low-income individuals. (20 points)

Note: These are the statutory criteria upon which funding decisions will be made. In addition to these criteria, FTA may also consider other factors, such as the size of the applicant's fleet and the level of FTA funding that may already have been awarded to applicants in prior years.

2. Review and Selection Process

Each application is screened by a panel of members represented by FTA headquarters and regional staff. Incomplete or non-responsive applications will be disqualified. FTA will make an effort to award every qualified applicant at least one lift. Prior year funding under the program is a factor, however, so depending upon demand, an applicant that received significant prior year funding may not be selected to receive additional funding.

VI. Award Administration Information

1. Award Notices

FTA will screen all applications to determine whether all required eligibility elements, as described in III. ''Eligibility Information'' are present. An FTA evaluation team will evaluate each application according to the criteria described in this announcement. FTA will notify all applicants, both those selected for funding and those not selected when the competitive selection process is complete. Projects selected for funding will be published in a **Federal Register** notice. Applicants selected for funding must then apply to the FTA regional office for the actual grant award, sign Certifications and Assurances, etc. and execute a grant contract before funds can be drawn down.

2. Administrative and National Policy Requirements

A. Grant Requirements

Applicants selected for funding must include documentation necessary to meet the requirements of FTA's Nonurbanized Area Formula program (Section 5311 under Title 49, United States Code). Technical assistance regarding these requirements is available from each FTA regional office. The regional offices will contact those applicants selected for funding regarding procedures for making the required certifications and assurances to FTA before grants are made.

The authority for these requirements is provided by the Transportation Equity Act for the 21st Century, Pub. L. 105–178, June 9, 1998, as amended by the TEA–21 Restoration Act 105–206, 112 Stat. 685, July 22, 1998, 49 U.S.C. chapter 53, Title 23, United States Code, DOT and FTA regulations at 49 CFR, and FTA Circulars.

B. Buy America

In the OTRB Accessibility program, FTA's Buy America regulations, 49 CFR Part 661, apply to the incremental capital cost of making vehicles accessible. Those regulations do not apply to associated labor costs. The following discussion relates to the contract between the grantee and the prime contractor.

The ''General Requirements'' found at 49 CFR 661.5 apply to that portion of the accessibility system being funded. That section requires that all of the manufacturing processes for the product take place in the United States and that all components of the product be made in the United States. A component is considered domestic if it is manufactured in the U.S.A., regardless of the origin of its subcomponents. The lift, the moveable seats, and the securement devices will all be considered components for purposes of this program; accordingly, as components, each must be manufactured in the United States. Should a recipient choose to request funding for only a specific component, such as the lift or the securement device, then the Buy America requirements would apply only to that item funded by FTA.

Three exceptions to the general requirements can be found at 49 CFR 661.7: first, a waiver may be requested when the application of the regulation is not in the public interest; second, a waiver may be requested if the materials and products being procured are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; and third, a price differential waiver may be requested where the results of competitive procurement show that there is a 25 percent price difference between the domestic and foreign products. FTA approval of a waiver must be received by the recipient of FTA funds prior to the execution of contract.

It should also be noted that FTA has issued a general public interest waiver for all purchases under the Federal ''small purchase'' threshold, which is currently $100,000. This waiver can be found in 49 CFR 661.7, Appendix A(e). In Section 3038(b) of TEA–21, Congress authorized FTA financing of the incremental capital costs of compliance with DOT's OTRB accessibility rule. Consistent with this provision, the small purchase waiver applies only to the incremental cost of the accessibility features FTA is funding. Where more than one bus is purchased, the grantee must consider the incremental cost increase for the entire procurement when determining if the small purchase waiver applies. For example, if $30,000 is the incremental cost for the accessibility features eligible under this program per bus (regardless of the Federal share contribution), then a procurement of three buses with a total such cost of $90,000, would qualify for the small purchase waiver. No special application to FTA would be required.

The grantee must obtain a certification from the bus manufacturer that all items included in the incremental cost for which the applicant is applying for funds meet Buy America requirements. The Buy America regulations can be found at *http://www.fta.dot.gov/library/legal/buyamer/.*

C. Labor Protection

Before FTA may award a grant for capital assistance, 49 U.S.C. 5333(b) requires that fair and equitable arrangements must be made to protect the interests of transit employees affected by FTA assistance. Those arrangements must be certified by the Secretary of Labor as meeting the requirements of the statute. When a labor organization represents a group of affected employees in the service area of an FTA project, the employee protective arrangement is usually the product of negotiations or discussions with the union. The grant applicant can facilitate Department of Labor (DOL) certification by identifying in the application any previously certified protective arrangements that have been applied to similar projects undertaken by the grant applicant, if any. Receiving funds under the OTRB Accessibility program, however, will not require the grantee's employees to be represented by organized labor. Nothing in the labor protection provisions in 49 U.S.C 5333(b) requires a motorcoach operator to become a union carrier or encourages union organizing in any manner. Upon receipt of a grant application requiring employee protective arrangements, FTA will transmit the application to DOL and request certification of the employee protective arrangements. In accordance with DOL guidelines, DOL notifies the relevant unions in the area of the project that a grant for assistance is pending and affords the grant applicant and union the opportunity to agree to an arrangement establishing the terms and conditions of the employee protections. If necessary, DOL furnishes technical and mediation assistance to the parties during their negotiations. The Secretary of Labor may determine the protections to be certified if the parties do not reach an agreement after good faith bargaining and mediation efforts have been exhausted. DOL will also set the protective conditions when affected employees in the service area are not represented by a union. When DOL determines that employee protective arrangements comply with labor protection requirements, DOL will provide a certification to FTA. The grant agreement between FTA and the grant applicant incorporates by reference the employee protective arrangements certified by DOL.

Applicants must identify any labor organizations that may represent their employees and all labor organizations that represent the employees of any other transit providers in the service area of the project.

For each local of a nationally affiliated union, the applicant must provide the name of the national organization and the number or other designation of the local union. (For example, Amalgamated Transit Union local 1258) Since DOL makes its referral to the national union's headquarters, there is no need to provide a means of contacting the local organization.

However, for each independent labor organization (*i.e.*, a union that is not affiliated with a national or international organization) the local information will be necessary (name of organization, address, contact person, phone, fax numbers).

Where a labor organization represents transit employees in the service area of the project, DOL must refer the proposed protective arrangements to each union and to each recipient. For this reason, please provide DOL with a contact person, address, telephone number and fax number for your company, and associated union information.

DOL issued a **Federal Register** notice addressing the new TEA–21 programs, including the OTRB Accessibility Program, ''Amendment to Section 5333(b) Guidelines to Carry Out New Programs Authorized by the Transportation Equity Act for the 21st Century (TEA–21)''; Final Rule, dated July 28, 1999. FTA issued a ''Dear Colleague'' letter, dated December 5, 2000, addressing DOL processing of grant applications. Attached to the letter is an application checklist, which provides information that DOL must have in order to review and certify FTA grant applications. This letter and attachment can be found at: *http://www.fta.dot.gov/office/public/c0019.html.*

Questions concerning protective arrangements and related matters pertaining to transit employees should be addressed to the Division of Statutory Programs, Department of Labor, 200 Constitution Avenue NW., Room N–5411, Washington, DC 20210; telephone (202) 693–0126, fax (202) 219–5338.

D. Planning

Applicants are encouraged to notify the appropriate state departments of transportation and metropolitan planning organizations (MPO) in areas likely to be served by equipment made accessible through funds made available in this program. Those organizations, in turn, should take appropriate steps to inform the public, and individuals requiring fully accessible services in particular, of operators' intentions to expand the accessibility of their services. Incorporation of funded projects in the plans and transportation improvement programs of states and metropolitan areas by states and MPOs also is encouraged, but is not required.

E. Standard Assurances

The Applicant assures that it will comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal administrative requirements in carrying out any project supported by the FTA grant. The Applicant acknowledges that it is under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with FTA. The Applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and affect the implementation of the project. The Applicant agrees that the most recent Federal requirements will apply to the project, unless FTA issues a written determination otherwise. The Applicant must submit the Certifications and Assurances for the FTA Over-the-Road Bus Accessibility Program found at Appendix B.

3. Reporting

Post-award reporting requirements include submission of final Financial Status Report and milestone report, or annual reports for grants remaining

open at the end of each Federal fiscal year (September 30). Documentation is required for payment.

VII. Agency Contact(s)

Contact the appropriate FTA Regional Administrator (see Appendix C) for application-specific information and issues. For general program information, contact Blenda Younger, Office of Program Management, (202) 366–2053, e-mail: *blenda.younger@fta.dot.gov.* A TDD is available at 1–800–877–8339 (TDD/FIRS).

Issued on: April 1, 2005.

Jennifer L. Dorn,

Administrator.

Appendix A—Over-the-Road Bus Accessibility Program Project Proposal Application (Paper or Electronic Project Narrative)

(See Section IV.2 of **Federal Register** announcement for detailed explanation of application content).

In addition to OMB Standard Form 424, Application For Federal Assistance, provide the following information:

1. Applicant Information
   A. Company Name:
   B. DUNS Number:
   C. For Notification of Project Selection Contact:
   Name of Individual:
   Address:
   FAX:
   Telephone number:
   D. Describe Services Provided by Company, including Areas Served:
   E. Intercity Fixed-Route Carriers:
   ____Large/Class I (gross annual operating revenues of $5.3 Million or more)
   ____Small (gross annual revenues of less than $5.3 Million)
   F. Existing Fleet and Employee Information:
   ____Total number of over-the-road buses in fleet
   ____Number of over-the-road buses in fleet used for intercity fixed-route service
   ____Number of over-the-road buses intercity-fixed-route service that currently have lifts
   ____Number of over-the-road buses in fleet used for Other Service, *e.g.*, Charter, Tour, & Commuter
   ____Number of over-the-road buses used in ''other'' service that currently have lifts
   ____Number of Employees
   G. Estimate of the proportion of service, if any, that is intercity fixed-route
   ____% of services is intercity fixed-route.
   H. Describe your technical, legal, and financial capacity to implement the proposed project. Include evidence of operating authority.
2. Project Information
   A. Federal Amount Requested (Up to 90% Federal Share):
   Intercity Fixed Route Service:
   $_____ for _____ New Over-the-road Buses
   $_____ for _____ Retrofits
   $_____ for _____ Employees—Training
   Other Service (Commuter, Charter, or Tour)
   $_____ for _____ New Over-the-road Buses
   $_____ for _____ Retrofits
   $_____ for _____ Employees—Training
   B. If funds are being requested for intercity fixed-route services, please describe how the service meets the definition of intercity fixed-route service, including how the service makes meaningful connections with scheduled intercity bus service to more distant points.
   C. Is service currently listed in ''Russell's Official National Motor Coach Guide''
   ____yes ____no. If yes, provide details. If not, why not?
   D. Document Matching Funds, including Amount and Source:
   E. Describe Project, including Components to be funded, *i.e.*, Lifts, Tie-downs, Moveable Seats, etc. and/or Training:
   F. Provide Project Time Line, including Significant Milestones such as Date of Contract for Purchase of Vehicle(s), and actual or expected delivery date of vehicles.
   G. Project Evaluation Criteria
   Provide information addressing the following criteria:
   - The identified need for over-the-road bus accessibility for persons with disabilities in the areas served by the applicant. (20 points)
   - The extent to which the applicant demonstrated innovative strategies and financial commitment to providing access to over-the-road buses to persons with disabilities. (20 points)
   - The extent to which the over-the-road bus operator acquired equipment required by DOT's over-the-road bus accessibility rule prior to the required time frame in the rule. (20 points)
   - The extent to which financing the costs of complying with DOT's rule presents a financial hardship for the applicant. (20 points)
   - The impact of accessibility requirements on the continuation of over-the-road bus service with particular consideration of the impact of the requirements on service to rural areas and for low income individuals. (20 points)
   H. Labor Information
   - List labor organizations that may represent your employees and all labor organizations that represent the employees of any transit providers in the service area of the project.
   - For each local of a nationally affiliated union, provide the name of the national organization and the number or other designation of the local union.
   - For each independent labor organization, provide the local information, including: name of organization, address, contact person, phone and fax numbers.
   - For transit employee unions in service area of project, provide information including: contact person, address, telephone number and fax number for your company and associated union information.

Appendix B—Federal Fiscal Year 2005 Certifications and Assurances for the Federal Transit Administration Over-the-Road Bus Accessibility Grants

This list is a comprehensive compilation of the certifications and assurances required by Federal law for the OTRB Accessibility Grants. At the end of this list is a Signature Page on which the Applicant and its attorney certify compliance with all certifications and assurances applicable to the OTRB Accessibility Grants. All Applicants are advised to read the entire text of these certifications and assurances to be confident of their responsibilities and commitments.

If an Applicant has submitted the Federal Transit Administration's (FTA) standard comprehensive Federal Fiscal Year 2005 Certifications and Assurances for Federal Transit Administration Assistance Programs, the Applicant need not submit these certifications and assurances. This is because the Categories I and II of certifications and assurances below are identical, respectively, to Categories 01 and 02 of FTA's standard certifications and assurances for Fiscal Year 2005.

References: The Transportation Equity Act for the 21st Century, Pub. L. 105–178, June 9, 1998, as amended, 49 U.S.C. chapter 53, Title 23, U.S.C., U.S. DOT and FTA regulations at 49 CFR, joint U.S. Architectural and Transportation Barriers Compliance Board/U.S. DOT regulations at 36 CFR Part 1194, and FTA Circulars.

I. Required of Each Applicant

Each Applicant for FTA assistance must provide all certifications and assurances in this Category ''01.'' FTA may not award any Federal assistance until the Applicant provides these certifications and assurances by selecting Category ''I.''

A. Authority of Applicant and Its Representative

The authorized representative of the Applicant and the attorney who sign these certifications, assurances, and agreements affirm that both the Applicant and its authorized representative have adequate authority under applicable state and local law and the Applicant's by-laws or internal rules to:

(1) Execute and file the application for Federal assistance on behalf of the Applicant;

(2) Execute and file the required certifications, assurances, and agreements on behalf of the Applicant binding the Applicant; and

(3) Execute grant agreements with FTA on behalf of the Applicant.

B. Standard Assurances

The Applicant assures that it will comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal requirements in carrying out any project supported by an FTA grant agreement. The Applicant agrees that it is under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with FTA. The Applicant recognizes that Federal laws, regulations, policies, and administrative practices may be modified from time to time

and those modifications may affect project implementation. The Applicant agrees that the most recent Federal requirements will apply to the project, unless FTA issues a written determination otherwise.

C. Intergovernmental Review Assurance

The Applicant assures that each application for Federal assistance it submits to FTA has been or will be submitted, as required by each state, for intergovernmental review to the appropriate state and local agencies. Specifically, the Applicant assures that it has fulfilled or will fulfill the obligations imposed on FTA by U.S. DOT regulations, ''Intergovernmental Review of Department of Transportation Programs and Activities,'' 49 CFR part 17.

D. Nondiscrimination Assurance

As required by 49 U.S.C. 5332 (which prohibits discrimination on the basis of race, color, creed, national origin, sex, or age, and prohibits discrimination in employment or business opportunity), Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000d, and U.S. DOT regulations, ''Nondiscrimination in Federally-Assisted Programs of the Department of Transportation—Effectuation of Title VI of the Civil Rights Act,'' 49 CFR part 21 at 21.7, the Applicant assures that it will comply with all requirements of 49 CFR part 21; FTA Circular 4702.1, ''Title VI Program Guidelines for Federal Transit Administration Recipients,'' and other applicable directives, so that no person in the United States, on the basis of race, color, national origin, creed, sex, or age will be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination in any program or activity (particularly in the level and quality of transportation services and transportation-related benefits) for which the Applicant receives Federal assistance awarded by the U.S. DOT or FTA.

Specifically, during the period in which Federal assistance is extended to the project, or project property is used for a purpose for which the Federal assistance is extended or for another purpose involving the provision of similar services or benefits, or as long as the Applicant retains ownership or possession of the project property, whichever is longer, the Applicant assures that:

(1) Each project will be conducted, property acquisitions will be undertaken, and project facilities will be operated in accordance with all applicable requirements of 49 U.S.C. 5332 and 49 CFR part 21, and understands that this assurance extends to its entire facility and to facilities operated in connection with the project.

(2) It will promptly take the necessary actions to effectuate this assurance, including notifying the public that complaints of discrimination in the provision of transportation-related services or benefits may be filed with U.S. DOT or FTA. Upon request by U.S. DOT or FTA, the Applicant assures that it will submit the required information pertaining to its compliance with these requirements.

(3) It will include in each subagreement, property transfer agreement, third party contract, third party subcontract, or participation agreement adequate provisions to extend the requirements of 49 U.S.C. 5332 and 49 CFR part 21 to other parties involved therein including any subrecipient, transferee, third party contractor, third party subcontractor at any level, successor in interest, or any other participant in the project.

(4) Should it transfer real property, structures, or improvements financed with Federal assistance provided by FTA to another party, any deeds and instruments recording the transfer of that property shall contain a covenant running with the land assuring nondiscrimination for the period during which the property is used for a purpose for which the Federal assistance is extended or for another purpose involving the provision of similar services or benefits.

(5) The United States has a right to seek judicial enforcement with regard to any matter arising under the Act, regulations, and this assurance.

(6) It will make any changes in its 49 U.S.C. 5332 and Title VI implementing procedures as U.S. DOT or FTA may request.

E. Assurance of Nondiscrimination on the Basis of Disability

As required by U.S. DOT regulations, ''Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance,'' at 49 CFR 27.9, the Applicant assures that, as a condition to the approval or extension of any Federal assistance awarded by FTA to construct any facility, obtain any rolling stock or other equipment, undertake studies, conduct research, or to participate in or obtain any benefit from any program administered by FTA, no otherwise qualified person with a disability shall be, solely by reason of that disability, excluded from participation in, denied the benefits of, or otherwise subjected to discrimination in any program or activity receiving or benefiting from Federal assistance administered by the FTA or any entity within U.S. DOT. The Applicant assures that project implementation and operations so assisted will comply with all applicable requirements of U.S. DOT regulations implementing the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794, *et seq.*, and the Americans with Disabilities Act of 1990, as amended, 42 U.S.C. 12101 *et seq.*, and implementing U.S. DOT regulations at 49 CFR parts 27, 37, and 38, and any applicable regulations and directives issued by other Federal departments or agencies.

F. Certifications and Assurances Required by the U.S. Office of Management and Budget (OMB) (SF–424B and SF–424D)

As required by OMB, the Applicant certifies that it:

(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 cost) to ensure proper planning, management, and completion of the project described in its application;

(2) Will give FTA, 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 project time periods following receipt of FTA approval;

(5) Will comply with all applicable Federal statutes relating to nondiscrimination including, but not limited to:

(a) Title VI of the Civil Rights Act, 42 U.S.C. 2000d, 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 through 1683, and 1685 through 1687, and U.S. DOT regulations, ''Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance,'' 49 CFR part 25, which prohibit 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 handicap;

(d) The Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 through 6107, which prohibits discrimination on the basis of age;

(e) The Drug Abuse Office and Treatment Act of 1972, Pub. L. 92–255, March 21, 1972, and amendments thereto, 21 U.S.C. 1174 *et seq.* relating to nondiscrimination on the basis of drug abuse;

(f) The Comprehensive Alcohol Abuse and Alcoholism Prevention Act of 1970, Pub. L. 91–616, Dec. 31, 1970, and amendments thereto, 42 U.S.C. 4581 *et seq.* relating to nondiscrimination on the basis of alcohol abuse or alcoholism;

(g) The Public Health Service Act of 1912, as amended, 42 U.S.C. 290dd–3 and 290ee–3, related to confidentiality of alcohol and drug abuse patient records;

(h) Title VIII of the Civil Rights Act, 42 U.S.C. 3601 *et seq.*, relating to nondiscrimination in the sale, rental, or financing of housing;

(i) Any other nondiscrimination provisions in the specific statutes under which Federal assistance for the project may be provided including, but not limited, to 49 U.S.C. 5332, which prohibits discrimination on the basis of race, color, creed, national origin, sex, or age, and prohibits discrimination in employment or business opportunity, and section 1101(b) of the Transportation Equity Act for the 21st Century, 23 U.S.C. 101 note, which provides for participation of disadvantaged business enterprises in FTA programs; and

(j) Any other nondiscrimination statute(s) that may apply to the project;

(6) Will comply with, or has complied with, the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended, (Uniform Relocation Act) 42 U.S.C.

4601 *et seq.*, which, among other things, 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 any purchase. As required by sections 210 and 305 of the Uniform Relocation Act, 42 U.S.C. 4630 and 4655, and U.S. DOT regulations, ''Uniform Relocation Assistance and Real Property Acquisition for Federal and Federally Assisted Programs,'' 49 CFR 24.4, the Applicant assures that it has the requisite authority under applicable state and local law to comply with the requirements of the Uniform Relocation Act, 42 U.S.C. 4601 *et seq.*, and U.S. DOT regulations, ''Uniform Relocation Assistance and Real Property Acquisition for Federal and Federally Assisted Programs,'' 49 CFR part 24, and will comply with or has complied with that Act and those implementing regulations, including but not limited to the following:

(a) The Applicant will adequately inform each affected person of the benefits, policies, and procedures provided for in 49 CFR part 24;

(b) The Applicant will provide fair and reasonable relocation payments and assistance as required by 42 U.S.C. 4622, 4623, and 4624; 49 CFR part 24; and any applicable FTA procedures, to or for families, individuals, partnerships, corporations, or associations displaced as a result of any project financed with FTA assistance;

(c) The Applicant will provide relocation assistance programs offering the services described in 42 U.S.C. 4625 to such displaced families, individuals, partnerships, corporations, or associations in the manner provided in 49 CFR part 24 and FTA procedures;

(d) Within a reasonable time before displacement, the Applicant will make available comparable replacement dwellings to displaced families and individuals as required by 42 U.S.C. 4625(c)(3);

(e) The Applicant will carry out the relocation process in such manner as to provide displaced persons with uniform and consistent services, and will make available replacement housing in the same range of choices with respect to such housing to all displaced persons regardless of race, color, religion, or national origin;

(f) In acquiring real property, the Applicant will be guided to the greatest extent practicable under state law, by the real property acquisition policies of 42 U.S.C. 4651 and 4652;

(g) The Applicant will pay or reimburse property owners for necessary expenses as specified in 42 U.S.C. 4653 and 4654, with the understanding that FTA will provide Federal financial assistance for the Applicant's eligible costs of providing payments for those expenses, as required by 42 U.S.C. 4631;

(h) The Applicant will execute such amendments to third party contracts and subagreements financed with FTA assistance and execute, furnish, and be bound by such additional documents as FTA may determine necessary to effectuate or implement the assurances provided herein; and

(i) The Applicant agrees to make these assurances part of or incorporate them by reference into any third party contract or subagreement, or any amendments thereto, relating to any project financed by FTA involving relocation or land acquisition and provide in any affected document that these relocation and land acquisition provisions shall supersede any conflicting provisions;

(7) To the extent applicable, will comply with the Davis-Bacon Act, as amended, 40 U.S.C. 3141 *et seq.*, the Copeland ''Anti-Kickback'' Act, as amended, 18 U.S.C. 874, and the Contract Work Hours and Safety Standards Act, as amended, 40 U.S.C. 3701 *et seq.*, regarding labor standards for federally assisted subagreements;

(8) To the extent applicable, will comply with the flood insurance purchase requirements of section 102(a) of the Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4012a(a), requiring Applicants and their subrecipients in a special flood hazard area to participate in the program and purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more;

(9) Will comply with the Lead-Based Paint Poisoning Prevention Act, 42 U.S.C. 4831(b), which prohibits the use of lead-based paint in the construction or rehabilitation of residence structures;

(10) Will not dispose of, modify the use of, or change the terms of the real property title or other interest in the site and facilities on which a construction project supported with FTA assistance takes place without permission and instructions from the awarding agency;

(11) To the extent required by FTA, will record the Federal interest in the title of real property, and will include a covenant in the title of real property acquired in whole or in part with Federal assistance funds to assure nondiscrimination during the useful life of the project;

(12) Will comply with FTA requirements concerning the drafting, review, and approval of construction plans and specifications of any construction project supported with FTA assistance. As required by U.S. DOT regulations, ''Seismic Safety,'' 49 CFR 41.117(d), before accepting delivery of any building financed with FTA assistance, it will obtain a certificate of compliance with the seismic design and construction requirements of 49 CFR part 41;

(13) Will provide and maintain competent and adequate engineering supervision at the construction site of any project supported with FTA assistance to ensure that the complete work conforms with the approved plans and specifications, and will furnish progress reports and such other information as may be required by FTA or the state;

(14) Will comply with any applicable environmental standards that may be prescribed to implement the following Federal laws and executive orders:

(a) Institution of environmental quality control measures under the National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4321–4335 and Executive Order No. 11514, as amended, 42 U.S.C. 4321 note;

(b) Notification of violating facilities pursuant to Executive Order No. 11738, 42 U.S.C. 7606 note;

(c) Protection of wetlands pursuant to Executive Order No. 11990, 42 U.S.C. 4321 note;

(d) Evaluation of flood hazards in floodplains in accordance with Executive Order 11988, 42 U.S.C. 4321 note;

(e) Assurance of project consistency with the approved state management program developed pursuant to the requirements of the Coastal Zone Management Act of 1972, as amended, 16 U.S.C. 1451–1465;

(f) Conformity of Federal actions to State (Clean Air) Implementation Plans under section 176(c) of the Clean Air Act of 1955, as amended, 42 U.S.C. 7401–7671q;

(g) Protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, 42 U.S.C. 300f–300j–6;

(h) Protection of endangered species under the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531–1544; and

(i) Environmental protections for Federal transportation programs, including, but not limited to, protections for parks, recreation areas, or wildlife or waterfowl refuges of national, state, or local significance or any land from a historic site of national, state, or local significance to be used in a transportation project as required by 49 U.S.C. 303(b) and (c);

(j) Protection of the components of the national wild and scenic rivers systems, as required under the Wild and Scenic Rivers Act of 1968, as amended, 16 U.S.C. 1271–1287; and

(k) Provision of assistance to FTA in complying with section 106 of the National Historic Preservation Act of 1966, as amended, 16 U.S.C. 470f; the Archaeological and Historic Preservation Act of 1974, as amended, 16 U.S.C. 469–469c; and Executive Order No. 11593 (identification and protection of historic properties), 16 U.S.C. 470 note;

(15) To the extent applicable, will comply with the requirements of the Hatch Act, 5 U.S.C. 1501 through 1508, and 7324 through 7326, which limit the political activities of state and local agencies and their officers and employees whose primary employment activities are financed in whole or part with Federal funds including a Federal loan, grant agreement, except, in accordance with 23 U.S.C. 142(g), the Hatch Act does not apply to a nonsupervisory employee of a transit system (or of any other agency or entity performing related functions) receiving FTA assistance to whom that Act does not otherwise apply;

(16) Will comply with the National Research Act, Pub. L. 93–348, July 12, 1974, as amended, 42 U.S.C. 289 *et seq.*, and U.S. DOT regulations, ''Protection of Human Subjects,'' 49 CFR part 11, regarding the protection of human subjects involved in research, development, and related activities supported by Federal assistance;

(17) Will comply with the Laboratory Animal Welfare Act of 1966, as amended, 7 U.S.C. 2131 *et seq.*, and U.S. Department of Agriculture regulations, ''Animal Welfare,'' 9 CFR subchapter A, parts 1, 2, 3, and 4,

regarding the care, handling, and treatment of warm blooded animals held or used for research, teaching, or other activities supported by Federal assistance;

(18) Will have performed the financial and compliance audits as required by the Single Audit Act Amendments of 1996, 31 U.S.C. 7501 *et seq.*, OMB Circular No. A–133, ''Audits of States, Local Governments, and Non-Profit Organizations,'' Revised, and the most recent applicable OMB A–133 Compliance Supplement provisions for the Department of Transportation; and

(19) Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing the project.

II. Lobbying

An Applicant that submits or intends to submit an application for Federal assistance exceeding $100,000 must provide the following certification. FTA may not award Federal assistance exceeding $100,000 until the Applicant provides this certification by selecting Category ''II.''

A. As required by U.S. DOT regulations, ''New Restrictions on Lobbying,'' at 49 CFR 20.110, the Applicant's authorized representative certifies to the best of his or her knowledge and belief that for each application for Federal assistance exceeding $100,000:

(1) No Federal appropriated funds have been or will be paid by or on behalf of the Applicant to any person to influence or attempt to influence an officer or employee of any Federal agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress regarding the award of Federal assistance, or the extension, continuation, renewal, amendment, or modification of any Federal assistance agreement; and

(2) If any funds other than Federal appropriated funds have been or will be paid to any person to influence or attempt to influence an officer or employee of any Federal agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any application for Federal assistance, the Applicant assures that it will complete and submit Standard Form-LLL, ''Disclosure Form to Report Lobbying,'' including information required by the instructions accompanying the form, which form may be amended to omit such information as authorized by 31 U.S.C. 1352.

(3) The language of this certification shall be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants).

B. The Applicant understands that this certification is a material representation of fact upon which reliance is placed and that submission of this certification is a prerequisite for providing Federal assistance for a transaction covered by 31 U.S.C. 1352. The Applicant also understands that any person who fails to file a required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

SIGNATURE PAGE

Certifications and Assurances for the FTA Over-the-Road Bus Accessibility Program

The Applicant agrees to comply with the applicable requirements of the following Categories of certifications and assurances it has selected below:

Category	Description	
I.	Required of Each Applicant.	
II.	Lobbying	

AFFIRMATION OF APPLICANT

Name of Applicant: _____

Name and Relationship of Authorized Representative: _____

_____

BY SIGNING BELOW, on behalf of the Applicant, I declare that the Applicant has duly authorized me to make the certifications and assurances set forth above and bind the Applicant's compliance. Thus, the Applicant agrees to comply with all Federal statutes, regulations, executive orders, and Federal requirements applicable to each application it makes to the Federal Transit Administration (FTA) in Federal Fiscal Year 2005.

FTA intends that the certifications and assurances the Applicant selects above, as representative of the certifications and assurances in set forth in this document, should apply, as required, to each Over-the-Road Bus Accessibility Grant for which the Applicant seeks now, or may later, seek FTA assistance during Federal Fiscal Year 2005.

The Applicant affirms the truthfulness and accuracy of the certifications and assurances it has made in the statements submitted herein with this document and any other submission made to FTA, and acknowledges that the provisions of the Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 *et seq.*, as implemented by U.S. DOT regulations, ''Program Fraud Civil Remedies,'' 49 CFR part 31 apply to any certification, assurance or submission made to FTA. The criminal fraud provisions of 18 U.S.C. 1001 apply to any certification, assurance, or submission made in connection with a Federal Transit program authorized in Chapter 53 or any other statute.

In signing this document, I declare under penalties of perjury that the foregoing certifications and assurances, and any other statements made by me on behalf of the Applicant are true and correct.

Signature: _____

Date: _____

Name: _____

Authorized Representative of Applicant

SIGNATURE PAGE

AFFIRMATION OF APPLICANT'S ATTORNEY

For (Name of Applicant):

_____

As the undersigned Attorney for the above named Applicant, I hereby affirm to the Applicant that it has authority under state and local law to make and comply with the certifications and assurances as indicated on the foregoing pages. I further affirm that, in my opinion, the certifications and assurances have been legally made and constitute legal and binding obligations on the Applicant.

I further affirm to the Applicant that, to the best of my knowledge, there is no legislation or litigation pending or imminent that might adversely affect the validity of these certifications and assurances, or of the performance of the project.

Signature: _____

Date: _____

Name: _____

Attorney for Applicant

Each Applicant for an FTA Over-the-Road Bus Accessibility Grant must provide an Affirmation of Applicant's Attorney pertaining to the Applicant's legal capacity. The Applicant may enter its signature in lieu of the Attorney's signature, provided the Applicant has on file this Affirmation, signed by the attorney and dated this Federal fiscal year.

(These Signature Pages must be appropriately completed and signed as indicated.)

Appendix C—FTA Regional Offices

Region I—Massachusetts, Rhode Island, Connecticut, New Hampshire,Vermont and Maine
Richard H. Doyle, FTA Regional Administrator, Volpe National Transportation Systems Center, Kendall Square, 55 Broadway, Suite 920, Cambridge, MA 02142–1093, (617) 494–2055

Region II—New York, New Jersey, Virgin Islands
Letitia Thompson, FTA Regional Administrator, One Bowling Green, Room 429, New York, NY 10004–1415, (212) 668–2170

Region III—Pennsylvania, Maryland, Virginia, West Virginia, Delaware, Washington, DC
Susan Borinsky, FTA Regional Administrator, 1760 Market Street, Suite 500, Philadelphia, PA 19103–4124, (215) 656–7100

Region IV—Georgia, North Carolina, South Carolina, Florida, Mississippi, Tennessee, Kentucky, Alabama, Puerto Rico
Hiram J. Walker, FTA Regional Administrator, 61 Forsyth Street, SW., Suite 17T50, Atlanta, GA 30303, (404) 562–3500

Region V—Illinois, Indiana, Ohio, Wisconsin, Minnesota, Michigan
Joel Ettinger, FTA Regional Administrator, 200 West Adams Street, Suite 320, Chicago, IL 60606–5232, (312) 353–2789

Region VI—Texas, New Mexico, Louisiana, Arkansas, Oklahoma
Robert Patrick, FTA Regional Administrator, 819 Taylor Street, Room 8A36, Ft. Worth, TX 76102, (817) 978–0550

Region VII—Iowa, Nebraska, Kansas, Missouri
Mokhtee Ahmad, Regional Administrator, 901 Locust Street, Suite 404, Kansas City, MO 64106, (816) 329–3920

Region VIII—Colorado, North Dakota, South Dakota, Montana, Wyoming, Utah
Lee Waddleton, FTA Regional Administrator, 12300 West Dakota

Avenue Suite 310, Lakewood, CO 80228–2583, (720) 963–3300

Region IX—California, Arizona, Nevada, Hawaii, American Samoa, Guam

Leslie Rogers, FTA Regional Administrator, 201 Mission Street, Suite 2210, San Francisco, CA 94105–1831, (415) 744–3133

Region X—Washington, Oregon, Idaho, Alaska

Richard Krochalis, FTA Regional Administrator, Jackson Federal Building, 915 Second Avenue, Suite 3142, Seattle, WA 98174–1002, (206) 220–7954

[FR Doc. 05–6856 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Research & Innovative Technology Administration

Agency Information Collection; Activity Under OMB Review; Report of Financial and Operating Statistics for Large Certificated Air Carriers

AGENCY: Research & Innovative Technology Administration (RITA), Bureau of Transportation Statistics (BTS), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) , this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of currently approved collections. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on December 17, 2004 (69 FR 75603).

DATES: Written comments should be submitted by May 9, 2005.

FOR FURTHER INFORMATION CONTACT: Bernie Stankus, Office of Airline Information, RTS–42, Room 4125, RITA, BTS, 400 Seventh Street, SW., Washington, DC 20590–0001, Telephone Number (202) 366–4387, Fax Number (202) 366–3383 or e-mail: *bernard.stankus@dot.gov.*

SUPPLEMENTARY INFORMATION:

Bureau of Transportation Statistics (BTS)

Title: Report of Financial and Operating Statistics for Large Certificated Air Carriers

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2138–0013.

Forms: BTS Form 41.

Affected Public: U.S. air large certificated carriers.

Abstract: Part 241 requires large certificated air carriers to submit, monthly, quarterly, semi-annual and annual financial, operational and aircraft inventory reports to DOT.

Estimated Annual Burden Hours: 42,500 hours.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not to, publication of both respondent's identity and its data, submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW., Washington, DC 20503, Attention BTS Desk Officer.

Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the Department concerning consumer protection. Comments should address whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on April 1, 2005.

Donald W. Bright,

Assistant Director, Office of Airline Information.

[FR Doc. 05–6954 Filed 4–6–05; 8:45 am]

BILLING CODE 4910–FE–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

Release of Waybill Data

The Surface Transportation Board has received a request from Baker & Miller PLLC on behalf of the Kansas City Southern Railway Company (WB595–2—3/29/2005) for permission to use certain data from the Board's 2002 and 2003 Carload Waybill Samples. A copy of the requests may be obtained from the Office of Economics, Environmental Analysis, and Administration.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics, Environmental Analysis, and Administration within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

For Further Information Contact: Mac Frampton, (202) 565–1541.

Vernon A. Williams,

Secretary.

[FR Doc. 05–6927 Filed 4–6–05; 8:45 am]

BILLING CODE 4915–01–P

Federal Register

Thursday,
April 7, 2005

Part II

Environmental Protection Agency

Notice of Availability; Documents Entitled Guidelines for Carcinogen Risk Assessment and Supplemental Guidance for Assessing Susceptibility From Early-Life Exposure to Carcinogens; Notices

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7895–2]

Notice of Availability of the Document Entitled Guidelines for Carcinogen Risk Assessment

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of availability of final document.

SUMMARY: This Notice announces the availability of the final document, *Guidelines for Carcinogen Risk Assessment* (EPA/630/P–03/001F), hereafter referred to as the Guidelines. These Guidelines were developed as part of an Agency-wide guidelines development program by a Technical Panel of the U.S. EPA's Risk Assessment Forum, which was composed of scientists from throughout the Agency. Selected drafts were peer reviewed internally by the U.S. EPA's Science Advisory Board, and by experts from universities, environmental groups, industry and other governmental agencies. The Guidelines were also subjected to several public comment periods. Issuance of these final Guidelines fulfills EPA's obligations under section 112(o) (7) of the Clean Air Act.

DATES: The Guidelines are available for use by EPA risk assessors as March 29, 2005.

ADDRESSES: This Notice contains the full Guidelines document. The Guidelines also are available electronically through the EPA Web site at *http://www.epa.gov/cancerguidelines.* A limited number of paper and CDROM copies will be available from the EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: (800) 490–9198 or (513) 489–8190; facsimile: (513) 489–8695. Please provide your name, mailing address and the title and number of the requested EPA publication (EPA/630/P–03–001F). Additionally, copies of the Guidelines will be available for inspection at EPA headquarters and regional libraries, through the U.S. Government Depository Library program.

FOR FURTHER INFORMATION CONTACT: Dr. William P. Wood, Risk Assessment Forum, National Center for Environmental Assessment (8601D), U.S. Environmental Protection Agency, Washington DC 20460, telephone: (202) 564–3361; facsimile: (202) 565–0062; or e-mail: *risk.forum@epamail.epa.gov.*

SUPPLEMENTARY INFORMATION: In the 1983 *Risk Assessment in the Federal Government: Managing the Process,* the National Academy of Sciences recommended that Federal regulatory agencies establish ''inference guidelines'' to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment process is maintained as a scientific effort separate from risk management. A task force within EPA accepted that recommendation and requested that EPA scientists begin to develop such guidelines. In 1984, EPA scientists began work on risk assessment guidelines for carcinogenicity, mutagenicity, suspect developmental toxicants, chemical mixtures and exposure assessment. Following extensive scientific and public review, these five guidelines were issued on September 24, 1986 (51 FR 33992–34054). Since 1986, additional risk assessment guidelines have been developed, revised and supplemented.

EPA continues to revisit the guidelines as experience and scientific consensus evolve. In 1996, the Agency published proposed revisions to EPA's 1986 cancer guidelines for public comment. Since the 1996 proposal, the document has undergone extensive public comment and scientific peer review, including three reviews by EPA's Science Advisory Board (SAB) in February 1997, January 1999 and July 1999. The July 1999 review panel was supplemented by the EPA Children's Health Protection Advisory Committee. Public comments were received concurrent to each of these reviews. In 2001 (66 FR 59593, November 29, 2001) an additional public comment period was held requesting new information gained through the use of the July 1999 draft final revised guidelines on issues including, but not limited to, the nature and use of default assumptions; definition and application of hazard descriptors; identification of carcinogenic mode(s) of action and, in particular, consideration of relevancy for children (*e.g.*, the potential for differential life stage susceptibility); and guidance on the use of the margin of exposure analysis. The notice also announced that the July 1999 draft final revised guidelines would serve as EPA's interim guidance to EPA risk assessors preparing cancer risk assessment, until the issuance of final guidelines. In May 2003 EPA made available for public comment a revised draft of the guidelines, and in February 2005 the guidelines underwent interagency review. The final Guidelines issued today are based, in part, upon the recommendations derived from public comments, workshops and recommendations of the SAB.

CAA section 112(o)(7) provides ''[t]he Administrator shall consider, but need not adopt, the recommendations contained in the report of the National Academy of Sciences prepared pursuant to this subsection and the views of the Science Advisory Board, with respect to such report. Prior to the promulgation of any standard under [CAA section 112(f)], and after notice and opportunity for comment, the Administrator shall publish revised Guidelines for Carcinogenic Risk Assessment or a detailed explanation of the reasons that any recommendations contained in the report of the National Academy of Sciences will not be implemented.''

In response to CAA section 112(o)(7), the 1994 National Research Council (NRC) report, and continuing developments in the science of cancer risk assessment, EPA began the process of revising its Guidelines for Carcinogen Risk Assessment. Revisions to the Guidelines were intended to make greater use of the increasing scientific understanding of the mechanisms that underlie the carcinogenic process. Several drafts of revisions to the Guidelines have been subject to extensive public comment and scientific peer review, including three reviews by EPA's SAB, as discussed above. EPA considered the 1994 recommendations of the NRC on the Guidelines. EPA's approach to those NRC recommendations is reflected in the Guidelines. Draft EPA responses to the NRC recommendations were presented in the preamble to the 1996 draft of these revised Guidelines (61 FR 18003, April 23, 1996). By issuing the final Guidelines which address the recommendations of the NRC, EPA has fulfilled its responsibilities under CAA section 112(o)(7).

Features of the Guidelines

The Guidelines are intended to make greater use of the increasing scientific understanding of the mechanisms that underlie the carcinogenic process. The final guidelines include discussions of all of the four steps of the risk assessment process and provide guidance to risk assessors on these steps. In applying these principles to the development of these Guidelines, the following key issues were highlighted: use of default options, the consideration of mode of action, understanding of biological changes, fuller characterization of carcinogenic potential, and consideration of differences in susceptibility.

Use of default options—Default options are approaches that EPA can

apply in risk assessments when scientific information about the effects of an agent on human health is unavailable, limited, or of insufficient quality. Under the final Guidelines, EPA's approach begins with a critical analysis of available information, and then invokes defaults if needed to address uncertainty or the absence of critical information.

Consideration of mode of action—Cancer refers to a group of diseases involving abnormal, malignant tissue growth. Research has revealed that the development of cancer involves a complex series of steps and that carcinogens may operate in a number of different ways. The final Guidelines emphasize the value of understanding the biological changes and how these changes might lead to the development of cancer. They also discuss ways to evaluate and use such information, including information about an agent's postulated mode of action, or the series of steps and processes that lead to cancer formation. Mode-of-action data, when available and of sufficient quality, may be used to draw conclusions about the potency of a chemical, its potential effects at low doses, whether findings in animals are relevant to humans, and which populations or lifestages may be particularly susceptible.

Fuller characterization of carcinogenic potential—In the final Guidelines, an agent's human carcinogenic potential is described in a weight-of-evidence narrative. The narrative summarizes the full range of available evidence and describes any conditions associated with conclusions about an agent's hazard potential. For example, the narrative may explain that a chemical appears to be carcinogenic by some routes of exposure but not by others (*e.g.*, by inhalation but not ingestion). Similarly, a hazard may be attributed to exposures during sensitive life-stages of development but not at other times. The narrative also summarizes uncertainties and key default options that have been invoked. To provide additional clarity and consistency in weight-of-evidence narratives, the Guidelines present a set of weight-of-evidence descriptors that accompany the narratives. The Guidelines emphasize that risk managers should consider the full range of information in the narratives and not focus exclusively on the descriptors. As in the case of the narratives, descriptors may apply only to certain routes of exposure, dose ranges and durations of exposure.

Consideration of differences in susceptibility—The Guidelines explicitly recognize that variation may exist among people in their susceptibility to carcinogens. Some subpopulations may experience increased susceptibility to carcinogens throughout their life, such as people who have inherited predisposition to certain cancer types or reduced capacity to repair genetic damage. Also, during certain lifestages the entire population may experience heightened susceptibility to carcinogens. In particular, EPA notes that childhood may be a lifestage of greater susceptibility for a number of reasons: rapid growth and development that occurs prenatally and after birth, differences related to an immature metabolic system, and differences in diet and behavior patterns that may increase exposure.

The final Guidelines explicitly call for consideration of possible sensitive subpopulations and/or lifestages (such as childhood). Therefore, concurrent with release of the final Guidelines, EPA published a separate guidance, entitled *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (EPA/630/R–03/003F), hereafter referred to as the Supplemental Guidance, describing possible approaches that could be used to assess risks resulting from early life exposure to potential carcinogens. The Supplemental Guidance is separate from the Guidelines so that it may be more easily updated in a timely manner given the expected rapid evolution of scientific understanding about the effects of early-life exposures. Availability of the Supplemental Guidance is announced in a separate notice, also published in today's **Federal Register**.

Risk Assessment Guidelines at EPA

These Guidelines set forth principles and procedures to guide EPA scientists in the conduct of cancer risk assessments and to inform Agency decision makers and the public about these procedures. Policies in this document are intended as internal guidance for EPA. So risk assessors and risk managers at EPA are the primary audience. These Guidelines also provide basic information to the public about EPA's risk assessment methods. In particular, the Guidelines emphasize that risk assessments should be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This approach means that Agency experts study scientific information on each agent under review and use the most scientifically appropriate interpretation to assess risk. The Guidelines also stress that this information be fully presented in Agency risk assessment documents, and that Agency scientists identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions and limitations, as well as the scientific basis and rationale for each assessment. The Guidelines are formulated in part to bridge gaps in risk assessment methodology and data. By identifying these gaps and the importance of the missing information to the risk assessment process, EPA wishes to encourage research and analysis that will lead to new risk assessment methods and data.

The Guidelines are guidance only. They do not establish any substantive ''rules'' under the Administrative Procedure Act or any other law and have no binding effect on EPA or any regulated entity, but instead will represent a non-binding statement of policy. EPA believes that the Guidelines represent a sound and up-to-date approach to cancer risk assessment and enhance the application of the best available science in EPA's risk assessments. However, EPA cancer risk assessments may be conducted differently than envisioned in the Guidelines for many reasons, including (but not limited to) new information, new scientific understanding or new science policy judgment. The science of risk assessment continues to develop rapidly, and specific components of the Guidelines may become outdated or may otherwise require modification in individual settings. Use of the Guidelines in future risk assessments will be based on decisions by EPA that approaches from the Guidelines are suitable and appropriate in the context of those particular risk assessments. These judgments will be tested through peer review, and risk assessments will be modified to use different approaches if appropriate.

Even though the Guidelines are not binding rules, EPA is issuing them in a manner consistent with the procedures in the Administrative Procedure Act that are generally applicable to rulemaking, including providing opportunity for public comment. EPA considered and responded to all significant public comments as it prepared the Guidelines and will send a copy of the final Guidelines to Congress. EPA certifies that the Guidelines will not have a significant impact on a substantial number of small entities, because the Guidelines are for the benefit of EPA and impose no requirements or costs on small entities.

Implementation

Beginning today, Guidelines and Supplemental Guidance serve as EPA's

recommendation to Agency risk assessors preparing cancer risk assessments. As EPA prepares cancer assessments under the Integrated Risk Information System (IRIS) program, as well as in other EPA programs, the Agency intends to begin to use the Guidelines and Supplemental Guidance. EPA also intends to consider the Guidelines and Supplemental Guidance along with other selection factors when EPA selects agents for reassessment in annual IRIS agendas (see for example, 70 FR 10616, March 4, 2005).

Dated: March 29, 2005.

Stephen L. Johnson,

Acting Administrator.

Contents

1. Introduction
1.1. Purpose and Scope of the Guidelines
1.2. Organization and Application of the Guidelines
1.2.1. Organization
1.2.2. Application
1.3. Key Features of the Cancer Guidelines
1.3.1. Critical Analysis of Available Information as the Starting Point for Evaluation
1.3.2. Mode of Action
1.3.3. Weight of Evidence Narrative
1.3.4. Dose-response Assessment
1.3.5. Susceptible Populations and Lifestages
1.3.6. Evaluating Risks from Childhood Exposures
1.3.7. Emphasis on Characterization
2. Hazard Assessment
2.1. Overview of Hazard Assessment and Characterization
2.1.1. Analyses of Data
2.1.2. Presentation of Results
2.2. Analysis of Tumor Data
2.2.1. Human Data
2.2.1.1. Assessment of Evidence of Carcinogenicity From Human Data
2.2.1.2. Types of Studies
2.2.1.3. Exposure Issues
2.2.1.4. Biological Markers
2.2.1.5. Confounding Actors
2.2.1.6. Statistical Considerations
2.2.1.6.1. Likelihood of Observing an Effect
2.2.1.6.2. Sampling and Other Bias Issues
2.2.1.6.3. Combining Statistical Evidence Across Studies
2.2.1.7. Evidence for Causality
2.2.2. Animal Data
2.2.2.1. Long-term Carcinogenicity Studies
2.2.2.1.1. Dosing Issues
2.2.2.1.2. Statistical Considerations
2.2.2.1.3. Concurrent and Historical Controls
2.2.2.1.4. Assessment of Evidence of Carcinogenicity From Long-term Animal Studies
2.2.2.1.5. Site Concordance
2.2.2.2. Perinatal Carcinogenicity Studies
2.2.2.3. Other Studies
2.2.3. Structural Analogue Data
2.3. Analysis of Other Key Data
2.3.1. Physicochemical Properties
2.3.2. Structure-Activity Relationships
2.3.3. Comparative Metabolism and Toxicokinetics
2.3.4. Toxicological and Clinical Findings
2.3.5. Events Relevant to Mode of Carcinogenic Action
2.3.5.1. Direct DNA-Reactive Effects
2.3.5.2. Indirect DNA Effects or Other Effects on Genes/Gene Expression
2.3.5.3. Precursor Events and Biomarker Information
2.3.5.4. Judging Data
2.4. Mode of Action—General Considerations and Framework for Analysis
2.4.1. General Considerations
2.4.2. Evaluating a Hypothesized Mode of Action
2.4.2.1. Peer Review
2.4.2.2. Use of the Framework
2.4.3. Framework for Evaluating Each Hypothesized Carcinogenic Mode of Action
2.4.3.1. Description of the Hypothesized Mode of Action
2.4.3.2. Discussion of the Experimental Support for the Hypothesized Mode of Action
2.4.3.3. Consideration of the Possibility of Other Modes of Action
2.4.3.4. Conclusions About the Hypothesized Mode of Action
2.4.4. Evolution with Experience
2.5. Weight of Evidence Narrative
2.6. Hazard Characterization
3. Dose-Response Assessment
3.1. Analysis of Dose
3.1.1. Standardizing Different Experimental Dosing Regimens
3.1.2. Toxicokinetic Data and Modeling
3.1.3. Cross-species Scaling Procedures
3.1.3.1. Oral Exposures
3.1.3.2. Inhalation Exposures
3.1.4. Route Extrapolation
3.2. Analysis in the Range of Observation
3.2.1. Epidemiologic Studies
3.2.2. Toxicodynamic (''Biologically Based'') Modeling
3.2.3. Empirical Modeling (''Curve Fitting'')
3.2.4. Point of Departure (POD)
3.2.5. Characterizing the POD: The POD Narrative
3.2.6. Relative Potency Factors
3.3. Extrapolation to Lower Doses
3.3.1. Choosing an Extrapolation Approach
3.3.2. Extrapolation Using a Toxicodynamic Model
3.3.3. Extrapolation Using a Low-dose Linear Model
3.3.4. Nonlinear Extrapolation to Lower Doses
3.3.5. Comparing and Combining Multiple Extrapolations
3.4. Extrapolation to Different Human Exposure Scenarios
3.5. Extrapolation to Susceptible Populations and Lifestages
3.6. Uncertainty
3.7. Dose-Response Characterization
4. Exposure Assessment
4.1. Defining the Assessment Questions
4.2. Selecting or Developing the Conceptual and Mathematical Models
4.3. Collecting Data or Selecting and Evaluating Available Data
4.3.1. Adjusting Unit Risks for Highly Exposed Populations and Lifestages
4.4. Exposure Characterization
5. Risk Characterization
5.1. Purpose
5.2. Application
5.3. Presentation of the Risk Characterization Summary
5.4. Content of the Risk Characterization Summary
Appendix: Major Default Options
Appendix B: EPA's Guidance for Data Quality Assessment
References

List of Figures

Figure 1–1. Flow chart for early-life risk assessment using mode of action framework
Figure 3–1. Compatibility of Alternative Points of Departure with Observed and Modeled Tumor Incidences
Figure 3–2. Crossing between 10% and 1% Dose-Response Curves for Bladder Carcinomas and Liver Carcinomas Induced by 2–AAF

1. Introduction

1.1. Purpose and Scope of the Guidelines

These guidelines revise and replace the U.S. Environmental Protection Agency's (EPA's, or the Agency's) *Guidelines for Carcinogen Risk Assessment,* published in 51 FR 33992, September 24, 1986 (U.S. EPA, 1986a) and the 1999 interim final guidelines (U.S. EPA, 1999a; see U.S. EPA 2001b). They provide EPA staff with guidance for developing and using risk assessments. They also provide basic information to the public about the Agency's risk assessment methods.

These cancer guidelines are used with other risk assessment guidelines, such as the *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986b) and the *Guidelines for Exposure Assessment* (U.S. EPA, 1992a). Consideration of other Agency guidance documents is also important in assessing cancer risks where procedures for evaluating specific target organ effects have been developed (e.g., assessment of thyroid follicular cell tumors, U.S. EPA, 1998a). All of EPA's guidelines should be consulted when conducting a risk assessment in order to ensure that information from studies on carcinogenesis and other health effects are considered together in the overall characterization of risk. This is particularly true in the case in which a precursor effect for a tumor is also a precursor or endpoint of other health effects or when there is a concern for a particular susceptible life-stage for which the Agency has developed guidance, for example, *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991a). The developmental guidelines discuss hazards to children that may result from exposures during preconception and prenatal or postnatal development to

sexual maturity. Similar guidelines exist for reproductive toxicant risk assessments (U.S. EPA, 1996a) and for neurotoxicity risk assessment (U.S. EPA, 1998b). The overall characterization of risk is conducted within the context of broader policies and guidance such as Executive Order 13045, ''Protection of Children From Environmental Health Risks and Safety Risks'' (Executive Order 13045, 1997) which is the primary directive to Federal agencies and departments to identify and assess environmental health risks and safety risks that may disproportionately affect children.

The cancer guidelines encourage both consistency in the procedures that support scientific components of Agency decision making and flexibility to allow incorporation of innovations and contemporaneous scientific concepts. In balancing these goals, the Agency relies on established scientific peer review processes (U.S. EPA, 2000a; OMB 2004). The cancer guidelines incorporate basic principles and science policies based on evaluation of the currently available information. The Agency intends to revise these cancer guidelines when substantial changes are necessary. As more information about carcinogenesis develops, the need may arise to make appropriate changes in risk assessment guidance. In the interim, the Agency intends to issue special reports, after appropriate peer review, to supplement and update guidance on single topics (e.g., U.S. EPA, 1991b). One such guidance document, *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (''Supplemental Guidance''), was developed in conjunction with these cancer guidelines (U.S. EPA., 2005). Because both the methodology and the data in the Supplemental Guidance (see Section 1.3.6) are expected to evolve more rapidly than the issues addressed in these cancer guidelines, the two were developed as separate documents. The Supplemental Guidance, however, as well as any other relevant (including subsequent) guidance documents, should be considered along with these cancer guidelines as risk assessments for carcinogens are generated. The use of supplemental guidance, such as the Supplemental Guidance for Assessing Cancer Susceptibility from Early-life Exposure to Carcinogens, has the advantage of allowing the Supplemental Guidance to be modified as more data become available. Thus, the consideration of new, peer-reviewed scientific understanding and data in an assessment can always be consistent with the purposes of these cancer guidelines.

These cancer guidelines are intended as guidance only. They do not establish any substantive ''rules'' under the Administrative Procedure Act or any other law and have no binding effect on EPA or any regulated entity, but instead represent a non-binding statement of policy. EPA believes that the cancer guidelines represent a sound and up-to-date approach to cancer risk assessment, and the cancer guidelines enhance the application of the best available science in EPA's risk assessments. However, EPA cancer risk assessments may be conducted differently than envisioned in the cancer guidelines for many reasons, including (but not limited to) new information, new scientific understanding, or new science policy judgment. The science of risk assessment continues to develop rapidly, and specific components of the cancer guidelines may become outdated or may otherwise require modification in individual settings. Use of the cancer guidelines in future risk assessments will be based on decisions by EPA that the approaches are suitable and appropriate in the context of those particular risk assessments. These judgments will be tested through peer review, and risk assessments will be modified to use different approaches if appropriate.

1.2. Organization and Application of the Cancer Guidelines

1.2.1. Organization

Publications by the Office of Science and Technology (OSTP, 1985) and the National Research Council (NRC) (NRC, 1983, 1994) provide information and general principles about risk assessment. Risk assessment uses available scientific information on the properties of an agent [1] and its effects in biological systems to provide an evaluation of the potential for harm as a consequence of environmental exposure. The 1983 and 1994 NRC documents organize risk assessment information into four areas: Hazard identification, dose-response assessment, exposure assessment, and risk characterization. This structure appears in these cancer guidelines, with additional emphasis placed on characterization of evidence and conclusions in each area of the assessment. In particular, the cancer guidelines adopt the approach of the NRC's 1994 report in adding a dimension of characterization to the hazard identification step: an evaluation of the conditions under which its expression is anticipated. Risk assessment questions addressed in these cancer guidelines are as follows.

- For hazard—Can the identified agent present a carcinogenic hazard to humans and, if so, under what circumstances?
- For dose response—At what levels of exposure might effects occur?
- For exposure—What are the conditions of human exposure?
- For risk—What is the character of the risk? How well do data support conclusions about the nature and extent of the risk from various exposures?

The risk characterization process first summarizes findings on hazard, dose response, and exposure characterizations and then develops an integrative analysis of the whole risk case. It ends in the writing of a technical risk characterization. Other documents, such as summaries for the risk managers and the public, reflecting the key points of the risk characterization are usually written. A summary for managers is a presentation for those who may or may not be familiar with the scientific details of cancer assessment. It also provides information for other interested readers. The initial steps in the risk characterization process are to make building blocks in the form of characterizations of the assessments of hazard, dose response, and exposure. The individual assessments and characterizations are then integrated to arrive at risk estimates for exposure scenarios of interest. As part of the characterization process, explicit evaluations are made of the hazard and risk potential for susceptible lifestages, including children (U.S. EPA, 1995, 2000b).

The 1994 NRC document also explicitly called attention to the role of the risk assessment process in identifying scientific uncertainties that, if addressed, could serve to reduce their uncertainty in future iterations of the risk assessment. NRC recommended that when the Agency ''reports estimates of risk to decisions-makers and the public, it should present not only point estimates of risk, but also the sources and magnitudes of uncertainty associated with these estimates'' (p. 15). Thus, the identified uncertainties serve as a feedback loop to the research community and decisionmakers, specifying areas and types of information that would be particularly useful.

There are several reasons for individually characterizing the hazard, dose response, and exposure

[1] The term ''agent'' refers generally to any chemical substance, mixture, or physical or biological entity being assessed, unless otherwise noted (See Section 1.2.2 for a note on radiation.).

assessments. One is that they are often done by different people than those who do the integrative analyses. The second is that there is very often a lapse of time between the conduct of hazard and dose-response analyses and the conduct of exposure assessment and integrative analysis. Thus, it is important to capture characterizations of assessments as the assessments are done to avoid the need to go back and reconstruct them. Finally, frequently a single hazard assessment is used by several programs for several different exposure scenarios. There may be one or several documents involved. ''Integrative analysis'' is a generic term; and many documents that have other titles may contain integrative analyses. In the following sections, the elements of these characterizations are discussed.

1.2.2. Application

The cancer guidelines apply within the framework of policies provided by applicable EPA statutes and do not alter such policies.

• The cancer guidelines cover the assessment of available data. They do not imply that one kind of data or another is prerequisite for regulatory action concerning any agent. It is important that, when evaluating and considering the use of any data, EPA analysts incorporate the basic standards of quality, as defined by the EPA Information Quality Guidelines (U.S. EPA, 2002a see Appendix B) and other Agency guidance on data quality such as the EPA Quality Manual for Environmental Programs (U.S. EPA, 2000e), as well as *OMB Guidelines for Ensuring and Maximizing the Quality, Utility, and Integrity of Information Disseminated by Federal Agencies* (OMB, 2002). It is very important that all analyses consider the basic standards of quality, including objectivity, utility, and integrity. A summary of the factors and considerations generally used by the Agency when evaluating and considering the use of scientific and technical information is contained in EPA's *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (U.S. EPA, 2003).

• Risk management applies directives in statutes, which may require consideration of potential risk or solely hazard or exposure potential, along with social, economic, technical, and other factors in decision making. Risk assessments may be used to support decisions, but in order to maintain their integrity as decision-making tools, they are not influenced by consideration of the social or economic consequences of regulatory action.

The assessment of risk from radiation sources is informed by the continuing examination of human data by the National Academy of Sciences/NRC in its series of numbered reports: ''Biological Effects of Ionizing Radiation.'' Although some of the general principles of these cancer guidelines may also apply to radiation risk assessments, some of the details of their risk assessment procedures may not, as they are most focused on other kinds of agents. Therefore, these cancer guidelines are not intended to provide the primary source of, or guidance for, the Agency's evaluation of the carcinogenic risks of radiation.

Not every EPA assessment has the same scope or depth, a factor recognized by the National Academy of Sciences (NRC, 1996). For example, EPA's Information Quality Guidelines (U.S. EPA, 2002a, see Appendix B) discuss influential information that ''will have or does have a clear and substantial impact * * * on important public policies or private sector decisions * * * that should adhere to a rigorous standard of quality.'' It is often difficult to know *a priori* how the results of a risk assessment are likely to be used by the Agency. Some risk assessments may be used by Agency economists and policy analysts, and the necessary information for such analyses, as discussed in detail later in this document, should be included when practicable (U.S. EPA, 2002a). On the other hand, Agency staff often conduct screening-level assessments for priority setting or separate assessments of hazard or exposure for ranking purposes or to decide whether to invest resources in collecting data for a full assessment. Moreover, a given assessment of hazard and dose response may be used with more than one exposure assessment that may be conducted separately and at different times as the need arises in studying environmental problems related to various exposure media. The cancer guidelines apply to these various situations in appropriate detail, given the scope and depth of the particular assessment. For example, a screening assessment may be based almost entirely on structure-activity relationships (SARs) and default options, when other data are not readily available. When more data and resources are readily available, assessments can use a critical analysis of all of the available data as the starting point of the risk assessment. Under these conditions, default options would only be used to address uncertainties or the absence of critical data. Default options are inferences based on general scientific knowledge of the phenomena in question and are also matters of policy concerning the appropriate way to bridge uncertainties that concern potential risk to human health.

These cancer guidelines do not suggest that all of the kinds of data covered here will need to be available or used for either assessment or decision making. The level of detail of an assessment is a matter of Agency management discretion regarding applicable decision-making needs. The Agency generally presumes that key cancer information (*e.g.*, assessments contained in the Agency's Integrated Risk Information System) is ''influential information'' as defined by the EPA Information Quality Guidelines and ''highly influential'' as defined by OMB's Information Quality Bulletin for Peer Review (OMB 2004).

1.3. Key Features of the Cancer Guidelines

1.3.1. Critical Analysis of Available Information as the Starting Point for Evaluation

As an increasing understanding of carcinogenesis is becoming available, these cancer guidelines adopt a view of default options that is consistent with EPA's mission to protect human health while adhering to the tenets of sound science. Rather than viewing default options as the starting point from which departures may be justified by new scientific information, *these cancer guidelines view a critical analysis of all of the available information that is relevant to assessing the carcinogenic risk as the starting point from which a default option may be invoked if needed to address uncertainty or the absence of critical information.* Preference is given to using information that has been peer reviewed, *e.g.*, reported in peer-reviewed scientific journals. The primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective (U.S. EPA, 1999b).

Use of health protective risk assessment procedures as described in these cancer guidelines means that estimates, while uncertain, are more likely to overstate than understate hazard and/or risk. NRC (1994) reaffirmed the use of default options as ''a reasonable way to cope with uncertainty about the choice of appropriate models or theory'' (p. 104). NRC saw the need to treat uncertainty in a predictable way that is

''scientifically defensible, consistent with the agency's statutory mission, and responsive to the needs of decision-makers'' (p. 86). The extent of health protection provided to the public ultimately depends upon what risk managers decide is the appropriate course of regulatory action. When risk assessments are performed using only one set of procedures, it may be difficult for risk managers to determine how much health protectiveness is built into a particular hazard determination or risk characterization. When there are alternative procedures having significant biological support, the Agency encourages assessments to be performed using these alternative procedures, if feasible, in order to shed light on the uncertainties in the assessment, recognizing that the Agency may decide to give greater weight to one set of procedures than another in a specific assessment or management decision.

Encouraging risk assessors to be receptive to new scientific information, NRC discussed the need for departures from default options when a ''sufficient showing'' is made. It called on EPA to articulate clearly its criteria for a departure so that decisions to depart from default options would be ''scientifically credible and receive public acceptance'' (p. 91). It was concerned that *ad hoc* departures would undercut the scientific credibility of a risk assessment. NRC envisioned that principles for choosing and departing from default options would balance several objectives, including ''protecting the public health, ensuring scientific validity, minimizing serious errors in estimating risks, maximizing incentives for research, creating an orderly and predictable process, and fostering openness and trustworthiness'' (p. 81).

Appendices N–1 and N–2 of NRC (1994) discussed two competing standards for choosing default options articulated by members of the committee. One suggested approach would evaluate a departure in terms of whether ''it is scientifically plausible'' and whether it ''tends to protect public health in the face of scientific uncertainty'' (p. 601). An alternative approach ''emphasizes scientific plausibility with regard to the use of alternative models'' (p. 631). Reaching no consensus on a single approach, NRC recognized that developing criteria for departures is an EPA policy matter.

The basis for invoking a default option depends on the circumstances. Generally, if a gap in basic understanding exists or if agent-specific information is missing, a default option may be used. If agent-specific information is present but critical analysis reveals inadequacies, a default option may also be used. If critical analysis of agent-specific information is consistent with one or more biologically based models as well as with the default option, the alternative models and the default option are both carried through the assessment and characterized for the risk manager. In this case, the default model not only fits the data, but also serves as a benchmark for comparison with other analyses. This case also highlights the importance of extensive experimentation to support a conclusion about mode of action, including addressing the issue of whether alternative modes of action are also plausible. Section 2.4 provides a framework for critical analysis of mode of action information to address the extent to which the available information supports the hypothesized mode of action, whether alternative modes of action are also plausible, and whether there is confidence that the same inferences can be extended to populations and lifestages that are not represented among the experimental data.

Generally, cancer risk decisions strive to be ''scientifically defensible, consistent with the agency's statutory mission, and responsive to the needs of decision-makers'' (NRC, 1994). Scientific defensibility would be evaluated through use of EPA's Science Advisory Board, EPA's Office of Pesticide Programs' Scientific Advisory Panel, or other independent expert peer review panels to determine whether a consensus among scientific experts exists. Consistency with the Agency's statutory mission would consider whether the risk assessment overall supports EPA's mission to protect human health and safeguard the natural environment. Responsiveness to the needs of decisionmakers would take into account pragmatic considerations such as the nature of the decision; the required depth of analysis; the utility, time, and cost of generating new scientific data; and the time, personnel, and resources allotted to the risk assessment.

With a multitude of types of data, analyses, and risk assessments, as well as the diversity of needs of decisionmakers, it is neither possible nor desirable to specify step-by-step criteria for decisions to invoke a default option. A discussion of major default options appears in the Appendix. Screening-level assessments may more readily use default parameters, even worst-case assumptions, that would not be appropriate in a full-scale assessment. On the other hand, significant risk management decisions will often benefit from a more comprehensive assessment, including alternative risk models having significant biological support. To the extent practicable, such assessments should provide central estimates of potential risks in conjunction with lower and upper bounds (*e.g.*, confidence limits) and a clear statement of the uncertainty associated with these estimates.

In the absence of sufficient data or understanding to develop of a robust, biologically based model, an appropriate policy choice is to have a single preferred curve-fitting model for each type of data set. Many different curve-fitting models have been developed, and those that fit the observed data reasonably well may lead to several-fold differences in estimated risk at the lower end of the observed range. In addition, goodness-of-fit to the experimental observations is not by itself an effective means of discriminating among models that adequately fit the data (OSTP, 1985). To provide some measure of consistency across different carcinogen assessments, EPA uses a standard curve-fitting procedure for tumor incidence data. Assessments that include a different approach should provide an adequate justification and compare their results with those from the standard procedure. Application of models to data should be conducted in an open and transparent manner.

1.3.2. Mode of Action

The use of mode of action [2] in the assessment of potential carcinogens is a main focus of these cancer guidelines. This area of emphasis arose because of the significant scientific advances that have developed concerning the causes of cancer induction. Elucidation of a mode of action for a particular cancer response in animals or humans is a data-rich determination. Significant

[2] The term ''*mode of action*'' is defined as a sequence of key events and processes, starting with interaction of an agent with a cell, proceeding through operational and anatomical changes, and resulting in cancer formation. A ''*key event*'' is an empirically observable precursor step that is itself a necessary element of the mode of action or is a biologically based marker for such an element. Mode of action is contrasted with ''*mechanism of action,*'' which implies a more detailed understanding and description of events, often at the molecular level, than is meant by mode of action. The toxicokinetic processes that lead to formation or distribution of the active agent to the target tissue are considered in estimating dose but are not part of the mode of action as the term is used here. There are many examples of possible modes of carcinogenic action, such as mutagenicity, mitogenesis, inhibition of cell death, cytotoxicity with reparative cell proliferation, and immune suppression.

information should be developed to ensure that a scientifically justifiable mode of action underlies the process leading to cancer at a given site. In the absence of sufficiently, scientifically justifiable mode of action information, EPA generally takes public health-protective, default positions regarding the interpretation of toxicologic and epidemiologic data: Animal tumor findings are judged to be relevant to humans, and cancer risks are assumed to conform with low dose linearity.

Understanding of mode of action can be a key to identifying processes that may cause chemical exposures to differentially affect a particular population segment or lifestage. Some modes of action are anticipated to be mutagenic and are assessed with a linear approach. This is the mode of action of radiation and several other agents that are known carcinogens. Other modes of action may be modeled with either linear or nonlinear [3] approaches after a rigorous analysis of available data under the guidance provided in the framework for mode of action analysis (see Section 2.4.3).

1.3.3. Weight of Evidence Narrative

The cancer guidelines emphasize the importance of weighing all of the evidence in reaching conclusions about the human carcinogenic potential of agents. This is accomplished in a single integrative step after assessing all of the individual lines of evidence, which is in contrast to the step-wise approach in the 1986 cancer guidelines. Evidence considered includes tumor findings, or lack thereof, in humans and laboratory animals; an agent's chemical and physical properties; its structure-activity relationships (SARs) as compared with other carcinogenic agents; and studies addressing potential carcinogenic processes and mode(s) of action, either *in vivo* or *in vitro.* Data from epidemiologic studies are generally preferred for characterizing human cancer hazard and risk. However, all of the information discussed above could provide valuable insights into the possible mode(s) of action and likelihood of human cancer hazard and risk. The cancer guidelines recognize the growing sophistication of research methods, particularly in their ability to reveal the modes of action of carcinogenic agents at cellular and subcellular levels as well as toxicokinetic processes.

Weighing of the evidence includes addressing not only the likelihood of human carcinogenic effects of the agent but also the conditions under which such effects may be expressed, to the extent that these are revealed in the toxicological and other biologically important features of the agent.

The weight of evidence narrative to characterize hazard summarizes the results of the hazard assessment and provides a conclusion with regard to human carcinogenic potential. The narrative explains the kinds of evidence available and how they fit together in drawing conclusions, and it points out significant issues/strengths/limitations of the data and conclusions. Because the narrative also summarizes the mode of action information, it sets the stage for the discussion of the rationale underlying a recommended approach to dose-response assessment.

In order to provide some measure of clarity and consistency in an otherwise free-form, narrative characterization, standard descriptors are used as part of the hazard narrative to express the conclusion regarding the weight of evidence for carcinogenic hazard potential. There are five recommended standard hazard descriptors: ''*Carcinogenic to Humans,*'' ''*Likely to Be Carcinogenic to Humans,*'' ''*Suggestive Evidence of Carcinogenic Potential,*'' ''*Inadequate Information to Assess Carcinogenic Potential,*'' and ''*Not Likely to Be Carcinogenic to Humans.*'' Each standard descriptor may be applicable to a wide variety of data sets and weights of evidence and is presented only in the context of a weight of evidence narrative. Furthermore, as described in Section 2.5 of these cancer guidelines, more than one conclusion may be reached for an agent.

1.3.4. Dose-Response Assessment

Dose-response assessment evaluates potential risks to humans at particular exposure levels. The approach to dose-response assessment for a particular agent is based on the conclusion reached as to its potential mode(s) of action for each tumor type. Because an agent may induce multiple tumor types, the dose-response assessment includes an analysis of all tumor types, followed by an overall synthesis that includes a characterization of the risk estimates across tumor types, the strength of the mode of action information of each tumor type, and the anticipated relevance of each tumor type to humans, including susceptible populations and lifestages (*e.g.*, childhood).

Dose-response assessment for each tumor type is performed in two steps: assessment of observed data to derive a point of departure (POD),[4] followed by extrapolation to lower exposures to the extent that is necessary. Data from epidemiologic studies, of sufficient quality, are generally preferred for estimating risks. When animal studies are the basis of the analysis, the estimation of a human-equivalent dose should utilize toxicokinetic data to inform cross-species dose scaling if appropriate and if adequate data are available. Otherwise, default procedures should be applied. For oral dose, based on current science, an appropriate default option is to scale daily applied doses experienced for a lifetime in proportion to body weight raised to the ¾ power (U.S. EPA, 1992b). For inhalation dose, based on current science, an appropriate default methodology estimates respiratory deposition of particles and gases and estimates internal doses of gases with different absorption characteristics. When toxicokinetic modeling (see Section 3.1.2) is used without toxicodynamic modeling (see Section 3.2.2), the dose-response assessment develops and supports an approach for addressing toxicodynamic equivalence, perhaps by retaining some of the cross-species scaling factor (see Section 3.1.3). Guidance is also provided for adjustment of dose from adults to children (see Section 4.3.1).

Response data on effects of the agent on carcinogenic processes are analyzed (nontumor data) in addition to data on tumor incidence. If appropriate, the analyses of data on tumor incidence and on precursor effects may be used in combination. To the extent the relationship between precursor effects and tumor incidence are known, precursor data may be used to estimate a dose-response function below the observable tumor data. Study of the dose-response function for effects

[3] The term ''*nonlinear*'' is used here in a narrower sense than its usual meaning in the field of mathematical modeling. In these cancer guidelines, the term ''*nonlinear*'' refers to threshold models (which show no response over a range of low doses that include zero) and some nonthreshold models (*e.g.*, a quadractic model, which shows some response at all doses above zero). In these cancer guidelines, a nonlinear model is one whose slope is zero at (and perhaps above) a dose of zero. A *low-dose-linear* model is one whose slope is greater than zero at a dose of zero. A low-dose-linear model approximates a straight line only at very low doses; at higher doses near the observed data, a low-dose-linear model can display curvature. The term ''*low-dose-linear*'' is often abbreviated ''linear,'' although a low-dose-linear model is not linear at all doses. Use of nonlinear approaches does not imply a biological threshold dose below which the response is zero. Estimating thresholds can be problematic; for example, a response that is not statistically significant can be consistent with a small risk that falls below an experiment's power of detection.

[4] *A ''point of departure''* (POD) marks the beginning of extrapolation to lower doses. The POD is an estimated dose (usually expressed in human-equivalent terms) near the lower end of the observed range, without significant extrapolation to lower doses.

believed to be part of the carcinogenic process influenced by the agent may also assist in evaluating the relationship of exposure and response in the range of observation and at exposure levels below the range of observation.

The first step of dose-response assessment is evaluation within the range of observation. Approaches to analysis of the range of observation of epidemiologic studies are determined by the type of study and how dose and response are measured in the study. In the absence of adequate human data for dose-response analysis, animal data are generally used. If there are sufficient quantitative data and adequate understanding of the carcinogenic process, a biologically based model may be developed to relate dose and response data on an agent-specific basis. Otherwise, as a default procedure, a standard model can be used to curve-fit the data.

The POD for extrapolating the relationship to environmental exposure levels of interest, when the latter are outside the range of observed data, is generally the lower 95% confidence limit on the lowest dose level that can be supported for modeling by the data. SAB (1997) suggested that, ''it may be appropriate to emphasize lower statistical bounds in screening analyses and in activities designed to develop an appropriate human exposure value, since such activities require accounting for various types of uncertainties and a lower bound on the central estimate is a scientifically-based approach accounting for the uncertainty in the true value of the ED_{10} [or central estimate].'' However, the consensus of the SAB (1997) was that, ''both point estimates and statistical bounds can be useful in different circumstances, and recommended that the Agency routinely calculate and present the point estimate of the ED_{10} [or central estimate] and the corresponding upper and lower 95% statistical bounds.'' For example, it may be appropriate to emphasize the central estimate in activities that involve formal uncertainty analysis that are required by OMB Circular A–4 (OMB, 2003) as well as ranking agents as to their carcinogenic hazard. Thus, risk assessors should calculate, to the extent practicable, and present the central estimate and the corresponding upper and lower statistical bounds (such as confidence limits) to inform decisionmakers.

The second step of dose-response assessment is extrapolation to lower dose levels, if needed. This extrapolation is based on extension of a biologically based model if supported by substantial data (see Section 3.3.2). Otherwise, default approaches can be applied that are consistent with current understanding of mode(s) of action of the agent, including approaches that assume linearity or nonlinearity of the dose-response relationship, or both. A default approach for linearity extends a straight line from the POD to zero dose/zero response (see Section 3.3.3). The linear approach is used when: (1) There is an absence of sufficient information on modes of action or (2) the mode of action information indicates that the dose-response curve at low dose is or is expected to be linear. Where alternative approaches have significant biological support, and no scientific consensus favors a single approach, an assessment may present results using alternative approaches. A nonlinear approach can be used to develop a reference dose or a reference concentration (see Section 3.3.4).

1.3.5. Susceptible Populations and Lifestages

An important use of mode of action information is to identify susceptible populations and lifestages. It is rare to have epidemiologic studies or animal bioassays conducted in susceptible individuals. This information need can be filled by identifying the key events of the mode of action and then identifying risk factors, such as differences due to genetic polymorphisms, disease, altered organ function, lifestyle, and lifestage, that can augment these key events. To do this, the information about the key precursor events is reviewed to identify particular populations or lifestages that can be particularly susceptible to their occurrence (see Section 2.4.3.4). Any information suggesting quantitative differences between populations or lifestages is flagged for consideration in the dose-response assessment (see Section 3.5 and U.S. EPA 2002b).

1.3.6. Evaluating Risks From Childhood Exposures

NRC (1994) recommended that ''EPA should assess risks to infants and children whenever it appears that their risks might be greater than those of adults.'' Executive Order 13045 (1997) requires that ''each Federal Agency shall make it a high priority to identify and assess environmental health and safety risks that may disproportionately affect children, and shall ensure that their policies, programs, and standards address disproportionate risks that result from environmental health risks or safety risks.'' In assessing risks to children, EPA considers both effects manifest during childhood and early-life exposures that can contribute to effects at any time later in life.

These cancer guidelines view childhood as a sequence of lifestages rather than viewing children as a subpopulation, the distinction being that a subpopulation refers to a portion of the population, whereas a lifestage is inclusive of the entire population. Exposures that are of concern extend from conception through adolescence and also include pre-conception exposures of both parents. These cancer guidelines use the term ''childhood'' in this more inclusive sense.

Rarely are there studies that directly evaluate risks following early-life exposure. Epidemiologic studies of early-life exposure to environmental agents are seldom available. Standard animal bioassays generally begin dosing after the animals are several weeks old, when many organ systems are mature. This could lead to an understatement of risk, because an accepted concept in the science of carcinogenesis is that young animals are usually more susceptible to the carcinogenic activity of a chemical than are mature animals (McConnell, 1992).

At this time, there is some evidence of higher cancer risks following early-life exposure. For radiation carcinogenesis, data indicate that risks for several forms of cancer are highest following childhood exposure (NRC, 1990; Miller, 1995; U.S. EPA, 1999c). These human results are supported by the few animal bioassays that include perinatal (prenatal or early postnatal) exposure. Perinatal exposure to some agents can induce higher incidences of the tumors seen in standard bioassays; some examples include vinyl chloride (Maltoni *et al.*, 1981), diethylnitrosamine (Peto *et al.*, 1984), benzidine, DDT, dieldrin, and safrole (Vesselinovitch *et al.*, 1979). Moreover, perinatal exposure to some agents, including vinyl chloride (Maltoni *et al.*, 1981) and saccharin (Cohen, 1995; Whysner and Williams, 1996), can induce different tumors that are not seen in standard bioassays. Surveys comparing perinatal carcinogenesis bioassays with standard bioassays for a limited number of chemicals (McConnell, 1992; U.S. EPA, 1996b) have concluded that

- The same tumor sites are usually observed following either perinatal or adult exposure, and
- Perinatal exposure in conjunction with adult exposure usually increases the incidence of tumors or reduces the latent period before tumors are observed.

The risk attributable to early-life exposure often appears modest compared with the risk from lifetime exposure, but it can be about 10-fold

higher than the risk from an exposure of similar duration occurring later in life (Ginsberg, 2003). Further research is warranted to investigate the extent to which these findings apply to specific agents, chemical classes, and modes of action or in general.

These empirical results are consistent with current understanding of the biological processes involved in carcinogenesis, which leads to a reasonable expectation that children can be more susceptible to many carcinogenic agents (Anderson *et al.*, 2000; Birnbaum and Fenton, 2003; Ginsberg, 2003; Miller *et al.*, 2002; Scheuplein *et al.*, 2002). Some aspects potentially leading to childhood susceptibility are listed below.

- Differences in the capacity to metabolize and clear chemicals can result in larger or smaller internal doses of the active agent(s).
- More frequent cell division during development can result in enhanced expression of mutations due to the reduced time available for repair of DNA lesions (Slikker *et al.*, 2004).
- Some embryonic cells, such as brain cells, lack key DNA repair enzymes.
- More frequent cell division during development can result in clonal expansion of cells with mutations from prior unrepaired DNA damage (Slikker *et al.*, 2004).
- Some components of the immune system are not fully functional during development (Holladay and Smialowicz, 2000; Holsapple *et al.*, 2003).
- Hormonal systems operate at different levels during different lifestages.
- Induction of developmental abnormalities can result in a predisposition to carcinogenic effects later in life (Anderson *et al.*, 2000; Birnbaum and Fenton, 2003; Fenton and Davis, 2002).

To evaluate risks from early-life exposure, these cancer guidelines emphasize the role of toxicokinetic information to estimate levels of the active agent in children and toxicodynamic information to identify whether any key events of the mode of action are of increased concern early in life. Developmental toxicity studies can provide information on critical periods of exposure for particular targets of toxicity.

An approach to assessing risks from early-life exposure is presented in Figure 1–1. In the hazard assessment, when there are mode of action data, the assessment considers whether these data have special relevance during childhood, considering the various aspects of development listed above. Examples of such data include toxicokinetics that predict a sufficiently large internal dose in children or a mode of action where a key precursor event is more likely to occur during childhood. There is no recommended default to settle the question of whether tumors arising through a mode of action are relevant during childhood; and adequate understanding the mode of action implies that there are sufficient data (on either the specific agent or the general mode of action) to form a confident conclusion about relevance during childhood (see Section 2.4.3.4).

In the dose-response assessment, the potential for susceptibility during childhood warrants explicit consideration in each assessment. These cancer guidelines encourage developing separate risk estimates for children according to a tiered approach that considers what pertinent data are available (see Section 3.5). Childhood may be a susceptible period; moreover, exposures during childhood generally are not equivalent to exposures at other times and may be treated differently from exposures occurring later in life (see Section 3.5). In addition, adjustment of unit risk estimates may be warranted when used to estimate risks from childhood exposure (see Section 4.4).

At this time, several limitations preclude a full assessment of children's risk. There are no generally used testing protocols to identify potential environmental causes of cancers that are unique to children, including several forms of childhood cancer and cancers that develop from parental exposures, and cases where developmental exposure may alter susceptibility to carcinogen exposure in the adult (Birnbaum and Fenton, 2003). Dose-response assessment is limited by an inability to observe how developmental exposure can modify incidence and latency and an inability to estimate the ultimate tumor response resulting from induced susceptibility to later carcinogen exposures.

To partially address the limitations identified above, EPA developed in conjunction with these cancer guidelines, *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (''Supplemental Guidance''). The Supplemental Guidance addresses a number of issues pertaining to cancer risks associated with early-life exposures generally, but provides specific guidance on procedures for adjusting cancer potency estimates only for carcinogens acting through a mutagenic mode of action. This Supplemental Guidance recommends, for such chemicals when no chemical-specific data exist, a default approach using estimates from chronic studies (*i.e.*, cancer slope factors) with appropriate modifications to address the potential for differential risk of early-lifestage exposure.

The Agency considered both the advantages and disadvantages to extending the recommended, age dependent adjustment factors for carcinogenic potency to carcinogenic agents for which the mode of action remains unknown. EPA decided to recommend these factors only for carcinogens acting through a mutagenic mode of action based on a combination of analysis of available data and long-standing science policy positions which govern the Agency's overall approach to carcinogen risk assessment. In general, the Agency prefers to rely on analyses of data, rather than general defaults. When data are available for a sensitive lifestage, they would be used directly to evaluate risks for that chemical and that lifestage on a case-by-case basis. In the case of nonmutagenic carcinogens, when the mode of action is unknown, the data were judged by EPA to be too limited and the modes of action too diverse to use this as a category for which a general default adjustment factor approach can be applied. In this situation, a linear low-dose extrapolation methodology (without further adjustment) is recommended. It is the Agency's long-standing science policy position that use of the linear low-dose extrapolation approach provides adequate public health conservatism in the absence of chemical-specific data indicating differential early-life sensitivity or when the mode of action is not mutagenic.

The Agency expects to produce additional supplemental guidance for other modes of action, as data from new research and toxicity testing indicate it is warranted. EPA intends to focus its research, and work collaboratively with its federal partners, to improve understanding of the implications of early life exposure to carcinogens. Development of guidance for estrogenic agents and chemicals acting through other processes resulting in endocrine disruption and subsequent carcinogenesis, for example, might be a reasonable priority in light of the human experience with diethylstilbesterol and the existing early life animal studies. It is worth noting that each mode of action for endocrine disruption will probably require separate analysis.

As the Agency examines additional carcinogenic agents, the age groupings may differ from those recommended for

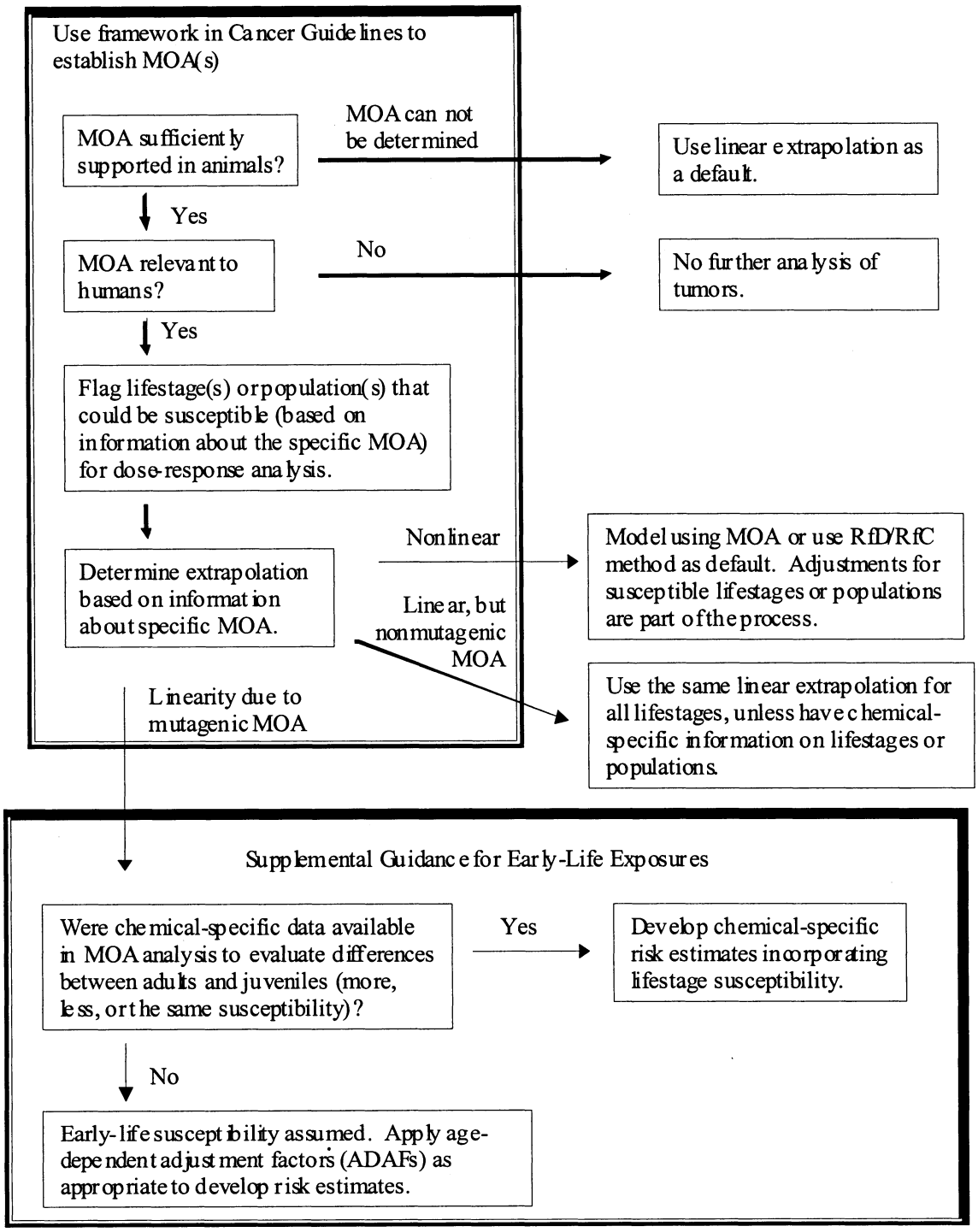
assessing cancer risks from early-life exposure to chemicals with a mutagenic mode of action. Puberty and its associated biological changes, for example, involve many biological processes that could lead to changes in sensitivity to the effects of some carcinogens, depending on their mode of action. The Agency is interested in identifying lifestages that may be particularly sensitive or refractory for carcinogenesis, and believes that the mode of action framework described in these cancer guidelines is an appropriate mechanism for elucidating these lifestages. For each additional mode of action evaluated, the various age groupings determined to be at differential risk may differ from those proposed in the Supplemental Guidance. For example, the age groupings selected for the age-dependent adjustments for carcinogens acting through a mutagenic mode of action were initially selected based on the available data, *i.e.*, for the laboratory animal age range representative of birth to < 2 years in humans. More limited data and information on human biology were used to determine a science-informed policy regarding 2 to < 16 years. Data were not available to refine the latter age group. If more data become available regarding carcinogens with a mutagenic mode of action, consideration may be given to further refinement of these age groups.

1.3.7. Emphasis on Characterization

The cancer guidelines emphasize the importance of a clear and useful characterization narrative that summarizes the analyses of hazard, dose-response, and exposure assessment. These characterizations summarize the assessments to explain the extent and weight of evidence, major points of interpretation and rationale for their selection, strengths and weaknesses of the evidence and the analysis, and discuss alternative conclusions and uncertainties that deserve serious consideration (U.S. EPA, 2000b). They serve as starting materials for the overall risk characterization process that completes the risk assessment.

BILLING CODE 6560–50–P

Figure 1-1. Flow chart for early-life risk assessment using mode of action framework.



BILLING CODE 6560–50–C

2. Hazard Assessment

2.1. Overview of Hazard Assessment and Characterization

2.1.1. Analyses of Data

The purpose of hazard assessment is to review and evaluate data pertinent to two questions: (1) Whether an agent may pose a carcinogenic hazard to human beings, and (2) under what circumstances an identified hazard may be expressed (NRC, 1994). Hazard assessment involves analyses of a variety of data that may range from observations of tumor responses to analysis of structure-activity relationships (SARs). The purpose of the assessment is not simply to assemble these separate evaluations; its purpose is to construct a total analysis examining what the biological data reveal as a whole about carcinogenic effects and mode of action of the agent, and their implications for human hazard and dose-response evaluation. Conclusions are drawn from weight-of-evidence evaluations based on the combined strength and coherence of inferences appropriately drawn from all of the available information. To the extent that data permit, hazard assessment addresses the question of mode of action of an agent as both an initial step in identifying human hazard potential and as a component in considering appropriate approaches to dose-response assessment.

The topics in this chapter include analysis of tumor data, both human and animal, and analysis of other key information about properties and effects that relate to carcinogenic potential. The chapter addresses how information can be used to evaluate potential modes of action. It also provides guidance on performing a weight of evidence evaluation.

2.1.2. Presentation of Results

Presentation of the results of hazard assessment should be informed by Agency guidance as discussed in Section 2.6. The results are presented in a technical hazard characterization that serves as a support to later risk characterization. It includes:

- A summary of the evaluations of hazard data,
- The rationales for its conclusions, and
- An explanation of the significant strengths or limitations of the conclusions.

Another presentation feature is the use of a weight of evidence narrative that includes both a conclusion about the weight of evidence of carcinogenic potential and a summary of the data on which the conclusion rests. This narrative is a brief summary that *in toto* replaces the alphanumerical classification system used in EPA's 1986 cancer guidelines (U.S. EPA, 1986a).

2.2. Analysis of Tumor Data

Evidence of carcinogenicity comes from finding tumor increases in humans or laboratory animals exposed to a given agent or from finding tumors following exposure to structural analogues to the compound under review. The significance of observed or anticipated tumor effects is evaluated in reference to all the other key data on the agent. This section contains guidance for analyzing human and animal studies to decide whether there is an association between exposure to an agent or a structural analogue and occurrence of tumors. Note that the use of the term ''tumor'' in these cancer guidelines is defined as malignant neoplasms or a combination of malignant and corresponding benign neoplasms.

Observation of only benign neoplasia may or may not have significance for evaluation under these cancer guidelines. Benign tumors that are not observed to progress to malignancy are assessed on a case-by-case basis. There is a range of possibilities for their overall significance. They may deserve attention because they are serious health problems even though they are not malignant; for instance, benign tumors may be a health risk because of their effect on the function of a target tissue such as the brain. They may be significant indicators of the need for further testing of an agent if they are observed in a short-term test protocol, or such an observation may add to the overall weight of evidence if the same agent causes malignancies in a long-term study. Knowledge of the mode of action associated with a benign tumor response may aid in the interpretation of other tumor responses associated with the same agent. In other cases, observation of a benign tumor response alone may have no significant health hazard implications when other sources of evidence show no suggestion of carcinogenicity.

2.2.1. Human Data

Human data may come from epidemiologic studies or case reports. (Clinical human studies, which involve intentional exposures to substances, may provide toxicokinetic data, but generally not data on carcinogenicity.) The most common sources of human data for cancer risk assessment are epidemiologic investigations. Epidemiology is the study of the distribution of disease in human populations and the factors that may influence that distribution. The goals of cancer epidemiology are to identify distribution of cancer risk and determine the extent to which the risk can be attributed causally to specific exposures to exogenous or endogenous factors (see Centers for Disease Control and Prevention [CDC, 2004]). Epidemiologic data are extremely valuable in risk assessment because they provide direct evidence on whether a substance is likely to produce cancer in humans, thereby avoiding issues such as: species-to-species inference, extrapolation to exposures relevant to people, effects of concomitant exposures due to lifestyles. Thus, epidemiologic studies typically evaluate agents under more relevant conditions. When human data of high quality and adequate statistical power are available, they are generally preferable over animal data and should be given greater weight in hazard characterization and dose-response assessment, although both can be used.

Null results from epidemiologic studies alone generally do not prove the absence of carcinogenic effects because such results can arise either from an agent being truly not carcinogenic or from other factors such as: inadequate statistical power, inadequate study design, imprecise estimates, or confounding factors. Moreover, null results from a well-designed and well-conducted epidemiologic study that contains usable exposure data can help to define upper limits for the estimated dose of concern for human exposure in cases where the overall weight of the evidence indicates that the agent is potentially carcinogenic in humans. Furthermore, data from a well designed and well conducted epidemiologic study that does not show positive results, in conjunction with compelling mechanistic information, can lend support to a conclusion that animal responses may not be predictive of a human cancer hazard.

Epidemiology can also complement experimental evidence in corroborating or clarifying the carcinogenic potential of the agent in question. For example, epidemiologic studies that show elevated cancer risk for tumor sites corresponding to those at which laboratory animals experience increased tumor incidence can strengthen the weight of evidence of human carcinogenicity. Furthermore, biochemical or molecular epidemiology may help improve understanding of the mechanisms of human carcinogenesis.

2.2.1.1. Assessment of Evidence of Carcinogenicity From Human Data

All studies that are considered to be of acceptable quality, whether yielding positive or null results, or even suggesting protective carcinogenic effects, should be considered in assessing the totality of the human evidence. Conclusions about the overall evidence for carcinogenicity from available studies in humans should be summarized along with a discussion of uncertainties and gaps in knowledge. Conclusions regarding the strength of the evidence for positive or negative associations observed, as well as evidence supporting judgments of causality, should be clearly described. In assessing the human data within the overall weight of evidence, determination about the strength of the epidemiologic evidence should clearly identify the degree to which the observed associations may be explained by other factors, including bias or confounding.

Characteristics that are generally desirable in epidemiologic studies include (1) Clear articulation of study objectives or hypothesis; (2) proper selection and characterization of comparison groups (exposed and unexposed groups or case and control groups); (3) adequate characterization of exposure; (4) sufficient length of follow-up for disease occurrence; (5) valid ascertainment of the causes of cancer morbidity and mortality; (6) proper consideration of bias and confounding factors; (7) adequate sample size to detect an effect; (8) clear, well-documented, and appropriate methodology for data collection and analysis; (9) adequate response rate and methodology for handling missing data; and (10) complete and clear documentation of results. No single criterion determines the overall adequacy of a study. Practical and resource constraints may limit the ability to address all of these characteristics in a study. The risk assessor is encouraged to consider how the limitations of the available studies might influence the conclusions. While positive biases may be due, for example, to a healthy worker effect, it is also important to consider negative biases, for example, workers who may leave the workforce due to illness caused either by high exposures to the agent or to effects of confounders such as smoking. The following discussions highlight the major factors included in an analysis of epidemiologic studies.

2.2.1.2. Types of Studies

The major types of cancer epidemiologic study designs used for examining environmental causes of cancer are analytical studies and descriptive studies. Each study type has well-known strengths and weaknesses that affect interpretation of results, as summarized below (Lilienfeld and Lilienfeld, 1979; Mausner and Kramer, 1985; Kelsey *et al.*, 1996; Rothman and Greenland, 1998).

Analytical epidemiologic studies, which include case-control and cohort designs, are generally relied on for identifying a causal association between human exposure and adverse health effects. In case-control studies, groups of individuals with (cases) and without (controls) a particular disease are identified and compared to determine differences in exposure. In cohort studies, a group of ''exposed'' and ''nonexposed'' individuals are identified and studied over time to determine differences in disease occurrence. Cohort studies can be performed either prospectively or retrospectively from historical records. The type of study chosen may depend on the hypothesis to be evaluated. For example, case-control studies may be more appropriate for rare cancers while cohort studies may be more appropriate for more commonly occurring cancers.

On the other hand, descriptive epidemiologic studies examine symptom or disease rates among populations in relation to personal characteristics such as age, gender, race, and temporal or environmental conditions. Descriptive studies are most frequently used to generate hypotheses about exposure factors, but subsequent analytical designs are necessary to infer causality. For example, cross-sectional designs might be used to compare the prevalence of cancer between areas near and far from a Superfund site. However, in studies where exposure and disease information applies only to the current conditions, it is not possible to infer that the exposure actually *caused* the disease. Therefore, these studies are used to identify patterns or trends in disease occurrence over time or in different geographical locations, but typical limitations in the characterization of populations in these studies make it difficult to infer the causal agent or degree of exposure.

Case reports describe a particular effect in an individual or group of individuals who were exposed to a substance. These reports are often anecdotal or highly selective in nature and generally are of limited use for hazard assessment. Specifically, cancer causality can rarely be inferred from case reports alone. Investigative follow-up may or may not accompany such reports. For cancer, the most common types of case series are associated with occupational and childhood exposures. Case reports can be particularly valuable for identifying unique features, such as an association with an uncommon tumor (*e.g.*, inhalation of vinyl chloride and hepatic angiosarcoma in workers or ingestion of diethylstilbestrol by mothers and clear-cell carcinoma of the vagina in offspring).

2.2.1.3. Exposure Issues

For epidemiologic data to be useful in determining whether there is an association between health effects and exposure to an agent, there should be adequate characterization of exposure information. In general, greater weight should be given to studies with more precise and specific exposure estimates.

Questions to address about exposure are: What can one reliably conclude about the exposure parameters including (but not limited to) the level, duration, route, and frequency of exposure of individuals in one population as compared with another? How sensitive are study results to uncertainties in these parameters?

Actual exposure measurements are not available for many retrospective studies. Therefore, surrogates are often used to reconstruct exposure parameters. These may involve attributing exposures to job classifications in a workplace or to broader occupational or geographic groupings. Use of surrogates carries a potential for misclassification, *i.e.*, individuals may be placed in an incorrect exposure group. Misclassification generally leads to reduced ability of a study to detect differences between study and referent populations.

When either current or historical monitoring data are available, the exposure evaluation includes consideration of the error bounds of the monitoring and analytic methods and whether the data are from routine or accidental exposures. The potential for misclassification and for measurement errors is amenable to both qualitative and quantitative analysis. These are essential analyses for judging a study's results, because exposure estimation is the most critical part of a retrospective study.

2.2.1.4. Biological Markers

Biological markers potentially offer excellent measures of exposure (Hulka and Margolin, 1992; Peto and Darby, 1994). In some cases, molecular or

cellular effects (*e.g.*, DNA or protein adducts, mutation, chromosomal aberrations, levels of thyroid-stimulating hormone) can be measured in blood, body fluids, cells, and tissues to serve as biomarkers of exposure in humans and animals (Callemen *et al.*, 1978; Birner *et al.*, 1990). As such, they can act as an internal surrogate measure of chemical dose, representing, as appropriate, either recent exposure (*e.g.*, serum concentration) or accumulated exposure over some period (*e.g.*, hemoglobin adducts). Validated markers of exposure such as alkylated hemoglobin from exposure to ethylene oxide (Van Sittert *et al.*, 1985) or urinary arsenic (Enterline *et al.*, 1987) can improve estimates of dose over the relevant time periods for the markers. Markers closely identified with effects promise to greatly increase the ability of studies to distinguish real effects from bias at low levels of relative risk between populations (Taylor *et al.*, 1994; Biggs *et al.*, 1993) and to resolve problems of confounding risk factors. However, when using molecular or cellular effects as biomarkers of exposure, since many of these changes are often not specific to just one type of exposure, it is important to be aware that changes may be due to exposures unrelated to the exposure of interest and attention must be paid to controlling for potential confounders.

Biochemical or molecular epidemiologic studies may use biological markers of effect as indicators of disease or its precursors. The application of techniques for measuring cellular and molecular alterations due to exposure to specific environmental agents may allow conclusions to be drawn about the mechanisms of carcinogenesis (see section 2.4 for more information on this topic).

2.2.1.5. Confounding Factors

Control for potential confounding factors is an important consideration in the evaluation of the design and in the analysis of observational epidemiologic studies. A confounder is a variable that is related to both the health outcome of concern (cancer) and exposure. Common examples include age, socioeconomic status, smoking habits, and diet. For instance, if older people are more likely to be exposed to a given contaminant as well as more likely to have cancer because of their age, age is considered a confounder. Adjustment for potentially confounding factors (from a statistical as contrasted with an epidemiologic point of view) can occur either in the design of the study (*e.g.*, individual or group matching on critical factors) or in the statistical analysis of the results (stratification or direct or indirect adjustment). Direct adjustment in the statistical analysis may not be possible owing to the presentation of the data or because needed information was not collected during the study. In this case, indirect comparisons may be possible. For example, in the absence of data on smoking status among individuals in the study population, an examination of the possible contribution of cigarette smoking to increased lung cancer risk may be based on information from other sources, such as the American Cancer Society's longitudinal studies (Hammand, 1966; Garfinkel and Silverberg, 1991). The effectiveness of adjustments contributes to the ability to draw inferences from a study.

Different studies involving exposure to an agent may have different confounding factors. If consistent increases in cancer risk are observed across a collection of studies with different confounding factors, the inference that the agent under investigation was the etiologic factor is strengthened.

There may also be instances where the agent of interest is a risk factor in conjunction with another agent. For instance, interaction as well as effect-measure modification are sometimes construed to be confounding, but they are different than confounding. Interaction is described as a situation in which two or more risk factors modify the effect of each other with regard to the occurrence of a given effect. This phenomenon is sometimes described as effect-measure modification or heterogeneity of effect (Szklo and Nieto, 2000). Effect-measure modification refers to variation in the magnitude of measure exposure effect across levels of another variable (Rothman and Greenland, 1998). The variable across which the effect measure varies and is called an *effect modifier* (*e.g.*, hepatitis virus B and aflatoxin in hepatic cancer). Interaction, on the other hand, means effect of the exposure on the outcome differs, depending on the presence of another variable (the effect modifier). When the effect of the exposure of interest is accentuated by another variable, it is said to be synergistic interaction. Synergistic interaction can be additive (*e.g.*, hepatitis virus B and aflatoxin in hepatic cancer) or multiplicative (*e.g.*, asbestos and smoking in lung cancer). If the effect of exposure is diminished or eliminated by another variable, it said to be antagonistic interaction (*e.g.*, intake of vitamin E and lower occurrence of lung cancer).

2.2.1.6. Statistical Considerations

The analysis should apply appropriate statistical methods to ascertain whether the observed association between exposure and effects would be expected by chance. A description of the method or methods used should include the reasons for their selection. Statistical analyses of the bias, confounding, and interaction are part of addressing the significance of an association and the power of a study to detect an effect.

The analysis augments examination of the results for the whole population with exploration of the results for groups with comparatively greater exposure or time since first exposure. This may support identifying an association or establishing a dose-response trend. When studies show no association, such exploration may apply to determining an upper limit on potential human risk for consideration alongside results of animal tumor effects studies.

2.2.1.6.1. Likelihood of Observing an Effect

The power of a study—the likelihood of observing an effect if one exists—increases with sample size, *i.e.*, the number of subjects studied from a population. (For example, a quadrupling of a background rate in the 1 per 10,000 range would require more subjects who have experienced greater or longer exposure or lengthier follow-up, than a doubling of a background rate in the 1 per 100 range.) If the size of the effect is expected to be very small at low doses, higher doses or longer durations of exposure may be needed to have an appreciable likelihood of observing an effect with a given sample size. Because of the often long latency period in cancer development, the likelihood of observing an effect also depends on whether adequate time has elapsed since exposure began for effects to occur. Since the design of the study and the choice of analysis, as well as the design level of certainty in the results and the magnitude of response in an unexposed population also affect the likelihood of observing an effect, it is important to carefully interpret the absence of an observed effect. A unique feature that can be ascribed to the effects of a particular agent (such as a tumor type that is seen only rarely in the absence of the agent) can increase sensitivity by permitting separation of bias and confounding factors from real effects. Similarly, a biomarker particular to the agent can permit these distinctions. Statistical re-analyses of data, particularly an examination of

different exposure indices, can give insight into potential exposure-response relationships. These are all factors to explore in statistical analysis of the data.

2.2.1.6.2. Sampling and Other Bias Issues

When comparing cases and controls or exposed and non-exposed populations, it would be preferable for the two populations to differ only in exposure to the agent in question. Because this is seldom the case, it is important to identify sources of sampling and other potential biases inherent in a study design or data collection methods.

Bias is a systematic error. In epidemiologic studies, bias can occur in the selection of cases and controls or exposed and non-exposed populations, as well as the follow up of the groups, or the classification of disease or exposure. The size of the risks observed can be affected by noncomparability between populations of factors such as general health, diet, lifestyle, or geographic location; differences in the way case and control individuals recall past events; differences in data collection that result in unequal ascertainment of health effects in the populations; and unequal follow-up of individuals (Rothman and Greenland, 1998). Other factors worth consideration can be inherent in the available cohorts, *e.g.*, use of occupational studies (the healthy worker effect), absence of one sex, or limitations in sample size for one or more ethnicities.

The mere presence of biases does not invalidate a study, but should be reflected in the judgment of its strengths or weaknesses. Acceptance of studies for assessment depends on identifying their sources of bias and the possible effects on study results.

2.2.1.6.3. Combining Statistical Evidence Across Studies

Meta-analysis is a means of integrating the results of multiple studies of similar health effects and risk factors. This technique is particularly useful when various studies yield varying degrees of risk or even conflicting associations (negative and positive). It is intended to introduce consistency and comprehensiveness into what otherwise might be a more subjective review of the literature. The value of such an analysis is dependent upon a systematic review of the literature that uses transparent criteria of inclusion and exclusion. In interpreting such analyses, it is important to consider the effects of differences in study quality, as well as the effect of publication bias. Meta-analysis may not be advantageous in some circumstances. These include when the relationship between exposure and disease is obvious from the individual studies; when there are only a few studies of the key health outcomes; when there is insufficient information from available studies related to disease, risk estimate, or exposure classification to insure comparability; or when there are substantial confounding or other biases that cannot be adjusted for in the analysis (Blair *et al.*, 1995; Greenland, 1987; Peto, 1992).

2.2.1.7. Evidence for Causality

Determining whether an observed association (risk) is causal rather than spurious involves consideration of a number of factors. Sir Bradford Hill (Hill, 1965) developed a set of guidelines for evaluating epidemiologic associations that can be used in conjunction with the discussion of causality such as the 2004 Surgeon General's report on smoking (CDC, 2004) and in other documents (*e.g.*, Rothman and Greenland 1998; IPCS, 1999). The critical assessment of epidemiologic evidence is conceptually based upon consideration of salient aspects of the evidence of associations so as to reach fundamental judgments as to the likely causal significance of the observed associations. In so doing, it is appropriate to draw from those aspects initially presented in Hill's classic monograph (Hill, 1965) and widely used by the scientific community in conducting such evidence-based reviews. A number of these aspects are judged to be particularly salient in evaluating the body of evidence available in this review, including the aspects described by Hill as strength, experiment, consistency, plausibility, and coherence. Other aspects identified by Hill, including temporality and biological gradient, are also relevant and considered here (*e.g.*, in characterizing lag structures and concentration-response relationships), but are more directly addressed in the design and analyses of the individual epidemiologic studies included in this assessment. As discussed below, these salient aspects are interrelated and considered throughout the evaluation of the epidemiologic evidence generally reflected in the integrative synthesis of the mode of action framework.

The general evaluation of the strength of the epidemiological evidence reflects consideration not only of the magnitude of reported effects estimates and their statistical significance, but also of the precision of the effects estimates and the robustness of the effects associations. Consideration of the robustness of the associations takes into account a number of factors, including in particular the impact of alternative models and model specifications and potential confounding factors, as well issues related to the consequences of measurement error. Consideration of the consistency of the effects associations involves looking across the results of studies conducted by different investigators in different places and times. Particular weight may be given, consistent with Hill's views, to the presence of ''similar results reached in quite different ways, *e.g.*, prospectively and retrospectively'' (Hill, 1965). Looking beyond the epidemiological evidence, evaluation of the biological plausibility of the associations observed in epidemiologic studies reflects consideration of both exposure-related factors and toxicological evidence relevant to identification of potential modes of action (MOAs). Similarly, consideration of the coherence of health effects associations reported in the epidemiologic literature reflects broad consideration of information pertaining to the nature of the biological markers evaluated in toxicologic and epidemiologic studies.

In identifying these aspects as being particularly salient in this assessment, it is also important to recognize that no one aspect is either necessary or sufficient for drawing inferences of causality. As Hill (1965) emphasized:

> None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as *a sine qua non*. What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question—is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?

While these aspects frame considerations weighed in assessing the epidemiologic evidence, they do not lend themselves to being considered in terms of simple formulas or hard-and-fast rules of evidence leading to answers about causality (Hill, 1965). One, for example, cannot simply count up the numbers of studies reporting statistically significant results or statistically non-significant results for carcinogenesis and related MOAs and reach credible conclusions about the relative strength of the evidence and the likelihood of causality. Rather, these important considerations are taken into account throughout the assessment with a goal of producing an objective appraisal of the evidence (informed by peer and public comment and advice),

which includes the weighing of alternative views on controversial issues. Thus, although these guidelines have become known as ''causal criteria,'' it is important to note that they cannot be used as a strictly quantitative checklist. Rather, these ''criteria'' should be used to determine the strength of the evidence for concluding causality. In particular, the absence of one or more of the ''criteria'' does not automatically exclude a study from consideration (*e.g.*, see discussion in CDC, 2004). The list below has been adapted from Hill's guidelines as an aid in judging causality.

(a) *Consistency of the observed association*. An inference of causality is strengthened when a pattern of elevated risks is observed across several independent studies. The reproducibility of findings constitutes one of the strongest arguments for causality. If there are discordant results among investigations, possible reasons such as differences in exposure, confounding factors, and the power of the study are considered.

(b) *Strength of the observed association*. The finding of large, precise risks increases confidence that the association is not likely due to chance, bias, or other factors. A modest risk, however, does not preclude a causal association and may reflect a lower level of exposure, an agent of lower potency, or a common disease with a high background level.

(c) *Specificity of the observed association*. As originally intended, this refers to increased inference of causality if one cause is associated with a single effect or disease (Hill, 1965). Based on our current understanding that many agents cause cancer at multiple sites, and many cancers have multiple causes, this is now considered one of the weaker guidelines for causality. Thus, although the presence of specificity may support causality, its absence does not exclude it.

(d) *Temporal relationship of the observed association*. A causal interpretation is strengthened when exposure is known to precede development of the disease. Because a latent period of up to 20 years or longer is often associated with cancer development in adults, the study should consider whether exposures occurred sufficiently long ago to produce an effect at the time the cancer is assessed. This is among the strongest criteria for an inference of causality.

(e) *Biological gradient (exposure-response relationship)*. A clear exposure-response relationship (*e.g.*, increasing effects associated with greater exposure) strongly suggests cause and effect, especially when such relationships are also observed for duration of exposure (*e.g.*, increasing effects observed following longer exposure times). There are many possible reasons that an epidemiologic study may fail to detect an exposure-response relationship. For example, an analysis that included decreasing exposures due to improved technology that is combined with higher prior exposure in an initial analysis can require a segmented analysis to apportion exposure. Other reasons for failure to detect a relationship may include a small range of exposures. Thus, the absence of an exposure-response relationship does not exclude a causal relationship.

(f) *Biological plausibility*. An inference of causality tends to be strengthened by consistency with data from experimental studies or other sources demonstrating plausible biological mechanisms. A lack of mechanistic data, however, is not a reason to reject causality.

(g) *Coherence*. An inference of causality may be strengthened by other lines of evidence that support a cause-and-effect interpretation of the association. Information is considered from animal bioassays, toxicokinetic studies, and short-term studies. The absence of other lines of evidence, however, is not a reason to reject causality.

(h) *Experimental evidence (from human populations)*. Experimental evidence is seldom available from human populations and exists only when conditions of human exposure have occurred to create a ''natural experiment'' at different levels of exposure. Strong evidence for causality can be provided when a change in exposure brings about a change in disease frequency, for example, the decrease in the risk of lung cancer that follows cessation of smoking.

(i) *Analogy*. SARs and information on the agent's structural analogues can provide insight into whether an association is causal. Similarly, information on mode of action for a chemical, as one of many structural analogues, can inform decisions regarding likely causality.

2.2.2. Animal Data

Various whole-animal test systems are currently used or are under development for evaluating potential carcinogenicity. Cancer studies involving chronic exposure for most of the lifespan of an animal are generally accepted for evaluation of tumor effects (Tomatis *et al.*, 1989; Rall, 1991; Allen *et al.*, 1988; but see Ames and Gold, 1990). Other studies of special design are useful for observing formation of preneoplastic lesions or tumors or investigating specific modes of action. Their applicability is determined on a case-by-case basis.

2.2.2.1. Long-Term Carcinogenicity Studies

The objective of long-term carcinogenesis bioassays is to determine the potential carcinogenic hazard and dose-response relationships of the test agent. Carcinogenicity rodent studies are designed to examine the production of tumors as well as preneoplastic lesions and other indications of chronic toxicity that may provide evidence of treatment-related effects and insights into the way the test agent produces tumors. Current standardized carcinogenicity studies in rodents test at least 50 animals per sex per dose group in each of three treatment groups and in a concurrent control group, usually for 18 to 24 months, depending on the rodent species tested (OECD, 1981; U.S. EPA, 1998c). The high dose in long-term studies is generally selected to provide the maximum ability to detect treatment-related carcinogenic effects while not compromising the outcome of the study through excessive toxicity or inducing inappropriate toxicokinetics (*e.g.*, overwhelming absorption or detoxification mechanisms). The purpose of two or more lower doses is to provide some information on the shape of the dose-response curve. Similar protocols have been and continue to be used by many laboratories worldwide.

All available studies of tumor effects in whole animals should be considered, at least preliminarily. The analysis should discard studies judged to be wholly inadequate in protocol, conduct, or results. Criteria for the technical adequacy of animal carcinogenicity studies have been published and should be used as guidance to judge the acceptability of individual studies (*e.g.*, NTP, 1984; OSTP, 1985; Chhabra *et al.*, 1990). As these criteria, in whole or in part, may be updated by the National Toxicology Program (NTP) and others, the analyst should consult the appropriate sources to determine both the current standards as well as those that were contemporaneous with the study. Care should be taken to include studies that provide some evidence bearing on carcinogenicity or that help interpret effects noted in other studies, even if these studies have some limitations of protocol or conduct. Such limited, but not wholly inadequate, studies can contribute as their deficiencies permit. The findings of

long-term rodent bioassays should be interpreted in conjunction with results of prechronic studies along with toxicokinetic studies and other pertinent information, if available. Evaluation of tumor effects takes into consideration both biological and statistical significance of the findings (Haseman, 1984, 1985, 1990, 1995). The following sections highlight the major issues in the evaluation of long-term carcinogenicity studies.

2.2.2.1.1. Dosing Issues

Among the many criteria for technical adequacy of animal carcinogenicity studies is the appropriateness of dose selection. The selection of doses for chronic bioassays is based on scientific judgments and sound toxicologic principles. Dose selection should be made on the basis of relevant toxicologic information from prechronic, mechanistic, and toxicokinetic and mechanistic studies. A scientific rationale for dose selection should be clearly articulated (*e.g.*, NTP, 1984; ILSI, 1997). How well the dose selection is made is evaluated after the completion of the bioassay.

Interpretation of carcinogenicity study results is profoundly affected by study exposure conditions, especially by inappropriate dose selection. This is particularly important in studies that do not show positive results for carcinogenicity, because failure to use a sufficiently high dose reduces the sensitivity of the studies. A lack of tumorigenic responses at exposure levels that cause significant impairment of animal survival may also not be acceptable. In addition, overt toxicity or qualitatively altered toxicokinetics due to excessively high doses may result in tumor effects that are secondary to the toxicity rather than directly attributable to the agent.

With regard to the appropriateness of the high dose, an adequate high dose would generally be one that produces some toxic effects without unduly affecting mortality from effects other than cancer or producing significant adverse effects on the nutrition and health of the test animals (OECD, 1981; NRC, 1993a). If the test agent does not appear to cause any specific target organ toxicity or perturbation of physiological function, an adequate high dose can be specified in terms of a percentage reduction of body weight gain over the lifespan of the animals. The high dose would generally be considered inadequate if neither toxicity nor change in weight gain is observed. On the other hand, significant increases in mortality from effects other than cancer generally indicate that an adequate high dose has been exceeded.

Other signs of treatment-related toxicity associated with an excessive high dose may include (a) Significant reduction of body weight gain (*e.g.*, greater than 10%), (b) significant increases in abnormal behavioral and clinical signs, (c) significant changes in hematology or clinical chemistry, (d) saturation of absorption and detoxification mechanisms, or (e) marked changes in organ weight, morphology, and histopathology. It should be noted that practical upper limits have been established to avoid the use of excessively high doses in long-term carcinogenicity studies of environmental chemicals (*e.g.*, 5% of the test substance in the feed for dietary studies or 1 g/kg body weight for oral gavage studies [OECD, 1981]).

For dietary studies, weight gain reductions should be evaluated as to whether there is a palatability problem or an issue with food efficiency; certainly, the latter is a toxic manifestation. In the case of inhalation studies with respirable particles, evidence of impairment of normal clearance of particles from the lung should be considered along with other signs of toxicity to the respiratory airways to determine whether the high exposure concentration has been appropriately selected (U.S. EPA, 2001a). For dermal studies, evidence of skin irritation may indicate that an adequate high dose has been reached (U.S. EPA, 1989).

In order to obtain the most relevant information from a long-term carcinogenicity study, it is important to maximize exposure conditions to the test material. At the same time, caution is appropriate in using excessive high-dose levels that would confound the interpretation of study results to humans. The middle and lowest doses should be selected to characterize the shape of the dose-response curve as much as possible. It is important that the doses be adequately spaced so that the study can provide relevant dose-response data for assessing human hazard and risk. If the testing of potential carcinogenicity is being combined with an evaluation of noncancer chronic toxicity, the study should be designed to include one dose in addition to the control(s) that is not expected to elicit adverse effects.

There are several possible outcomes regarding the study interpretation of the significance and relevance of tumorigenic effects associated with exposure or dose levels below, at, or above an adequate high dose. The general guidance is given here; for each case, the information at hand should be evaluated and a rationale should be given for the position taken.

- *Adequately high dose*. If an adequately high dose has been used, tumor effects are judged positive or negative depending on the presence or absence of significant tumor incidence increases, respectively.
- *Excessively high dose*. If toxicity or mortality is excessive at the high dose, interpretation depends on whether or not tumors are found.

—Studies that show tumor effects only at excessive doses may be compromised and may or may not carry weight, depending on the interpretation in the context of other study results and other lines of evidence. Results of such studies, however, are generally not considered suitable for dose-response extrapolation if it is determined that the mode(s) of action underlying the tumorigenic responses at high doses is not operative at lower doses.

—Studies that show tumors at lower doses, even though the high dose is excessive and may be discounted, should be evaluated on their own merits.

—If a study does not show an increase in tumor incidence at a toxic high dose and appropriately spaced lower doses are used without such toxicity or tumors, the study is generally judged as negative for carcinogenicity.

- *Inadequately high dose*. Studies of inadequate sensitivity where an adequately high dose has not been reached may be used to bound the dose range where carcinogenic effects might be expected.

2.2.2.1.2. Statistical Considerations

The main aim of statistical evaluation is to determine whether exposure to the test agent is associated with an increase of tumor development. Statistical analysis of a long-term study should be performed for each tumor type separately. The incidence of benign and malignant lesions of the same cell type, usually within a single tissue or organ, are considered separately but may be combined when scientifically defensible (McConnell *et al.*, 1986).

Trend tests and pairwise comparison tests are the recommended tests for determining whether chance, rather than a treatment-related effect, is a plausible explanation for an apparent increase in tumor incidence. A trend test such as the Cochran-Armitage test (Snedecor and Cochran, 1967) asks whether the results in all dose groups together increase as dose increases. A pairwise comparison test such as the

Fisher exact test (Fisher, 1950) asks whether an incidence in one dose group is increased over that of the control group. By convention, for both tests a statistically significant comparison is one for which p is less than 0.05 that the increased incidence is due to chance. Significance in either kind of test is sufficient to reject the hypothesis that chance accounts for the result.

A statistically significant response may or may not be biologically significant and vice versa. The selection of a significance level is a policy choice based on a trade-off between the risks of false positives and false negatives. A result with a significance level of greater or less than 5% (the most common significance level) is examined to see if the result confirms other scientific information. When the assessment departs from a simple 5% level, this should be highlighted in the risk characterization. A two-tailed test or a one-tailed test can be used. In either case a rationale is provided.

Statistical power can affect the likelihood that a statistically significant result could reasonably be expected. This is especially important in studies or dose groups with small sample sizes or low dose rates. Reporting the statistical power can be useful for comparing and reconciling positive and negative results from different studies.

Considerations of multiple comparisons should also be taken into account. Haseman (1983) analyzed typical animal bioassays that tested both sexes of two species and concluded that, because of multiple comparisons, a single tumor increase for a species-sex-site combination that is statistically significant at the 1% level for common tumors or 5% for rare tumors corresponds to a 7–8% significance level for the study as a whole. Therefore, animal bioassays presenting only one significant result that falls short of the 1% level for a common tumor should be treated with caution.

2.2.2.1.3. Concurrent and Historical Controls

The standard for determining statistical significance of tumor incidence comes from a comparison of tumors in dosed animals with those in concurrent control animals. Additional insights about both statistical and biological significance can come from an examination of historical control data (Tarone, 1982; Haseman, 1995). Historical control data can add to the analysis, particularly by enabling identification of uncommon tumor types or high spontaneous incidence of a tumor in a given animal strain. Identification of common or uncommon situations prompts further thought about the meaning of the response in the current study in context with other observations in animal studies and with other evidence about the carcinogenic potential of the agent. These other sources of information may reinforce or weaken the significance given to the response in the hazard assessment. Caution should be exercised in simply looking at the ranges of historical responses, because the range ignores differences in survival of animals among studies and is related to the number of studies in the database.

In analyzing results for uncommon tumors in a treated group that are not statistically significant in comparison with concurrent controls, the analyst may be informed by the experience of historical controls to conclude that the result is in fact unlikely to be due to chance. However, caution should be used in interpreting results. In analyzing results for common tumors, a different set of considerations comes into play. Generally speaking, statistically significant increases in tumors should not be discounted simply because incidence rates in the treated groups are within the range of historical controls or because incidence rates in the concurrent controls are somewhat lower than average. Random assignment of animals to groups and proper statistical procedures provide assurance that statistically significant results are unlikely to be due to chance alone. However, caution should be used in interpreting results that are barely statistically significant or in which incidence rates in concurrent controls are unusually low in comparison with historical controls.

In cases where there may be reason to discount the biological relevance to humans of increases in common animal tumors, such considerations should be weighed on their own merits and clearly distinguished from statistical concerns.

When historical control data are used, the discussion should address several issues that affect comparability of historical and concurrent control data, such as genetic drift in the laboratory strains, differences in pathology examination at different times and in different laboratories (*e.g.*, in criteria for evaluating lesions; variations in the techniques for the preparation or reading of tissue samples among laboratories), and comparability of animals from different suppliers. The most relevant historical data come from the same laboratory and the same supplier and are gathered within 2 or 3 years one way or the other of the study under review; other data should be used only with extreme caution.

2.2.2.1.4. Assessment of Evidence of Carcinogenicity From Long-term Animal Studies

In general, observation of tumors under different circumstances lends support to the significance of the findings for animal carcinogenicity. Significance is generally increased by the observation of more of the factors listed below. For a factor such as malignancy, the severity of the observed pathology can also affect the significance. The following observations add significance to the tumor findings:

- Uncommon tumor types;
- Tumors at multiple sites;
- Tumors by more than one route of administration;
- Tumors in multiple species, strains, or both sexes;
- Progression of lesions from preneoplastic to benign to malignant;
- Reduced latency of neoplastic lesions;
- Metastases;
- Unusual magnitude of tumor response;
- Proportion of malignant tumors; and
- Dose-related increases.

In these cancer guidelines, tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans. Mode of action may help inform this assumption on a chemical-specific basis. Moreover, the absence of tumors in well-conducted, long-term animal studies in at least two species provides reasonable assurance that an agent may not be a carcinogenic concern for humans.

2.2.2.1.5. Site Concordance

Site concordance of tumor effects between animals and humans should be considered in each case. Thus far, there is evidence that growth control mechanisms at the level of the cell are homologous among mammals, but there is no evidence that these mechanisms are site concordant. Moreover, agents observed to produce tumors in both humans and animals have produced tumors either at the same site (*e.g.*, vinyl chloride) or different sites (*e.g.*, benzene)(NRC, 1994). Hence, site concordance is not always assumed between animals and humans. On the other hand, certain modes of action with consequences for particular tissue sites (*e.g.*, disruption of thyroid function) may lead to an anticipation of site concordance.

2.2.2.2. Perinatal Carcinogenicity Studies

The objective of perinatal carcinogenesis studies is to determine

the carcinogenic potential and dose-response relationships of the test agent in the developing organism. Some investigators have hypothesized that the age of initial exposure to a chemical carcinogen may influence the carcinogenic response (Vesselinovitch *et al.*, 1979; Rice, 1979; McConnell, 1992). Current standardized long-term carcinogenesis bioassays generally begin dosing animals at 6–8 weeks of age and continue dosing for the lifespan of the animal (18–24 months). This protocol has been modified in some cases to investigate the potential of the test agent to induce transplacental carcinogenesis or to investigate the potential differences following perinatal and adult exposures, but currently there is not a standardized protocol for testing agents for carcinogenic effects following prenatal or early postnatal exposure.

Several cancer bioassay studies have compared adult and perinatal exposures (see McConnell, 1992; U.S. EPA, 1996b). A review of these studies reveals that perinatal exposure rarely identifies carcinogens that are not found in standard animal bioassays. Exposure that is perinatal can increase the incidence of a given type of tumor. The increase may reflect an increased length of exposure and a higher dose for the developing organism relative to the adult or an increase in susceptibility in some cases. Additionally, exposure that is perinatal through adulthood sometimes reduces the latency period for tumors to develop in the growing organism (U.S. EPA, 1996b). EPA evaluates the usefulness of perinatal studies on an agent-by-agent basis (*e.g.*, U.S. EPA, 1997a, b).

Perinatal study data analysis generally follows the principles discussed above for evaluating other long-term carcinogenicity studies. When differences in responses between perinatal animals and adult animals suggest an increased susceptibility of perinatal or postnatal animals, such as the ones below, a separate evaluation of the response should be prepared:

- A difference in dose-response relationship,
- The presence of different tumor types,
- An earlier onset of tumors, or
- An increase in the incidence of tumors.

2.2.2.3. Other Studies

Intermediate-term and acute dosing studies often use protocols that screen for carcinogenic or preneoplastic effects, sometimes in a single tissue. Some protocols involve the development of various proliferative lesions, such as foci of alteration in the liver (Goldsworthy *et al.*, 1986). Others use tumor endpoints, such as the induction of lung adenomas in the sensitive strain A mouse (Maronpot *et al.*, 1986) or tumor induction in initiation-promotion studies using various organs such as the bladder, intestine, liver, lung, mammary gland, and thyroid (Ito *et al.*, 1992). In these tests, the selected tissue rather than the whole animal is, in a sense, the test system. Important information concerning the steps in the carcinogenic process and mode of action can be obtained from ''start/stop'' experiments. In these protocols, an agent is given for a period of time to induce particular lesions or effects and then stopped in order to evaluate the progression or reversibility of processes (Todd, 1986; Marsman and Popp, 1994).

Assays in genetically engineered rodents may provide insight into the chemical and gene interactions involved in carcinogenesis (Tennant *et al.*, 1995). These mechanistically based approaches involve activated oncogenes that are introduced (transgenic) or tumor suppressor genes that are deleted (knocked out). If appropriate genes are selected, not only may these systems provide information on mechanisms, but the rodents typically show tumor development earlier than in the standard bioassay. Transgenic mutagenesis assays also represent a mechanistic approach for assessing the mutagenic properties of agents as well as developing quantitative linkages between exposure, internal dose, and mutation related to tumor induction (Morrison and Ashby, 1994; Sisk *et al.*, 1994; Hayward *et al.*, 1995).

The support that these studies give to a determination of carcinogenicity rests on their contribution to the consistency of other evidence about an agent. For instance, benzoyl peroxide has promoter activity on the skin, but the overall evidence may be less supportive (Kraus *et al.*, 1995). These studies also may contribute information about mode of action. It is important to recognize the limitations of these experimental protocols, such as short duration, limited histology, lack of complete development of tumors, or experimental manipulation of the carcinogenic process, that may limit their contribution to the overall assessment. Generally, their results are appropriate as aids in the interpretation of other toxicological evidence (*e.g.*, rodent chronic bioassays), especially regarding potential modes of action. On the basis of currently available information, it is unlikely that any of these assays, which are conducted for 6 months with 15 animals per group, will replace all chronic bioassays for hazard identification (Spalding *et al.*, 2000; Gulezian *et al.*, 2000; ILSI, 2001).

2.2.3. Structural Analogue Data

For some chemical classes, there is significant available information, largely from rodent bioassays, on the carcinogenicity of analogues. Analogue effects are instructive in investigating carcinogenic potential of an agent as well as in identifying potential target organs, exposures associated with effects, and potential functional class effects or modes of action. All appropriate studies should be included and analyzed, whether indicative of a positive effect or not. Evaluation includes tests in various animal species, strains, and sexes; with different routes of administration; and at various doses, as data are available. Confidence in conclusions is a function of how similar the analogues are to the agent under review in structure, metabolism, and biological activity. It is important to consider this confidence to ensure a balanced position.

2.3. Analysis of Other Key Data

The physical, chemical, and structural properties of an agent, as well as data on endpoints that are thought to be critical elements of the carcinogenic process, provide valuable insights into the likelihood of human cancer risk. The following sections provide guidance for analyses of these data.

2.3.1. Physicochemical Properties

Physicochemical properties affect an agent's absorption, tissue distribution (bioavailability), biotransformation, and degradation in the body and are important determinants of hazard potential (and dose-response analysis). Properties that should be analyzed include, but are not limited to, molecular weight, size, and shape; valence state; physical state (gas, liquid, solid); water or lipid solubility, which can influence retention and tissue distribution; and potential for chemical degradation or stabilization in the body.

An agent's potential for chemical reaction with cellular components, particularly with DNA and proteins, is also important. The agent's molecular size and shape, electrophilicity, and charge distribution are considered in order to decide whether they would facilitate such reactions.

2.3.2. Structure-Activity Relationships (SARs)

SAR analyses and models can be used to predict molecular properties, surrogate biological endpoints, and carcinogenicity (see, *e.g.*, Richard, 1998a, b; Richard and Williams, 2002;

Contrera *et al.*, 2003). Overall, these analyses provide valuable initial information on agents, they may strengthen or weaken concern, and they are part of the weight of evidence.

Currently, SAR analysis is most useful for chemicals and metabolites that are believed to initiate carcinogenesis through covalent interaction with DNA (*i.e.*, DNA-reactive, mutagenic, electrophilic, or proelectrophilic chemicals) (Ashby and Tennant, 1991). For organic chemicals, the predictive capability of SAR analysis combined with other toxicity information has been demonstrated (Ashby and Tennant, 1994). The following parameters are useful in comparing an agent to its structural analogues and congeners that produce tumors and affect related biological processes such as receptor binding and activation, mutagenicity, and general toxicity (Woo and Arcos, 1989):

- Nature and reactivity of the electrophilic moiety or moieties present;
- Potential to form electrophilic reactive intermediate(s) through chemical, photochemical, or metabolic activation;
- Contribution of the carrier molecule to which the electrophilic moiety(ies) is attached;
- Physicochemical properties (*e.g.*, physical state, solubility, octanol/water partition coefficient, half-life in aqueous solution);
- Structural and substructural features (*e.g.*, electronic, stearic, molecular geometric);
- Metabolic pattern (*e.g.*, metabolic pathways and activation and detoxification ratio); and
- Possible exposure route(s) of the agent.

Suitable SAR analysis of non-DNA-reactive chemicals and of DNA-reactive chemicals that do not appear to bind covalently to DNA should be based on knowledge or postulation of the probable mode(s) of action of closely related carcinogenic structural analogues (*e.g.*, receptor mediated, cytotoxicity related). Examination of the physicochemical and biochemical properties of the agent may then provide the rest of the information needed in order to make an assessment of the likelihood of the agent's activity by that mode of action.

2.3.3. Comparative Metabolism and Toxicokinetics

Studies of the absorption, distribution, biotransformation, and excretion of agents permit comparisons among species to assist in determining the implications of animal responses for human hazard assessment, supporting identification of active metabolites, identifying changes in distribution and metabolic pathway or pathways over a dose range, and making comparisons among different routes of exposure.

If extensive data are available (*e.g.*, blood/tissue partition coefficients and pertinent physiological parameters of the species of interest), physiologically based toxicokinetic models can be constructed to assist in a determination of tissue dosimetry, species-to-species extrapolation of dose, and route-to-route extrapolation (Conolly and Andersen, 1991; see Section 3.1.2). If sufficient data are not available, it may be assumed as a default that toxicokinetic and metabolic processes are qualitatively comparable among species. Discussion of appropriate procedures for quantitative, interspecies comparisons appears in Chapter 3.

The *qualitative* question of whether an agent is absorbed by a particular route of exposure is important for weight of evidence classification, discussed in Section 2.5. Decisions about whether route of exposure is a limiting factor on expression of any hazard, *e.g.*, absorption does not occur by a specified route, are generally based on studies in which effects of the agent or its structural analogues have been observed by different routes, on physical-chemical properties, or on toxicokinetics studies.

Adequate metabolism and toxicokinetic data can be applied toward the following, as data permit. Confidence in conclusions is enhanced when *in vivo* data are available.

- *Identifying metabolites and reactive intermediates of metabolism and determining whether one or more of these intermediates is likely to be responsible for the observed effects.* Information on the reactive intermediates focuses on SAR analysis, analysis of potential modes of action, and estimation of internal dose in dose-response assessment (D'Souza *et al.*, 1987; Krewski *et al.*, 1987).
- *Identifying and comparing the relative activities of metabolic pathways in animals and in humans, and at different ages.* This analysis can provide insights for extrapolating results of animal studies to humans.
- *Describing anticipated distribution within the body and possibly identifying target organs.* Use of water solubility, molecular weight, and structure analysis can support qualitative inferences about anticipated distribution and excretion. In addition, describing whether the agent or metabolite of concern will be excreted rapidly or slowly or whether it will be stored in a particular tissue or tissues to be mobilized later can identify issues in comparing species and formulating dose-response assessment approaches.
- *Identifying changes in toxicokinetics and metabolic pathways with increases in dose.* These changes may result in important differences between high and low dose levels in disposition of the agent or generation of its active forms. These studies play an important role in providing a rationale for dose selection in carcinogenicity studies.
- *Identifying and comparing metabolic process differences by age, sex, or other characteristic so that susceptible subpopulations can be recognized.* For example, metabolic capacity with respect to P450 enzymes in newborn children is extremely limited compared to that in adults, so that a carcinogenic metabolite formed through P450 activity will have limited effect in the young, whereas a carcinogenic agent deactivated through P450 activity will result in increased susceptibility of this lifestage (Cresteil, 1998). A variety of changes in toxicokinetics and physiology occur from the fetal stage to post-weaning to young child. Any of these changes may make a difference for risk (Renwick, 1998).
- *Determining bioavailability via different routes of exposure by analyzing uptake processes under various exposure conditions.* This analysis supports identification of hazards for untested routes. In addition, use of physicochemical data (*e.g.*, octanol-water partition coefficient information) can support an inference about the likelihood of dermal absorption (Flynn, 1990).

Attempts should be made in all of these areas to clarify and describe as much as possible the variability to be expected because of differences in species, sex, age, and route of exposure. The analysis takes into account the presence of subpopulations of individuals who are particularly vulnerable to the effects of an agent because of toxicokinetic or metabolic differences (genetically or environmentally determined) (Bois *et al.*, 1995) and is a special emphasis for assessment of risks to children.

2.3.4. Toxicological and Clinical Findings

Toxicological findings in experimental animals and clinical observations in humans are important resources for the cancer hazard assessment. Such findings provide information on physiological effects and effects on enzymes, hormones, and other important macromolecules as well

as on target organs for toxicity. For example, given that the cancer process represents defects in processes such as terminal differentiation, growth control, and cell death, developmental studies of agents may provide an understanding of the activity of an agent that carries over to cancer assessment. Toxicity studies in animals by different routes of administration support comparison of absorption and metabolism by those routes. Data on human variability in standard clinical tests may also provide insight into the range of human susceptibility and the common mechanisms of agents that affect the tested parameters.

2.3.5. Events Relevant to Mode of Carcinogenic Action

Knowledge of the biochemical and biological changes that precede tumor development (which include, but are not limited to, mutagenesis, increased cell proliferation, inhibition of programmed cell death, and receptor activation) may provide important insight for determining whether a cancer hazard exists and may help inform appropriate consideration of the dose-response relationship below the range of observable tumor response. Because cancer can result from a series of genetic alterations in the genes that control cell growth, division, and differentiation (Vogelstein *et al.*, 1988; Hanahan and Weinberg, 2000; Kinzler and Vogelstein, 2002), the ability of an agent to affect genotype (and hence gene products) or gene expression is of obvious importance in evaluating its influence on the carcinogenic process. Initial and key questions to examine are: Does the agent (or its metabolite) interact directly with DNA, leading to mutations that bring about changes in gene products or gene expression? Does the agent bring about effects on gene expression via other nondirect DNA interaction processes?

Furthermore, carcinogenesis involves a complex series and interplay of events that alter the signals a cell receives from its extracellular environment, thereby promoting uncontrolled growth. Many, but not all, mutagens are carcinogens, and some, but not all, agents that induce cell proliferation lead to tumor development. Thus, understanding the range of key steps in the carcinogenic process upon which an agent might act is essential for evaluating its mode of action. Determination of carcinogens that are operating by a mutagenic mode of action, for example, entails evaluation of *in vivo* or *in vitro* short-term testing results for genetic endpoints, metabolic profiles, physicochemical properties, and structure-activity relationship (SAR) analyses in a weight-of-evidence approach (Dearfield *et al.*, 1991; U.S. EPA, 1986b; Waters *et al.*, 1999). Key data for a mutagenic mode of action may be evidence that the carcinogen or a metabolite is DNA-reactive and/or has the ability to bind to DNA. Also, mutagenic carcinogens usually produce positive effects in multiple test systems for different genetic endpoints, particularly gene mutations and structural chromosome aberrations, and in tests performed *in vivo* which generally are supported by positive tests *in vitro.* Additionally, carcinogens may be identified as operating via a mutagenic mode of action if they have similar properties and SAR to mutagenic carcinogens. Endpoints that provide insight into an agent's ability to alter gene products and gene expression, together with other features of an agent's potential mode of carcinogenic action, are discussed below.

2.3.5.1. Direct DNA-Reactive Effects

It is well known that many carcinogens are electrophiles that interact with DNA, resulting in DNA adducts and breakage (referred to in these cancer guidelines as direct DNA effects). Usually during the process of DNA replication, these DNA lesions can be converted into and fixed as mutations and chromosomal alterations that then may initiate and otherwise contribute to the carcinogenic process (Shelby and Zeiger, 1990; Tinwell and Ashby, 1991; IARC, 1999). Thus, studies of mutations and other genetic lesions continue to inform the assessment of potential human cancer hazard and in the understanding of an agent's mode of carcinogenic action.

EPA has published testing guidelines for detecting the ability of an agent to damage DNA and produce mutations and chromosomal alterations (as discussed in Dearfield *et al.*, 1991). Briefly, standard tests for gene mutations in bacteria and mammalian cells *in vitro* and *in vivo* and for structural chromosomal aberrations *in vitro* and *in vivo* are important examples of relevant methods. New molecular approaches, such as mouse mutations and cancer transgenic models, are providing a means to examine mutation at tissue sites where the tumor response is observed (Heddle and Swiger, 1996; Tennant *et al.*, 1999). Additionally, continued improvements in fluorescent-based chromosome staining methods (fluorescent *in situ* hybridization [FISH]) will allow the detection of specific chromosomal abnormalities in relevant target tissues (Tucker and Preston, 1998).

Endpoints indicative of DNA damage but not measures of mutation *per se,* such as DNA adducts or strand breakage, may be detected in relevant target tissues and thus contribute to evaluating an agent's mutagenic potential. Evidence of chemical-specific DNA adducts (*e.g.*, reactions at oxygen sites in DNA bases or with ring nitrogens of guanine and adenine) provides information on a mutagen's ability to directly interact with DNA (La and Swenberg, 1996). Some planar molecules (*e.g.*, 9-aminoacridine) intercalate between base pairs of DNA, which results in a physical distortion in DNA that may lead to mutations when DNA replicates. As discussed below, some carcinogens do not interact directly with DNA, but they can produce increases in endogenous levels of DNA adducts (*e.g.*, 8-hydroxyguanine) by indirect mechanisms.

2.3.5.2. Indirect DNA Effects or Other Effects on Genes/Gene Expression

Although some carcinogens may result in an elevation of mutations or cytogenetic anomalies, as detected in standard assays, they may do so by indirect mechanisms. These effects may be brought about by chemical-cell interactions rather than by the chemical (or its metabolite) directly interacting with DNA. An increase in mutations might be due to cytotoxic exposures causing regenerative proliferation or to mitogenic influences (Cohen and Ellwein, 1990). Increased cell division may elevate mutation by clonal expansion of initiated cells or by increasing the number of genetic errors by rapid cell division and reduced time for DNA repair. Some agents might result in an elevation of mutations by interfering with the enzymes involved in DNA repair and recombination (Barrett and Lee, 1992). Damage to certain critical DNA repair genes or other genes (*e.g.*, the p53 gene) may result in genomic instability, which predisposes cells to further genetic alterations and increases the probability of neoplastic progression (Harris and Hollstein, 1993; Levine *et al.*, 1994; Rouse and Jackson, 2002). Likewise, DNA repair processes may be saturated at certain doses of a chemical, leading to an elevation of genetic alterations.

The initiation of programmed cell death (apoptosis) can potentially be blocked by an agent, thereby permitting replication of cells carrying genetic errors that would normally be removed from the proliferative pool. At certain doses an agent may also generate reactive oxygen species that produce oxidative damage to DNA and other

macromolecules (Chang *et al.* 1988; Kehrer, 1993; Clayson *et al.*, 1994). The role of cellular alterations that are attributable to oxidative damage in tumorigenesis (*e.g.*, 8-hydroxyguanine) is currently unclear.

Several carcinogens have been shown to induce aneuploidy (the loss or gain of chromosomes) (Barrett, 1992; Gibson *et al.*, 1995). Aneuploidy can result in the loss of heterozygosity or genomic instability (Cavenee *et al.*, 1986; Fearon and Vogelstein, 1990). Agents that cause aneuploidy typically interfere with the normal process of chromosome segregation by interacting with non-DNA targets such as the proteins needed for chromosome segregation and chromosome movement. Whether this chromosome imbalance is the cause or the effect of tumorigenesis is not clear. Thus, it is important to understand if the agent induces aneuploidy as a key early event in the carcinogenic process.

It is possible for an agent to alter gene expression by transcriptional, translational, or post-translational modifications. For example, perturbation of DNA methylation patterns may cause effects that contribute to carcinogenesis (Jones, 1986; Holliday, 1987; Goodman and Counts, 1993; Chuang *et al.*, 1996; Baylin and Bestor, 2002). Overexpression of genes by DNA amplification has been observed in certain tumors (Vainio *et al.*, 1992). Mechanisms of altering gene expression may involve cellular reprogramming through hormonal or receptor-mediated mechanisms (Barrett, 1992; Ashby *et al.*, 1994).

Both cell proliferation and programmed cell death can be part of the maintenance of homeostasis in many normal tissues, and alterations in the level or rate of either can be important elements of the carcinogenic process. The balance between the two can directly affect the survival and growth of initiated cells as well as preneoplastic and tumor cell populations (*i.e.*, increase in cell proliferation or decrease in cell death) (Moolgavkar, 1986; Cohen and Ellwein, 1990, 1991; Cohen *et al.*, 1991; Bellamy *et al.*, 1995). Thus, measurements of these events can contribute to the weight of the evidence for cancer hazard prediction and to mode of action understanding. In studies of proliferative effects, distinctions should be made between mitogenesis and regenerative proliferation (Cohen and Ellwein, 1990, 1991; Cohen *et al.*, 1991).

In applying information from studies on cell proliferation and apoptosis to risk assessment, it is important to identify the tissues and target cells involved, to measure effects in both normal and neoplastic tissue, to distinguish between apoptosis and necrosis, and to determine the dose that affects these processes. Gap-junctional intercellular communication is believed to play a role in tissue and organ development and in the maintenance of a normal cellular phenotype within tissues. A growing body of evidence suggests that chemical interference with gap-junctional intercellular communication is a contributing factor in tumor development (Swierenga and Yamasaki, 1992; Yamasaki, 1995).

2.3.5.3. Precursor Events and Biomarker Information

Most testing schemes for mutagenicity and other short-term assays were designed for hazard identification purposes; thus, these assays are generally conducted using acute exposures. For data on ''precursor steps'' to be useful in informing the dose-response curve for tumor induction below the level of observation, it is often useful for data to come from *in vivo* studies and from studies where exposure is repeated or given over an extended period of time. Although consistency of results across different assays and animal models provides a stronger basis for drawing conclusions, it is desirable to have data on the precursor event in the same target organ, sex, animal strain, and species as the tumor data. In evaluating an agent's mode of action, it is usually not sufficient to determine that some event commences upon dosing. It is important to understand whether it is a necessary event that plays a key role in the process that leads to tumor development versus an effect of the cancer process itself or simply an associated event.

Various endpoints can serve as biological markers of effects in biological systems or samples. These may help identify doses at which elements of the carcinogenic process are operating; aid in interspecies extrapolations when data are available from both experimental animal and human cells; and under certain circumstances, provide insights into the possible shape of the dose-response curve below levels where tumor incidences are observed (*e.g.*, Choy, 1993).

Genetic and other findings (such as changes in proto-oncogenes and tumor suppressor genes in preneoplastic and neoplastic tissue or, possibly, measures of endocrine disruption) can indicate the potential for disease and, as such, serve as biomarkers of effect. They, too, can be used in different ways.

- The spectrum of genetic changes in proliferative lesions and tumors following chemical administration to experimental animals can be determined and compared with that in spontaneous tumors in control animals, in animals exposed to other agents of varying structural and functional activities, and in persons exposed to the agent under study.
- Biomarkers of effect and/or precursors may help to identify subpopulations of individuals who may be at an elevated risk for a certain cancer or exposure to a certain agent, *e.g.*, cytochrome P450 2D6/debrisoquine sensitivity for lung cancer (Caporaso *et al.*, 1989) or inherited colon cancer syndromes (Kinzler *et al.*, 1991; Peltomäki *et al.*, 1993).
- As with biomarkers of exposure, it may be justified in some cases to use biomarkers of effect and/or precursors for dose-response assessment or to provide insight into the potential shape of the dose-response curve at doses below those at which tumors are induced experimentally.

In applying biomarker data to cancer assessment an assessment should consider:

- Analytical methodology,
- Routes of exposure,
- Exposure to mixtures,
- Time after exposure,
- Sensitivity and specificity of biomarkers, and
- Dose-response relationships.

2.3.5.4. Judging Data

Criteria that are generally applicable for judging the adequacy of mechanistically based data include:

- Mechanistic relevance of the data to carcinogenicity,
- Number of studies of each endpoint,
- Consistency of results in different test systems and different species,
- Similar dose-response relationships for tumor and mode of action-related effects,
- Conduct of the tests in accordance with generally accepted protocols, and
- Degree of consensus and general acceptance among scientists regarding interpretation of the significance and specificity of the tests.

Although important information can be gained from *in vitro* test systems, a higher level of confidence is generally given to data that are derived from *in vivo* systems, particularly those results that show a site concordance with the tumor data.

It is important to remember that when judging and considering the use of any data, the basic standard of quality, as defined by the EPA Information Quality Guidelines, should be satisfied.

2.4. Mode of Action—General Considerations and Framework for Analysis

2.4.1. General Considerations

The interaction between the biology of the organism and the chemical properties of the agent determine whether there is an adverse effect. Thus, mode of action analysis is based on physical, chemical, and biological information that helps to explain key events in an agent's influence on development of tumors. The entire range of information developed in the assessment is reviewed to arrive at a reasoned judgment. An agent may work by more than one mode of action, both at different sites and at the same tumor site. Thus the mode of action and human relevance cannot necessarily be generalized to other toxic endpoints or tissues or cell types without additional analyses (IPCS, 1999; Meek *et al.*, 2003). At least some information bearing on mode of action (*e.g.*, SAR, screening tests for mutagenicity) is present for most agents undergoing assessment of carcinogenicity, even though certainty about exact molecular mechanisms may be rare.

Information for mode of action analysis generally includes tumor data in humans and animals and among structural analogues, as well as the other key data. The more complete the data package and the generic knowledge about a given mode of action, the more confidence one has and the more one can rely on assessment of available data rather than reverting to default options to address the absence of information on mode of action. Reasoned judgments are generally based on a data-rich source of chemical, chemical class, and tumor type-specific information. Many times there will be conflicting data and gaps in the information base; it is important to carefully evaluate these uncertainties before reaching any conclusion.

In making decisions about potential modes of action and the relevance of animal tumor findings to humans (Ashby *et al.*, 1990; Ashby and Tennant, 1991; Tennant, 1993; IPCS 1999; Sonich-Mullin *et al.*, 2001; Meek *et al.*, 2003), very often the results of chronic animal studies may give important clues. Some of the important factors to review include:

- Tumor types, for example, those responsive to endocrine influence or those produced by DNA-reactive carcinogens;
- Number of studies and of tumor sites, sexes, and species affected or unaffected in those studies and if the data present a coherent story;
- Similarity of metabolic activation and detoxification for a specific chemical between humans and tested species;
- Influence of route of exposure on the spectrum of tumors and whether they occur at point of exposure or systemic sites;
- Effect of high dose exposures on the target organ or systemic toxicity that may not reflect typical physiological conditions, for example, urinary chemical changes associated with stone formation, effects on immune surveillance;
- Presence of proliferative lesions, for example, hepatic foci, or hyperplasia;
- Effect of dose and time on the progression of lesions from preneoplastic to benign tumors, then to malignant;
- Ratio of malignant to benign tumors as a function of dose and time;
- Time of appearance of tumors after commencing exposure;
- Development of tumors that invade locally or systemically, or lead to death;
- Tumors at organ sites with high or low background historical incidence in laboratory animals;
- Biomarkers in tumor cells, both induced and spontaneous, for example, DNA or protein adducts, mutation spectra, chromosome changes, oncogene activation; and/or
- Shape of the dose-response curve in the range of tumor observation, for example, linear versus nonlinear.

Some of the myriad ways in which information from chronic animal studies influences mode of action judgments include, but are not limited to, the following:

- Multisite and multispecies tumor effects that are often associated with mutagenic agents;
- Tumors restricted to one sex or species suggesting an influence restricted to gender, strain, or species;
- Late onset of tumors that are primarily benign, are at sites with a high historical background incidence, or show reversal of lesions on cessation of exposure suggesting a growth-promoting mode of action;
- The possibility that an agent acting differently in different tissues; or
- The possibility that has more than one mode of action in a single tissue.

Simple knowledge of sites of tumor increase in rodent studies can give preliminary clues as to mode of action. Experience at the National Toxicology Program (NTP) indicates that substances that are DNA reactive and that produce gene mutations may be unique in producing tumors in certain anatomical sites, whereas tumors at other sites may arise from both mutagenic or nonmutagenic influences (Ashby and Tennant, 1991; Huff *et al.*, 1991).

The types of data and their influence on judgments regarding mode of action are expected to evolve, both as science advances and as the risk assessment community gains more experience with these analyses. This section contains a framework for evaluating hypothesized mode(s) of action. This framework has similarities to and differences with the concepts presented in other MOA frameworks (*e.g.*, IPCS, 1999; Sonich-Mullin *et al.*, 2001; Meek *et al.*, 2003). Differences are often due to the context of the use for the framework. For example, the Meek *et al.* (2003) presents a stand-alone document for addressing mode of action issues; thus, it recommends that conclusions concerning MOA be rendered separately. In these cancer guidelines, however, they are incorporated into the context of all of the data regarding weight of the evidence for carcinogenicity.

2.4.2. Evaluating an Hypothesized Mode of Action

2.4.2.1. Peer Review

In reaching conclusions, the question of ''general acceptance'' of a mode of action should be tested as part of the independent peer review that EPA obtains for its assessment and conclusions. In some cases the mode of action may already have been established by development of a large body of research information and characterization of the phenomenon over time. In some cases there will have been development of an Agency policy (*e.g.*, mode of action involving alpha-2u-globulin in the male rat [U.S. EPA, 1991b]) or a series of previous assessments in which both the mode of action and its applicability to particular cases has been explored. If so, the assessment and its peer review can focus on the evidence that a particular agent acts in this mode. The peer review should also evaluate the strengths and weaknesses of competing modes of action.

In other cases, the mode of action may not have previously been the subject of an Agency document. If so, the data to support both the mode of action and the associated activity of the agent should undergo EPA assessment and subsequent peer review.

2.4.2.2. Use of the Framework

The framework supports a full analysis of mode of action information, but it can also be used as a screen to decide whether sufficient information is available to evaluate or whether the data

gaps are too substantial to justify further analysis. Mode of action conclusions are used to address the question of human relevance of animal tumor responses, to address differences in anticipated response among humans, such as between children and adults or men and women; and as the basis of decisions about the anticipated shape of the dose-response relationship. Guidance on the latter appears in Section 3.

This framework is intended to provide an analytical approach for evaluating the mode of action. It is neither a checklist nor a list of required criteria. As the type and amount of information will depend on the mode of action postulated, scientific judgment is important to determine if the weight of evidence is sufficient.

2.4.3. Framework for Evaluating Each Hypothesized Carcinogenic Mode of Action

This framework is intended to be an analytic tool for judging whether available data support a mode of carcinogenic action hypothesized for an agent. It is based upon considerations for causality in epidemiologic investigations originally articulated by Hill (1965) but later modified by others and extended to experimental studies. The original Hill criteria were applied to epidemiologic data, whereas this framework is applied to a much wider assortment of experimental data, so it retains the basic principles of Hill but is much modified in content.

The modified Hill criteria can be useful for organizing thinking about aspects of causation, and they are consistent with the scientific method of developing hypotheses and testing those hypotheses experimentally. During analysis by EPA, and as guidance for peer review, a key question is whether the data to support a mode of action meet the standards generally applied in experimental biology regarding inference of causation.

All pertinent studies are reviewed in analyzing a mode of action, and an overall weighing of evidence is performed, laying out the strengths, weaknesses, and uncertainties of the case as well as potential alternative positions and rationales. Identifying data gaps and research needs is also part of the assessment.

To evaluate whether an hypothesized mode of action is operative, an analysis starts with an outline of the scientific findings regarding the hypothesized key events leading to cancer, and then weighing information to determine whether there is a causal relationship between these events and cancer formation, *i.e.*, that the effects are critical for induction of tumors. It is not generally expected that the complete sequence will be known at the molecular level. Instead, empirical observations made at different levels of biological organization—biochemical, cellular, physiological, tissue, organ, and system—are analyzed.

Several important points should be considered when working with the framework:

- The topics listed for analysis should *not* be regarded as a checklist of necessary ''proofs.'' The judgment of whether an hypothesized mode of action is supported by available data takes account of the analysis as a whole.
- The framework provides a structure for organizing the facts upon which conclusions as to mode of action rest. The purpose of using the framework is to make analysis transparent and to allow the reader to understand the facts and reasoning behind a conclusion.
- The framework does not dictate an answer. The weight of evidence that is sufficient to support a decision about a mode of action may be less or more, depending on the purpose of the analysis, for example, screening, research needs identification, or full risk assessment. To make the reasoning transparent, the purpose of the analysis should be made apparent to the reader.
- Toxicokinetic studies may contribute to mode of action analysis by contributing to identifying the active form(s) of an agent that is central to the mode of action. Apart from contributing in this way, toxicokinetics studies may reveal effects of saturation of metabolic processes. These may not be considered key events in a mode of action, but they are given separate consideration in assessing dose metrics and potential nonlinearity of the dose-response relationship.
- Generally, ''sufficient'' support is a matter of scientific judgment in the context of the requirements of the decisionmaker or in the context of science policy guidance regarding a certain mode of action.
- Even when an hypothesized mode of action is supported for a described response in a specific tissue, it may not explain other tumor responses observed, which should get separate consideration in hazard and dose-response assessment.

For each tumor site being evaluated, the mode of action analysis should begin with a description of the relevant data and key events that may be associated with an hypothesized mode of action and its sequence of key events (*see* Section 2.4.3.1). This can be followed by a discussion of various aspects of the experimental support for hypothesized mode(s) of action in animals and humans (*see* Section 2.4.3.2). The possibility of other modes of action also should be considered and discussed (*see* Section 2.4.3.3); if there is evidence for more than one mode of action, each should receive a separate analysis. Conclusions about each hypothesized mode of action should address whether the mode of action is supported in animals and is relevant to humans and which populations or lifestages can be particularly susceptible (*see* Section 2.4.3.4). In a risk assessment document, the analysis of an hypothesized mode of action can be presented before or with the characterization of an agent's potential hazard to humans.

2.4.3.1. Description of the Hypothesized Mode of Action

Summary description of the hypothesized mode of action. For each tumor site, the mode of action analysis begins with a description of the hypothesized mode of action and its sequence of key events. If there is evidence for more than one mode of action, each receives a separate analysis.

Identification of key events. In order to judge how well data support involvement of a key event in carcinogenic processes, the experimental definition of the event or events should be clear and reproducible. To support an association, experiments should define and measure an event consistently.

- Can a list of events be identified that are key to the carcinogenic process?
- Are the events well defined?

Pertinent observations may include, but are not limited to, receptor-ligand changes, cytotoxicity, cell cycle effects, increased cell growth, organ weight differences, histological changes, hormone or other protein perturbations, or DNA and chromosome effects.

2.4.3.2. Discussion of the Experimental Support for the Hypothesized Mode of Action

The experimental support for the hypothesized mode of action should be discussed from several viewpoints patterned after the Hill criteria (see Section 2.2.1.7). For illustration, the explanation of each topic includes typical questions to be addressed to the available empirical data and experimental observations anticipated to be pertinent. The latter will vary from case to case. For a particular mode of action, certain observations may be established as essential in practice or policy, for example, measures of thyroid hormone levels in supporting thyroid

hormone elevation as a key event in carcinogenesis.

Strength, consistency, specificity of association. A statistically significant association between events and a tumor response observed in well-conducted studies is generally supportive of causation. Consistent observations in a number of such studies with differing experimental designs increase that support, because different designs may reduce unknown biases. Studies showing ''recovery,'' *i.e.,* absence or reduction of carcinogenicity when the event is blocked or diminished, are particularly useful tests of the association. Specificity of the association, without evidence of other modes of action, strengthens a causal conclusion. A lack of strength, consistency, and specificity of association weakens the causal conclusions for a particular mode of action.

- What is the level of statistical and biological significance for each event and for cancer?
- Do independent studies and different experimental hypothesis-testing approaches produce the same associations?
- Does the agent produce effects other than those hypothesized?
- Is the key event associated with precursor lesions?

Pertinent observations include tumor response associated with events (site of action logically relates to event[s]), precursor lesions associated with events, initiation-promotion studies, and stop/recovery studies.

Dose-response concordance. If a key event and tumor endpoints increase with dose such that the key events forecast the appearance of tumors at a later time or higher dose, a causal association can be strengthened. Dose-response associations of the key event with other precursor events can add further strength. Difficulty arises when an event is not causal but accompanies the process generally. For example, if tumors and the hypothesized precursor both increase with dose, the two responses will be correlated regardless of whether a causal relationship exists. This is similar to the issue of confounding in epidemiologic studies. Dose-response studies coupled with mechanistic studies can assist in clarifying these relationships.

- What are the correlations among doses producing events and cancer?

Pertinent observations include, but are not limited to, 2-year bioassay observation of lesions correlated with observations of hormone changes and the same lesions in shorter term studies or in interim sacrifice.

Temporal relationship. If an event is shown to be causally linked to tumorigenesis, it will precede tumor appearance. An event may also be observed contemporaneously or after tumor appearance; these observations may add to the strength of association but not to the temporal association.

- What is the ordering of events that underlie the carcinogenic process?
- Is this ordering consistent among independent studies?

Pertinent observations include studies of varying duration observing the temporal sequence of events and development of tumors.

Biological plausibility and coherence. It is important that the hypothesized mode of action and the events that are part of it be based on contemporaneous understanding of the biology of cancer to be accepted. If the body of information under scrutiny is consistent with other examples (including structurally related agents) for which the hypothesized mode of action is accepted, the case is strengthened. Because some modes of action can be anticipated to evoke effects other than cancer, the available toxicity database on noncancer effects, for example, reproductive effects of certain hormonal disturbances, can contribute to this evaluation.

- Is the mode of action consistent with what is known about carcinogenesis in general and for the case specifically?
- Are carcinogenic effects and events consistent across structural analogues?
- Is the database on the agent internally consistent in supporting the purported mode of action, including relevant noncancer toxicities?

Pertinent observations include the scientific basis for considering an hypothesized mode of action generally, given the contemporaneous state of knowledge of carcinogenic processes; previous examples of data sets showing the mode of action; data sets on analogues; and coherence of data in this case from cancer and noncancer toxicity studies.

2.4.3.3. Consideration of the Possibility of Other Modes of Action

The possible involvement of more than one mode of action at the tumor site should be considered. Pertinent observations that are not consistent with the hypothesized mode of action can suggest the possibility of other modes of action. Some pertinent observations can be consistent with more than one mode of action. Furthermore, different modes of action can operate in different dose ranges; for example, an agent can act predominantly through cytotoxicity at high doses and through mutagenicity at lower doses where cytotoxicity may not occur.

If there is evidence for more than one mode of action, each should receive a separate analysis. There may be an uneven level of experimental support for the different modes of action. Sometimes this can reflect disproportionate resources spent on investigating one particular mode of action and not the validity or relative importance of the other possible modes of action. Ultimately, however, the information on all of the modes of action should be integrated to better understand how and when each mode acts, and which mode(s) may be of interest for exposure levels relevant to human exposures of interest.

2.4.3.4. Conclusions About the Hypothesized Mode of Action

Conclusions about the hypothesized mode of action should address the issues listed below. For those agents for which the mode of action is considered useful for the risk assessment, the weight of the evidence concerning mode of action in animals as well as its relevance for humans would be incorporated into the weight of evidence narrative (Section 2.5).

(a) *Is the hypothesized mode of action sufficiently supported in the test animals?* Associations observed between key events and tumors may or may not support an inference of causation. The conclusion that the agent causes one or more key events that results in tumors is strengthened as more aspects of causation are satisfied and weakened as fewer are satisfied. Consistent results in different experiments that test the hypothesized mode of action build support for that mode of action. Replicating results in a similar experiment does not generally meaningfully strengthen the original evidence, and discordant results generally weaken that support. Experimental challenge to the hypothesized mode of action, where interrupting the sequence of key events suppresses the tumor response or enhancement of key events increases the tumor response, creates very strong support for the mode of action.

(b) *Is the hypothesized mode of action relevant to humans?* If an hypothesized mode of action is sufficiently supported in the test animals, the sequence of key precursor events should be reviewed to identify critical similarities and differences between the test animals and humans. The question of concordance can be complicated by cross-species differences in toxicokinetics or toxicodynamics. For example, the active

agent can be formed through different metabolic pathways in animals and humans. Any information suggesting quantitative differences between animals and humans is flagged for consideration in the dose-response assessment. This includes the potential for different internal doses of the active agent or for differential occurrence of a key precursor event.

''Relevance'' of a potential mode of action is considered in the context of characterization of hazard, not level of risk. Anticipated levels of human exposure are not used to determine whether the hypothesized mode of action is relevant to humans. Exposure information is integrated into the overall risk characterization.

The question of relevance considers all populations and lifestages. It is possible that the conditions under which a mode of action operates exist primarily in a particular population or lifestage, for example, in those with a pre-existing hormonal imbalance. Other populations or lifestages may not be analogous to the test animals, in which case the question of relevance would be decided by inference.

Special attention should be paid to whether tumors can arise from childhood exposure, considering various aspects of development during these lifestages. Because the studies that support a mode of action are typically conducted in mature animals, conclusions about relevance during childhood generally rely on inference. There is currently no standard Agency position regarding the issue of whether tumors arising through the hypothesized mode of action are relevant during childhood; understanding the mode of action implies that there are sufficient data (on either the specific agent or the general mode of action) to form a confident conclusion about relevance during childhood.

(c) *Which populations or lifestages can be particularly susceptible to the hypothesized mode of action?* If an hypothesized mode of action is judged relevant to humans, information about the key precursor event(s) is reviewed to identify populations or lifestages that might reasonably expected to be particularly susceptible to their occurrence. Although agent-specific data would provide the strongest indication of susceptibility, this review may also rely on general knowledge about the precursor events and characteristics of individuals susceptible to these events. Any information suggesting quantitative differences between populations or lifestages should be flagged for consideration in the dose-response assessment (see Section 3.5). This includes the potential for a higher internal dose of the active agent or for an increased occurrence of a key precursor event. Quantitative differences may result in separate risk estimates for susceptible populations or lifestages.

The possibility that childhood is a susceptible period for exposure should be explicitly addressed. Generic understanding of the mode of action can be used to gauge childhood susceptibility, and this determination can be refined through analysis of agent-specific data.

2.4.4. Evolution With Experience

Several groups have proposed or incorporated mode of action into their risk assessments (see, *e.g.,* U.S. EPA, 1991b; Sonich-Mullin *et al.*, 2001; Meek *et al.*, 2003). As the frameworks and mandates under which these evaluations were produced differ, the specific procedures described in and conclusions drawn may also differ. Nevertheless, the number of case studies from all venues remains limited. More experience with differing modes of action are expected to highlight and illustrate the strengths and limitations of the general framework proposed in these cancer guidelines. Moreover, additional toxicological techniques may expand or change scientific judgments regarding which information is useful for mode of action determinations. As warranted, additional guidance may be proposed as experience is gained and/or as toxicological knowledge advances.

2.5. Weight of Evidence Narrative

The *weight of evidence narrative* is a short summary (one to two pages) that explains an agent's human carcinogenic potential and the conditions that characterize its expression. It should be sufficiently complete to be able to stand alone, highlighting the key issues and decisions that were the basis for the evaluation of the agent's potential hazard. It should be sufficiently clear and transparent to be useful to risk managers and non-expert readers. It may be useful to summarize all of the significant components and conclusions in the first paragraph of the narrative and to explain complex issues in more depth in the rest of the narrative.

The weight of the evidence should be presented as a narrative laying out the complexity of information that is essential to understanding the hazard and its dependence on the quality, quantity, and type(s) of data available, as well as the circumstances of exposure or the traits of an exposed population that may be required for expression of cancer. For example, the narrative can clearly state to what extent the determination was based on data from human exposure, from animal experiments, from some combination of the two, or from other data. Similarly, information on mode of action can specify to what extent the data are from *in vivo* or *in vitro* exposures or based on similarities to other chemicals. The extent to which an agent's mode of action occurs only on reaching a minimum dose or a minimum duration should also be presented. A hazard might also be expressed disproportionately in individuals possessing a specific gene; such characterizations may follow from a better understanding of the human genome. Furthermore, route of exposure should be used to qualify a hazard if, for example, an agent is not absorbed by some routes. Similarly, a hazard can be attributable to exposures during a susceptible lifestage on the basis of our understanding of human development.

The weight of evidence-of-evidence narrative should highlight:

- The quality and quantity of the data;
- All key decisions and the basis for these major decisions; and
- Any data, analyses, or assumptions that are unusual for or new to EPA.

To capture this complexity, a weight of evidence narrative generally includes:

- Conclusions about human carcinogenic potential (choice of descriptor(s), described below),
- A summary of the key evidence supporting these conclusions (for each descriptor used), including information on the type(s) of data (human and/or animal, *in vivo* and/or *in vitro*) used to support the conclusion(s),
- Available information on the epidemiologic or experimental conditions that characterize expression of carcinogenicity (*e.g.*, if carcinogenicity is possible only by one exposure route or only above a certain human exposure level),
- A summary of potential modes of action and how they reinforce the conclusions,
- Indications of any susceptible populations or lifestages, when available, and
- A summary of the key default options invoked when the available information is inconclusive.

To provide some measure of clarity and consistency in an otherwise free-form narrative, the weight of evidence descriptors are included in the first sentence of the narrative. Choosing a descriptor is a matter of judgment and cannot be reduced to a formula. Each descriptor may be applicable to a wide

variety of potential data sets and weights of evidence. These descriptors and narratives are intended to permit sufficient flexibility to accommodate new scientific understanding and new testing methods as they are developed and accepted by the scientific community and the public. Descriptors represent points along a continuum of evidence; consequently, there are gradations and borderline cases that are clarified by the full narrative. Descriptors, as well as an introductory paragraph, are a short summary of the complete narrative that preserves the complexity that is an essential part of the hazard characterization. Users of these cancer guidelines and of the risk assessments that result from the use of these cancer guidelines should consider the entire range of information included in the narrative rather than focusing simply on the descriptor.

In borderline cases, the narrative explains the case for choosing one descriptor and discusses the arguments for considering but not choosing another. For example, between ''suggestive'' and ''likely'' or between ''suggestive'' and ''inadequate,'' the explanation clearly communicates the information needed to consider appropriately the agent's carcinogenic potential in subsequent decisions.

Multiple descriptors can be used for a single agent, for example, when carcinogenesis is dose-or route-dependent. For example, if an agent causes point-of-contact tumors by one exposure route but adequate testing is negative by another route, then the agent could be described as likely to be carcinogenic by the first route but not likely to be carcinogenic by the second. Another example is when the mode of action is sufficiently understood to conclude that a key event in tumor development would not occur below a certain dose range. In this case, the agent could be described as likely to be carcinogenic above a certain dose range but not likely to be carcinogenic below that range.

Descriptors can be selected for an agent that has not been tested in a cancer bioassay if sufficient other information, *e.g.*, toxicokinetic and mode of action information, is available to make a strong, convincing, and logical case through scientific inference. For example, if an agent is one of a well-defined class of agents that are understood to operate through a common mode of action and if that agent has the same mode of action, then in the narrative the untested agent would have the same descriptor as the class. Another example is when an untested agent's effects are understood to be caused by a human metabolite, in which case in the narrative the untested agent could have the same descriptor as the metabolite. As new testing methods are developed and used, assessments may increasingly be based on inferences from toxicokinetic and mode of action information in the absence of tumor studies in animals or humans.

When a well-studied agent produces tumors only at a point of initial contact, the descriptor generally applies only to the exposure route producing tumors unless the mode of action is relevant to other routes. The rationale for this conclusion would be explained in the narrative.

When tumors occur at a site other than the point of initial contact, the descriptor generally applies to all exposure routes that have not been adequately tested at sufficient doses. An exception occurs when there is convincing information, *e.g.*, toxicokinetic data that absorption does not occur by another route.

When the response differs qualitatively as well as quantitatively with dose, this information should be part of the characterization of the hazard. In some cases reaching a certain dose range can be a precondition for effects to occur, as when cancer is secondary to another toxic effect that appears only above a certain dose. In other cases exposure duration can be a precondition for hazard if effects occur only after exposure is sustained for a certain duration. These considerations differ from the issues of relative absorption or potency at different dose levels because they may represent a discontinuity in a dose-response function.

When multiple bioassays are inconclusive, mode of action data are likely to hold the key to resolution of the more appropriate descriptor. When bioassays are few, further bioassays to replicate a study's results or to investigate the potential for effects in another sex, strain, or species may be useful.

When there are few pertinent data, the descriptor makes a statement about the database, for example, ''Inadequate Information to Assess Carcinogenic Potential,'' or a database that provides ''Suggestive Evidence of Carcinogenic Potential.'' With more information, the descriptor expresses a conclusion about the agent's carcinogenic potential to humans. If the conclusion is positive, the agent could be described as ''Likely to Be Carcinogenic to Humans'' or, with strong evidence, ''Carcinogenic to Humans.'' If the conclusion is negative, the agent could be described as ''Not Likely to Be Carcinogenic to Humans.''

Although the term ''likely'' can have a probabilistic connotation in other contexts, its use as a weight of evidence descriptor does not correspond to a quantifiable probability of whether the chemical is carcinogenic. This is because the data that support cancer assessments generally are not suitable for numerical calculations of the probability that an agent is a carcinogen. Other health agencies have expressed a comparable weight of evidence using terms such as ''Reasonably Anticipated to Be a Human Carcinogen'' (NTP) or ''Probably Carcinogenic to Humans'' (International Agency for Research on Cancer).

The following descriptors can be used as an introduction to the weight of evidence narrative. The examples presented in the discussion of the descriptors are illustrative. The examples are neither a checklist nor a limitation for the descriptor. The complete weight of evidence narrative, rather than the descriptor alone, provides the conclusions and the basis for them.

''Carcinogenic to Humans.'' This descriptor indicates strong evidence of human carcinogenicity. It covers different combinations of evidence.

- This descriptor is appropriate when there is convincing epidemiologic evidence of a causal association between human exposure and cancer.
- Exceptionally, this descriptor may be equally appropriate with a lesser weight of epidemiologic evidence that is strengthened by other lines of evidence. It can be used when *all* of the following conditions are met: (a) There is strong evidence of an association between human exposure and either cancer or the key precursor events of the agent's mode of action but not enough for a causal association, *and* (b) there is extensive evidence of carcinogenicity in animals, *and* (c) the mode(s) of carcinogenic action and associated key precursor events have been identified in animals, *and* (d) there is strong evidence that the key precursor events that precede the cancer response in animals are anticipated to occur in humans and progress to tumors, based on available biological information. In this case, the narrative includes a summary of both the experimental and epidemiologic information on mode of action and also an indication of the relative weight that each source of information carries, *e.g.,* based on human information, based on limited human and extensive animal experiments.

''*Likely to Be Carcinogenic to Humans.*'' This descriptor is appropriate when the weight of the evidence is adequate to demonstrate carcinogenic

potential to humans but does not reach the weight of evidence for the descriptor ''Carcinogenic to Humans.'' Adequate evidence consistent with this descriptor covers a broad spectrum. As stated previously, the use of the term ''likely'' as a weight of evidence descriptor does not correspond to a quantifiable probability. The examples below are meant to represent the broad range of data combinations that are covered by this descriptor; they are illustrative and provide neither a checklist nor a limitation for the data that might support use of this descriptor. Moreover, additional information, e.g., on mode of action, might change the choice of descriptor for the illustrated examples. Supporting data for this descriptor may include:

- An agent demonstrating a plausible (but not definitively causal) association between human exposure and cancer, in most cases with some supporting biological, experimental evidence, though not necessarily carcinogenicity data from animal experiments;
- An agent that has tested positive in animal experiments in more than one species, sex, strain, site, or exposure route, with or without evidence of carcinogenicity in humans;
- A positive tumor study that raises additional biological concerns beyond that of a statistically significant result, for example, a high degree of malignancy, or an early age at onset;
- A rare animal tumor response in a single experiment that is assumed to be relevant to humans; or
- A positive tumor study that is strengthened by other lines of evidence, for example, either plausible (but not definitively causal) association between human exposure and cancer *or* evidence that the agent or an important metabolite causes events generally known to be associated with tumor formation (such as DNA reactivity or effects on cell growth control) likely to be related to the tumor response in this case.

''*Suggestive Evidence of Carcinogenic Potential.*'' This descriptor of the database is appropriate when the weight of evidence is suggestive of carcinogenicity; a concern for potential carcinogenic effects in humans is raised, but the data are judged not sufficient for a stronger conclusion. This descriptor covers a spectrum of evidence associated with varying levels of concern for carcinogenicity, ranging from a positive cancer result in the only study on an agent to a single positive cancer result in an extensive database that includes negative studies in other species. Depending on the extent of the database, additional studies may or may not provide further insights. Some examples include:

- A small, and possibly not statistically significant, increase in tumor incidence observed in a single animal or human study that does not reach the weight of evidence for the descriptor ''Likely to Be Carcinogenic to Humans.'' The study generally would not be contradicted by other studies of equal quality in the same population group or experimental system (see discussions of *conflicting evidence and differing results,* below);
- A small increase in a tumor with a high background rate in that sex and strain, when there is some but insufficient evidence that the observed tumors may be due to intrinsic factors that cause background tumors and not due to the agent being assessed. (When there is a high background rate of a specific tumor in animals of a particular sex and strain, then there may be biological factors operating independently of the agent being assessed that could be responsible for the development of the observed tumors.) In this case, the reasons for determining that the tumors are not due to the agent are explained;
- Evidence of a positive response in a study whose power, design, or conduct limits the ability to draw a confident conclusion (but does not make the study fatally flawed), but where the carcinogenic potential is strengthened by other lines of evidence (such as structure-activity relationships); or
- A statistically significant increase at one dose only, but no significant response at the other doses and no overall trend.

''*Inadequate Information to Assess Carcinogenic Potential.*'' This descriptor of the database is appropriate when available data are judged inadequate for applying one of the other descriptors. Additional studies generally would be expected to provide further insights. Some examples include:

- Little or no pertinent information;
- Conflicting evidence, that is, some studies provide evidence of carcinogenicity but other studies of equal quality in the same sex and strain are negative. *Differing results,* that is, positive results in some studies and negative results in one or more different experimental systems, do not constitute *conflicting evidence,* as the term is used here. Depending on the overall weight of evidence, differing results can be considered either suggestive evidence or likely evidence; or
- Negative results that are not sufficiently robust for the descriptor, ''Not Likely to Be Carcinogenic to Humans.''

''Not Likely to Be Carcinogenic to Humans.'' This descriptor is appropriate when the available data are considered robust for deciding that there is no basis for human hazard concern. In some instances, there can be positive results in experimental animals when there is strong, consistent evidence that each mode of action in experimental animals does not operate in humans. In other cases, there can be convincing evidence in both humans and animals that the agent is not carcinogenic. The judgment may be based on data such as:

- Animal evidence that demonstrates lack of carcinogenic effect in both sexes in well-designed and well-conducted studies in at least two appropriate animal species (in the absence of other animal or human data suggesting a potential for cancer effects),
- Convincing and extensive experimental evidence showing that the only carcinogenic effects observed in animals are not relevant to humans,
- Convincing evidence that carcinogenic effects are not likely by a particular exposure route (*see* Section 2.3), or
- Convincing evidence that carcinogenic effects are not likely below a defined dose range.

A descriptor of ''not likely'' applies only to the circumstances supported by the data. For example, an agent may be ''Not Likely to Be Carcinogenic'' by one route but not necessarily by another. In those cases that have positive animal experiment(s) but the results are judged to be not relevant to humans, the narrative discusses why the results are not relevant.

Multiple Descriptors. More than one descriptor can be used when an agent's effects differ by dose or exposure route. For example, an agent may be ''Carcinogenic to Humans'' by one exposure route but ''Not Likely to Be Carcinogenic'' by a route by which it is not absorbed. Also, an agent could be ''Likely to Be Carcinogenic'' above a specified dose but ''Not Likely to Be Carcinogenic'' below that dose because a key event in tumor formation does not occur below that dose.

2.6. Hazard Characterization

The *hazard characterization* contains the hazard information needed for a full risk characterization (U.S. EPA, 2000b). It presents the results of the hazard assessment and explains how the weight of evidence conclusion was reached. The hazard characterization summarizes, in plain language, conclusions about the agent's potential effects, whether they can be expected to

depend qualitatively on the circumstances of exposure, and if anyone can be expected to be especially susceptible. It discusses the extent to which these conclusions are supported by data or are the result of default options invoked because the data are inconclusive. It explains how complex cases with differing results in different studies were resolved. The hazard characterization highlights the major issues addressed in the hazard assessment and discusses alternative interpretations of the data and the degree to which they are supportable scientifically and are consistent with EPA guidelines.

When the conclusion is supported by mode of action information, the hazard characterization also provides a clear summary of the mode of action conclusions (*see* Section 2.4.3.4), including the completeness of the data, the strengths and limitations of the inferences made, the potential for other modes of action, and the implications of the mode of action for selecting viable approaches to the dose-response assessment. The hazard characterization also discusses the extent to which mode of action information is available to address the potential for disproportionate risks in specific populations or lifestages or the potential for enhanced risks on the basis of interactions with other agents or stressors, if anticipated.

Topics that can be addressed in a hazard characterization include:

- Summary of the results of the hazard assessment;
- Identification of any likely susceptible populations and lifestages, especially attending to children, infants, and fetuses;
- Conclusions about the agent's mode of action, and implications for selecting approaches to the dose-response assessment;
- Identification of the available lines of evidence (*e.g.*, animal bioassays, epidemiologic studies, toxicokinetic information, mode of action studies, and information about structural analogues or metabolites), highlighting data quality and coherence of results from different lines of evidence; and
- Strengths and limitations of the hazard assessment, highlighting significant issues in interpreting the data, alternative interpretations that are considered equally plausible, critical data gaps, and default options invoked when the available information is inconclusive.

3. Dose-Response Assessment

Dose-response assessment estimates potential risks to humans at exposure levels of interest. Dose-response assessments are useful in many applications: Estimating risk at different exposure levels, estimating the risk reduction for different decision options, estimating the risk remaining after an action is taken, providing the risk information needed for benefit-cost analyses of different decision options, comparing risks across different agents or health effects, and setting research priorities. The purpose of the assessment should consider the quality of the data available, which will vary from case to case.

A dose-response analysis is generally developed from each study that reports quantitative data on dose and response. Alternative measures of dose are available for analyzing human and animal studies (*see* Section 3.1). A two-step approach distinguishes analysis of the dose-response data from inferences made about lower doses. The first step is an analysis of dose and response in the range of observation of the experimental or epidemiologic studies (*see* Section 3.2). Modeling is encouraged to incorporate a wide range of experimental data into the dose-response assessment (*see* Sections 3.1.2, 3.2.1, 3.2.2, 3.2.3). The modeling yields a point of departure (POD) near the lower end of the observed range, without significant extrapolation to lower doses (*see* Sections 3.2.4, 3.2.5). The second step is extrapolation to lower doses (*see* Section 3.3). The extrapolation approach considers what is known about the agent's mode of action (*see* Section 3.3.1). Both linear and nonlinear approaches are available (*see* Sections 3.3.3, 3.3.4). When multiple estimates can be developed, the strengths and weaknesses of each are presented. In some cases, they may be combined in a way that best represents human cancer risk (*see* Section 3.3.5). Special consideration is given to describing dose-response differences attributable to different human exposure scenarios (*see* Section 3.4) and to susceptible populations and lifestages (*see* Section 3.5). It is important to discuss significant uncertainties encountered in the analysis (*see* Section 3.6) and to characterize other important aspects of the dose-response assessment (*see* Section 3.7).

The scope, depth, and use of a dose-response assessment vary in different circumstances. Although the quality of dose-response data is not necessarily related to the weight of evidence descriptor, dose-response assessments are generally completed for agents considered ''Carcinogenic to Humans'' and ''Likely to Be Carcinogenic to Humans.'' When there is suggestive evidence, the Agency generally would not attempt a dose-response assessment, as the nature of the data generally would not support one; however, when the evidence includes a well-conducted study, quantitative analyses may be useful for some purposes, for example, providing a sense of the magnitude and uncertainty of potential risks, ranking potential hazards, or setting research priorities. In each case, the rationale for the quantitative analysis is explained, considering the uncertainty in the data and the suggestive nature of the weight of evidence. These analyses generally would not be considered Agency consensus estimates. Dose-response assessments are generally not done when there is inadequate evidence, although calculating a bounding estimate from an epidemiologic or experimental study that does not show positive results can indicate the study's level of sensitivity and capacity to detect risk levels of concern.

Cancer is a collection of several diseases that develop through cell and tissue changes over time. Dose-response assessment procedures based on tumor incidence have seldom taken into account the effects of key precursor events within the whole biological process due to lack of empirical data and understanding about these events. In this discussion, response data include measures of key precursor events considered integral to the carcinogenic process in addition to tumor incidence. These responses may include changes in DNA, chromosomes, or other key macromolecules; effects on growth signal transduction, including induction of hormonal changes; or physiological or toxic effects that include proliferative events diagnosed as precancerous but not pathology that is judged to be cancer. Analysis of such responses may be done along with that of tumor incidence to enhance the tumor dose-response analysis. If dose-response analysis of nontumor key events is more informative about the carcinogenic process for an agent, it can be used in lieu of, or in conjunction with, tumor incidence analysis for the overall dose-response assessment.

As understanding of mode of action improves and new types of data become available, dose-response assessment will continue to evolve. These cancer guidelines encourage the development and application of new methods that improve dose-response assessment by reflecting new scientific understanding and new sources of information.

3.1. Analysis of Dose

For each effect observed, dose-response assessment should begin by determining an appropriate *dose metric.* Several dose metrics have been used, *e.g.*, delivered dose, body burden, and area under the curve, and others may be appropriate depending on the data and mode of action.

Selection of an appropriate dose metric considers what data are available and what is known about the agent's mode of action at the target site, and uncertainties involved in estimation and application of alternative metrics. The dose metric specifies:

- The agent measured, preferably the active agent (administered agent or a metabolite);
- Proximity to the target site (exposure concentration, potential dose, internal dose, or delivered dose,[5] reflecting increasing proximity); and
- The time component of the effective dose (cumulative dose, average dose, peak dose, or body burden).

Analyses can be based on estimates of animal dose metrics or human dose metrics. The assessment should describe the approach used to select a dose metric and the reasons for this approach. The final analysis, however, should determine a human equivalent dose metric. This facilitates comparing results from different datasets and effects by using human equivalent dose/concentrations as common metrics. When appropriate, it may be necessary to convert dose metrics across exposure routes. When route-to-route extrapolations are made, the underlying data, algorithms, and assumptions are clearly described.

Timing of exposure can also be important. When there is a susceptible lifestage, doses during the susceptible period are not equivalent to doses at other times, and they would be analyzed separately.

[5] *Exposure* is contact of an agent with the outer boundary of an organism. *Exposure concentration* is the concentration of a chemical in its transport or carrier medium at the point of contact. *Dose* is the amount of a substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. *Potential dose* is the amount ingested, inhaled, or applied to the skin. *Applied dose* is the amount of a substance presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). *Absorbed dose* is the amount crossing a specific absorption barrier (*e.g.*, the exchange boundaries of skin, lung, and digestive tract) through uptake processes. *Internal dose* is a more general term, used without respect to specific absorption barriers or exchange boundaries. *Delivered dose* is the amount of the chemical available for interaction by any particular organ or cell (U.S. EPA, 1992a).

3.1.1. Standardizing Different Experimental Exposure Regimens

Complex exposure or dosing regimens are often present in experimental and epidemiologic studies. The resulting internal dose depends on many variables, including concentration, duration, frequency of administration, and duration of recovery periods between administrations. Internal dose also depends on variables that are intrinsic to the exposed individual, such as lifestage and rates of metabolism and clearance. To facilitate comparing results from different study designs and to make inferences about human exposures, a summary estimate of the dose metric, whether the administered dose or inhalation exposure concentration or an internal metric, may be derived for a complex exposure regimen.

Toxicokinetic modeling is the preferred approach for estimating dose metrics from exposure. Toxicokinetic models generally describe the relationship between exposure and measures of internal dose over time. More complex models can reflect sources of intrinsic variation, such as polymorphisms in metabolism and clearance rates. When a robust model is not available, or when the purpose of the assessment does not warrant developing a model, simpler approaches may be used.

For chronic exposure studies, the cumulative exposure or dose administered often is expressed as an average over the duration of the study, as one consistent dose metric. This approach implies that a higher dose administered over a short duration is equivalent to a commensurately lower dose administered over a longer duration. Uncertainty usually increases as the duration becomes shorter relative to the averaging duration or the intermittent doses become more intense than the averaged dose. Moreover, doses during any specific susceptible or refractory period would not be equivalent to doses at other times. For these reasons, cumulative exposure or potential dose may be replaced by a more appropriate dose metric when indicated by the data.

For mode of action studies, the dose metric should be calculated over a duration that reflects the time to occurrence of the key precursor effects. Mode of action studies are often of limited duration, as the precursors can be observed after less-than-chronic exposures. When the experimental exposure regimen is specified on a weekly basis (for example, 4 hours a day, 5 days a week), the daily exposure may be averaged over the week, where appropriate.

Doses in studies at the cellular or molecular level can be difficult to relate to organ- or organism-level dose metrics. Toxicokinetic modeling can sometimes be used to relate doses at the cellular or molecular level to doses or exposures at higher levels of organization.

3.1.2. Toxicokinetic Data and Modeling

In the absence of chemical-specific data, physiologically based toxicokinetic modeling is potentially the most comprehensive way to account for biological processes that determine internal dose. Physiologically based models commonly describe blood flow between physiological compartments and simulate the relationship between applied dose and internal dose. Toxicokinetic models generally need data on absorption, distribution, metabolism, and elimination of the administered agent and its metabolites.

Additionally, in the case of inhalation exposures, models can explicitly characterize the geometry of the respiratory tract and the airflow through it, as well as the interaction of this airflow with the entrained particles or fibers and gases (Kimbell *et al.*, 2001; Subramaniam *et al.*, 2003). Because of large interspecies differences in airway morphometry such models can be particularly useful in interspecies extrapolations. When employed, however, the potential for large inter-individual differences in airway morphometry, are considered to ensure that the models provide information representative of human populations.

Toxicokinetic models can improve dose-response assessment by revealing and describing nonlinear relationships between applied and internal dose. Nonlinearity observed in a dose-response curve often can be attributed to toxicokinetics (Hoel *et al.*, 1983; Gaylor *et al.*, 1994), involving, for example, saturation or induction of enzymatic processes at high doses. In some cases, toxicokinetic processes tend to become linear at sufficiently low doses (Hattis, 1990).

A discussion of confidence should accompany the presentation of model results and include consideration of model validation and sensitivity analysis, stressing the predictive performance of the model and whether the model is sufficient to support decision-making. Quantitative uncertainty analysis is important for evaluating the performance of a model, whether the model is based primarily on default assumptions or chemical-specific data. The uncertainty analysis covers questions of *model uncertainty*

(*e.g.*, Is the model based on the appropriate biology and how does that affect estimates of dose metrics?) and *parameter uncertainty* (*e.g.*, Do the data support unbiased and stable estimates of the model parameters?). When a delivered dose measure is used in animal-to-human extrapolation, the assessment discusses the confidence of the target tissue and its toxicodynamics being the same in both species (*see* Section 3.6). Toxicokinetic modeling results may be presented alone as the preferred method of estimating human equivalent exposures or doses, or these results may be presented in parallel with default procedures (*see* Section 3.1.3), depending on the confidence in the modeling.

3.1.3. Cross-Species Scaling Procedures

Standard cross-species scaling procedures are available when the data are not sufficient to support a toxicokinetic model or when the purpose of the assessment does not warrant developing one. The aim is to define exposure levels for humans and animals that are expected to produce the same degree of effect (U.S. EPA, 1992b), taking into account differences in scale between test animals and humans, such as size and lifespan.

3.1.3.1. Oral Exposures

For oral exposures, administered doses should be scaled from animals to humans on the basis of equivalence of $mg/kg^{3/4}$-d (milligrams of the agent normalized by the ¾ power of body weight per day) (U.S. EPA, 1992b). The ¾ power is consistent with current science, including empirical data that allow comparison of potencies in humans and animals, and it is also supported by analysis of the allometric variation of key physiological parameters across mammalian species. It is generally more appropriate at low doses, where sources of nonlinearity such as saturation of enzyme activity are less likely to occur. This scaling is intended as an unbiased estimate rather than a conservative one. Equating exposure concentrations in food or water is an alternative version of the same approach, because daily intakes of food or water are approximately proportional to the ¾ power of body weight.

The aim of these cross-species scaling procedures is to estimate administered doses in animals and humans that result in equal lifetime risks. It is useful to recognize two components of this equivalence: *toxicokinetic equivalence*, which determines administered doses in animals and humans that yield equal tissue doses, and *toxicodynamic equivalence*, which determines tissue doses in animals and humans that yield equal lifetime risks (U.S. EPA, 1992b). Toxicokinetic modeling (see Section 3.1.2) addresses factors associated with toxicokinetic equivalence, and toxicodynamic modeling (*see* Section 3.2.2) addresses factors associated with toxicodynamic equivalence. When toxicokinetic modeling is used without toxicodynamic modeling, the dose-response assessment develops and supports an approach for addressing toxicodynamic equivalence, perhaps by retaining some of the cross-species scaling factor (*e.g.*, using the square root of the cross-species scaling factor or using a factor of 3 to cover toxicodynamic differences between animals and humans, as is currently done in deriving inhalation reference concentrations [U.S. EPA, 1994]).

When assessing risks from childhood exposure, the $mg/kg^{3/4}$-d scaling factor does not use the child's body weight (U.S. EPA, 1992b). This reflects several uncertainties in extrapolating risks to children:

- The data supporting the $mg/kg^{3/4}$-d scaling factor were derived for differences across species and may not apply as well to differently sized individuals of the same species or to different lifestages.
- In addition to metabolic differences, there are also important toxicodynamic differences; for example, children have faster rates of cell division than do adults, so scaling across different lifestages and species simultaneously may be particularly uncertain.

3.1.3.2. Inhalation Exposures

For inhalation exposures experimental exposure concentrations are replaced with human equivalent concentrations calculated using EPA's methods for deriving inhalation reference concentrations (U.S. EPA, 1994), which give preference to the use of toxicokinetic modeling. When toxicokinetic models are unavailable, default dosimetry models are employed to extrapolate from experimental exposure concentrations to human equivalent concentrations. When toxicokinetic modeling or dosimetry modeling is used without toxicodynamic modeling, the dose-response assessment develops and supports an approach for addressing toxicodynamic equivalence.

The default dosimetry models typically involve the use of species-specific physiologic and anatomic factors relevant to the form of the agent (*e.g.*, particle or gas) and categorized with regard to whether the response occurs either locally (*i.e.*, within the respiratory tract) or remotely. For example, current default models (U.S. EPA, 1994) use parameters such as:

- Inhalation rate and surface area of the affected part of the respiratory tract for gases eliciting the response locally,
- Blood:gas partition coefficients for remote acting gases,
- Fractional deposition with inhalation rate and surface area of the affected part of the respiratory tract for particles eliciting the response locally, and
- Fractional deposition with inhalation rate and body weight for particles eliciting the response remotely.

The current default values for some parameters used in the default models (*e.g.*, breathing rate and respiratory tract surface area) are based on data from adults (U.S. EPA, 1994). The human respiratory system passes through several distinct stages of maturation and growth during the first several years of life and into adolescence (Pinkerton and Joad, 2000), during which characteristics important to disposition of inhaled toxicants may vary. Children and adults breathing the same concentration of an agent may receive different doses to the body or lungs (U.S. EPA, 2002b). Consequently, it may be appropriate to evaluate the default models by considering physiologic and anatomic factors representative of early lifestages, for example through the substitution of child-specific parameters (U.S. EPA, 2002b). Such evaluation uses the default model and dosimetric adjustment in use at the time of the assessment coupled with the best understanding of child-specific parameters at that time (*e.g.*, drawn from the scientific literature). This analysis is undertaken with caution: (1) because of the correlations between activity level, breathing rate, respiratory tract dimensions, and body weight and (2) to avoid the possibility of mismatching the type of agent (gas or particle) and its site of response (within the respiratory tract or remote from the respiratory tract) with the relevant dosimetry factors in use at the time of the assessment. Analyses of children's inhalation dosimetry are also considered when using model structures beyond the default models (*e.g.*, physiologically based toxicokinetic models).

When using dosimetry modeling, the comparison of human-equivalent concentrations for different lifestages (*e.g.*, for an adult and a child) can indicate whether it is important to carry both concentrations forward in the dose-response assessment or whether a verbal characterization of any findings will suffice.

3.1.4. Route Extrapolation

In certain situations, an assessment based on studies of one exposure route may be applied to another exposure route. Route-to-route extrapolation has both qualitative and quantitative aspects. For the qualitative aspect, the assessor should weigh the degree to which positive results by one exposure route support a judgment that similar results would be expected by another route. In general, confidence in making such a judgment is strengthened when tumors are observed at a site distant from the portal of entry and when absorption is similar through both routes. In the absence of contrary data, a qualitative default option can be used: If the agent is absorbed through an exposure route to give an internal dose, it may be carcinogenic by that route.

When a qualitative extrapolation can be supported, quantitative extrapolation may still be problematic due to the absence of adequate data. The differences in biological processes among routes of exposure (oral, inhalation, dermal) can be great because of, for example, first-pass effects and different results from different exposure patterns. There is no generally applicable method for accounting for these differences in uptake processes in a quantitative route-to-route extrapolation of dose-response data in the absence of good data on the agent of interest. Therefore, route-to-route extrapolation of dose data relies on a case-by-case analysis of available data. When good data on the agent itself are limited, an extrapolation analysis can be based on expectations from physical and chemical properties of the agent, properties and route-specific data on structurally analogous compounds, or *in vitro* or *in vivo* uptake data on the agent.

Route-to-route uptake models may be applied if model parameters are suitable for the compound of interest. Such models are currently considered interim methods; further model development and validation is awaiting the development of more extensive data. For screening or hazard ranking, route-to-route extrapolation may be based on assumed quantitative comparability as a default, as long as it is reasonable to assume absorption by compared routes. When route-to-route extrapolation is used, the assessor's degree of confidence in both the qualitative and quantitative extrapolation is discussed in the assessment and highlighted in the dose-response characterization.

Toxicokinetic modeling can be used to compare results of studies by different exposure routes. Results can also be compared on the basis of internal dose for effects distant from the point of contact.

Route extrapolation can be used to understand how internal dose and subsequent effects depend on exposure route. If testing by different exposure routes is available, the observation of similar or dissimilar internal doses can be important in determining whether and what conclusions can be made concerning the dose-response function(s) for different routes of exposure.

3.2. Analysis in the Range of Observation

The principle underlying these cancer guidelines is to use approaches that include as much information as possible. Quantitative information about key precursor events can be used to develop a toxicodynamic model. Alternatively, such information can be fitted by empirical models to extend the dose-response analysis of tumor incidence to lower doses and response levels. The analysis in the range of observation is used to establish a POD near the lower end of the observed range (*see* Section 3.3).

3.2.1. Epidemiologic Studies

Ideally, epidemiologic data would be used to select the dose-response function for human exposures. Because epidemiologic data are usually limited and many models may fit the data (Samet *et al.*,1998), other factors may influence model choice. For epidemiologic studies, including those with grouped data, analysis by linear models in the range of observation is generally appropriate unless the fit is poor. The relatively small exposure range observed in many epidemiologic studies, for example, makes it difficult to discern the shape of the exposure-or dose-response curve. Exposure misclassification and errors in exposure estimation also obscure the shape of the dose-response curve. When these errors are unsystematic or random, the result is frequently to bias the risk estimates toward zero. When a linear model fits poorly, more flexible models that allow for low-dose linearity, for example, a linear-quadratic model or a Hill model (Murrell *et al.*, 1998), are often considered next.

Analysis of epidemiologic studies depends on the type of study and quality of the data, particularly the availability of quantitative measures of exposure. The objective is to develop a dose-response curve that estimates the incidence of cancer attributable to the dose (as estimated from the exposure) to the agent. In some cases, *e.g.*, tobacco smoke or occupational exposures, the data are in the range of the exposures of interest. In other cases, as with data from animal experiments, information from the observable range is extrapolated to exposures of interest.

Analysis of effects raises additional issues:

- Many studies collect information from death certificates, which leads to estimates of mortality rather than incidence. Because survival rates vary for different cancers, the analysis may be improved by adjusting mortality figures to reflect the relationship between incidence and mortality.
- Epidemiologic studies, by their nature, are limited in the extent to which they can control for effects due to exposures from other agents. In some cases, the agent can have discernible interactive effects with another agent, making it possible to estimate the contribution of each agent as a risk factor for the effects of the other. For example, competing risks in a study population can limit the observed occurrence of cancer, while additive effects may lead to an increase occurrence of cancer. In the case of rates not already so adjusted, the analysis can be improved by correcting for competing or additive risks that are not similar in exposed and comparison groups.
- Comparison groups that are not free from exposure to the agent can bias the risk estimates toward zero. The analysis can be improved by considering background exposures in the exposed and comparison groups.
- The latent period for most cancers implies that exposures immediately preceding the detection of a tumor would be less likely to have contributed to its development and, therefore, may count less in the analysis. Study subjects who were first exposed near the end of the study may not have had adequate time since exposure for cancer to develop; therefore, analysis of their data may be similar to analysis of data for those who were not exposed. However, for carcinogens that act on multiple stages of the carcinogenic process, especially the later stages, all periods of exposure. including recent exposures, may be important.

Some study designs can yield only a partial characterization of the overall hazard and therefore risk as, for example, in studies that: (1) investigate only one effect (typical of many case-control studies), (2) include only one population segment (*e.g.*, male workers or workers of one socioeconomic class), or (3) include only one lifestage (*e.g.*, childhood leukemia following maternal exposure to contaminated drinking water). To obtain a more complete

characterization that includes risks of other cancers, estimates from these studies can be supplemented with estimates from other studies that investigated other cancers, population segments, or lifestages (*see* Section 3.5).

When several studies are available for dose-response analysis, *meta-analysis* can provide a systematic approach to weighing positive studies and those studies that do not show positive results, and calculating an overall risk estimate with greater precision. Issues considered include the comparability of studies, heterogeneity across studies, and the potential for a single large study to dominate the analysis. Confidence in a meta-analysis is increased when it considers study quality, including definition of the study population and comparison group, measurement of exposure, potential for exposure misclassification, adequacy of follow-up period, and analysis of confounders (*see* Section 2.2.1.3).

3.2.2. Toxicodynamic (''Biologically Based'') Modeling

Toxicodynamic modeling can be used when there are sufficient data to ascertain the mode of action (see Section 2.4) and quantitatively support model parameters that represent rates and other quantities associated with the key precursor events of the mode of action. Toxicodynamic modeling is potentially the most comprehensive way to account for the biological processes involved in a response. Such models seek to reflect the sequence of key precursor events that lead to cancer. Toxicodynamic models can contribute to dose-response assessment by revealing and describing nonlinear relationships between internal dose and cancer response. Such models may provide a useful approach for analysis in the range of observation, provided the purpose of the assessment justifies the effort involved.

If a new model is developed for a specific agent, extensive data on the agent are important for identifying the form of the model, estimating its parameters, and building confidence in its results. Conformance to the observed tumor incidence data alone does not establish a model's validity, as a model can be designed with a sufficiently large number of parameters so as to fit any given dataset. Peer review, including both an examination of the scientific basis supporting the model and an independent evaluation of the model's performance, is an essential part of evaluating the new model.

If a standard model already exists for the agent's mode of action, the model can be adapted for the agent by using agent-specific data to estimate the model's parameters. An example is the two-stage clonal expansion model developed by Moolgavkar and Knudson (1981) and Chen and Farland (1991). These models continue to be improved as more information becomes available.

It is possible for different models to provide equivalent fits to the observed data but to diverge substantially in their projections at lower doses. When model parameters are estimated from tumor incidence data, it is often the case that different combinations of parameter estimates can yield similar results in the observed range. For this reason, critical parameters (*e.g.*, mutation rates and cell birth and death rates) are estimated from laboratory studies and not by curve-fitting to tumor incidence data (Portier, 1987). This approach reduces model uncertainty (*see* Section 3.6) and ensures that the model does not give answers that are biologically unrealistic. This approach also provides a robustness of results, where the results are not likely to change substantially if fitted to slightly different data.

Toxicodynamic modeling can provide insight into the relationship between tumors and key precursor events. For example, a model that includes cell proliferation can be used to explore the extent to which small increases in the cell proliferation rate can lead to large lifetime tumor incidences (Gaylor and Zheng, 1996). In this way, toxicodynamic modeling can be used to select and characterize an appropriate precursor response level (see Section 3.2.2, 3.2.5).

3.2.3. Empirical Modeling (''Curve Fitting'')

When a toxicodynamic model is not available or when the purpose of the assessment does not warrant developing such a model, empirical modeling (sometimes called ''curve fitting'') should be used in the range of observation. A model can be fitted to data on either tumor incidence or a key precursor event. Goodness-of-fit to the experimental observations is not by itself an effective means of discriminating among models that adequately fit the data (OSTP, 1985). Many different curve-fitting models have been developed, and those that fit the observed data reasonably well may lead to several-fold differences in estimated risk at the lower end of the observed range. Another problem occurs when a multitude of alternatives are presented without sufficient context to make a reasoned judgment about the alternatives. This form of model uncertainty reflects primarily the availability of different computer models and not biological information about the agent being assessed or about carcinogenesis in general. In cases where curve-fitting models are used because the data are not adequate to support a toxicodynamic model, there generally would be no biological basis to choose among alternative curve-fitting models. However, in situations where there are alternative models with significant biological support, the decisionmaker can be informed by the presentation of these alternatives along with their strengths and uncertainties.

Quantitative data on precursors can be used in conjunction with, or in lieu of, data on tumor incidence to extend the dose-response curve to lower doses. Caution is used with rates of molecular events such as mutation or cell proliferation or signal transduction. Such rates can be difficult to relate to cell or tissue changes overall. The timing of observations of these phenomena, as well as the cell type involved, is linked to other precursor events to ensure that the measurement is truly a key event (Section 2.4).

For incidence data on either tumors or a precursor, an established empirical procedure is used to provide objectivity and consistency among assessments. The procedure models incidence, corrected for background, as an increasing function of dose. The models are sufficiently flexible in the observed range to fit linear and nonlinear datasets. Additional judgments and perhaps alternative analyses are used when the procedure fails to yield reliable results. For example, when a model's fit is poor, the highest dose is often omitted in cases where it is judged that the highest dose reflects competing toxicity that is more relevant at high doses than at lower doses. Another example is when there are large differences in survival across dose groups; here, models that includes time-to-tumor or time-to-event information may be useful.

For continuous data on key precursor effects, empirical models can be chosen on the basis of the structure of the data. The rationale for the choice of model, the alternatives considered and rejected, and a discussion of model uncertainty are included in the dose-response characterization.

3.2.4. Point of Departure (POD)

For each tumor response, a POD from the observed data should be estimated to mark the beginning of extrapolation to lower doses. The POD is an estimated dose (expressed in human-equivalent terms) near the lower end of the observed range without significant extrapolation to lower doses.

The POD is used as the starting point for subsequent extrapolations and analyses. For linear extrapolation, the POD is used to calculate a *slope factor* (see Section 3.3.3), and for nonlinear extrapolation the POD is used in the calculation of a *reference dose* or *reference concentration* (*see* Section 3.3.4). In a risk characterization, the POD is part of the determination of a *margin of exposure* (*see* Section 5.4). With appropriate adjustments, it can also be used as the basis for *hazard rankings* that compare different agents or health effects.

The lowest POD is used that is adequately supported by the data. If the POD is above some data points, it can fail to reflect the shape of the dose-response curve at the lowest doses and can introduce bias into subsequent extrapolations (*see* Figure 3–1). On the other hand, if the POD is far below all observed data points, it can introduce model uncertainty and parameter uncertainty (*see* Section 3.6) that increase with the distance between the data and the POD. Use of a POD at the lowest level supported by the data seeks to balance these considerations. It uses information from the model(s) a small distance below the observed range rather than discarding this information and using extrapolation procedures in a range where the model(s) can provide some useful information. Statistical tests involving the ratio of the central estimate and its lower bound (*i.e.*, ED_{xx}/LED_{xx}) can be useful for evaluating how well the data support a model's estimates at a particular response level. (Note that the ability to model at a particular response level is not the same as the study's ability to identify an increase at that response level as statistically significant.)

The POD for extrapolating the relationship to environmental exposure levels of interest, when the latter are outside the range of observed data, is generally the lower 95% confidence limit on the lowest dose level that can be supported for modeling by the data. SAB (1997) suggested that, ''it may be appropriate to emphasize lower statistical bounds in screening analyses and in activities designed to develop an appropriate human exposure value, since such activities require accounting for various types of uncertainties and a lower bound on the central estimate is a scientifically-based approach accounting for the uncertainty in the true value of the ED_{10} [or central estimate].'' However, the consensus of the SAB (1997) was that, ''both point estimates and statistical bounds can be useful in different circumstances, and recommended that the Agency routinely calculate and present the point estimate of the ED_{10} [or central estimate] and the corresponding upper and lower 95% statistical bounds.'' For example, it may be appropriate to emphasize the central estimate in activities that involve formal uncertainty analysis that are required by OMB Circular A–4 (OMB, 2003) as well as ranking agents as to their carcinogenic hazard. Thus, risk assessors should calculate, to the extent practicable, and present the central estimate and the corresponding upper and lower statistical bounds (such as confidence limits) to inform decisionmakers.

When tumor data are used, a POD is obtained from the modeled tumor incidences. Conventional cancer bioassays, with approximately 50 animals per group, generally can support modeling down to an increased incidence of 1–10%; epidemiologic studies, with larger sample sizes, below 1%. Various models commonly used for carcinogens yield similar estimates of the POD at response levels as low as 1% (Krewski and Van Ryzin, 1981; Gaylor *et al.*, 1994). Consequently, response levels at or below 10% can often be used as the POD. As a modeling convention, the lower bound on the doses associated with standard response levels of 1, 5, and 10% can be analyzed, presented, and considered. For making comparisons at doses within the observed range, the ED_{10} and LED_{10} are also reported and can be used, with appropriate adjustments, in hazard rankings that compare different agents or health effects (U.S. EPA, 2002c). A *no-observed-adverse-effect level* (NOAEL) generally is not used for assessing the potential for carcinogenic response when one or more models can be fitted to the data.

When good quality precursor data are available and are clearly tied to the mode of action of the compound of interest, models that include both tumors and their precursors may be advantageous for deriving a POD. Such models can provide insight into quantitative relationships between tumors and precursors (*see* Section 3.2.2), possibly suggesting the precursor response level that is associated with a particular tumor response level. The goal is to use precursor data to extend the observed range below what can be observed in tumor studies. EPA is continuing to examine this issue and anticipates that findings and conclusions may result in supplemental guidance to these cancer guidelines. If the precursor data are drawn from small samples or if the quantitative relationship between tumors and precursors is not well defined, then the tumor data will provide a more reliable POD. Precursor effects may or may not be biologically adverse in themselves; the intent is to consider not only tumors but also damage that can lead to subsequent tumor development by the agent. Analysis of continuous data may differ from discrete data; Murrell *et al.* (1998) discuss alternative approaches to deriving a POD from continuous data.

3.2.5. Characterizing the POD: The POD Narrative

As a single-point summary of a single dose-response curve, the POD alone does not convey all the critical information present in the data from which it is derived. To convey a measure of uncertainty, the POD should be presented as a central estimate with upper and lower bounds. A POD narrative summarizes other important features of the database and the POD that are important to account for in low-dose extrapolations or other analyses.

(a) *Nature of the response.* Is the POD based on tumors or a precursor? If on tumors, does the POD measure incidence or mortality? Is it a lifetime measure or was the study terminated early? The relationships between precursors and tumors, incidence and mortality, and lifetime and early-termination results vary from case to case. Modeling can provide quantitative insight into these relationships, for example, linking a change in a precursor response to a tumor incidence (see Section 3.2.2). This can aid in evaluating the significance of the response at the POD and adjusting different PODs to make them comparable.

(b) *Level of the response.* What level of response is associated with the POD, for example, 1% cancer risk, 10% cancer risk, or 10% change in a precursor measure?

(c) *Nature of the study population.* Is the POD based on humans or animals? How large is the effective sample size? Is the study group representative of the general population, of healthy adult workers, or of a susceptible group? Are both sexes represented? Did exposure occur during a susceptible lifestage?

(d) *Slope of the dose-response curve at the POD.* How does response change as dose is reduced below the POD? A steep slope indicates that risk decreases rapidly as dose decreases. On the other hand, a steep slope also indicates that errors in an exposure assessment can lead to large errors in estimating risk. Both aspects of the slope are important. The slope also indicates whether dose-response curves for different effects are likely to cross below the POD. For example, in the ED_{01} study where 2-

acetylaminofluorene caused bladder carcinomas and liver carcinomas in mice (Littlefield et al., 1980), the dose-response curves for these tumors cross between 10% and 1% response (see Figure 3–2). This crossing, which can be inferred from the slopes of the curves at a 10% response, shows how considering the slope can lead to better inferences about the predominant effects expected at lower doses. Mode of action data can also be useful; quantitative information about key precursor events can be used to describe how risk decreases as dose decreases below the POD.

(e) *Relationship of the POD with other cancers.* How does the POD for this cancer relate to PODs for other cancers observed in the database? For example, a POD based on male workers would not reflect the implications of mammary tumors in female rats or mice.

(f) *Extent of the overall cancer database.* Have potential cancer responses been adequately studied (*e.g.,* were all tissues examined), or is the database limited to particular effects, population segments, or lifestages? Do the mode of action data suggest a potential for cancers not observed in the database (*e.g.,* disruption of particular endocrine pathways leading to related cancers)?

3.2.6. Relative Potency Factors

Relative potency factors (of which toxicity equivalence factors are a special case) can be used for a well-defined class of agents that operate through a common mode of action for the same toxic endpoint. A complete dose-response assessment is conducted for one well-studied member of the class that serves as the *index chemical* for the class. The other members of the class are tied to the index chemical by relative potency factors that are based on characteristics such as relative toxicological outcomes, relative metabolic rates, relative absorption rates, quantitative SARs, or receptor binding characteristics (U.S. EPA, 2000c). Examples of this approach are the *toxicity equivalence factors* for dioxin-like compounds and the relative potency factors for some carcinogenic polycyclic aromatic hydrocarbons. Whenever practicable, toxicity equivalence factors should be validated and accompanied by quantitative uncertainty analysis.

3.3. Extrapolation to Lower Doses

The purpose of low-dose extrapolation is to provide as much information as possible about risk in the range of doses below the observed data. The most versatile forms of low-dose extrapolation are dose-response models that characterize risk as a probability over a range of environmental exposure levels. These risk probabilities allow estimates of the risk reduction under different decision options and estimates of the risk remaining after an action is taken and provide the risk information needed for benefit-cost analyses of different decision options.

When a dose-response model is not developed for lower doses, another form of low-dose extrapolation is a safety assessment that characterizes the safety of one lower dose, with no explicit characterization of risks above or below that dose. Although this type of extrapolation may be adequate for evaluation of some decision options, it may not be adequate for other purposes (*e.g.,* benefit-cost analyses) that require a quantitative characterization of risks across a range of doses. At this time, safety assessment is the default approach for tumors that arise through a nonlinear mode of action; however, EPA continues to explore methods for quantifying dose-response relationships over a range of environmental exposure levels for tumors that arise through a nonlinear mode of action (U.S. EPA, 2002c). EPA program offices that need this more explicit dose-response information may develop and apply methods that are informed by the methods described in these cancer guidelines.

3.3.1. Choosing an Extrapolation Approach

The approach for extrapolation below the observed data considers the understanding of the agent's mode of action at each tumor site (*see* Section 2.4). Mode of action information can suggest the likely shape of the dose-response curve at lower doses. The extent of inter-individual variation is also considered, with greater variation spreading the response over a wider range of doses.

Linear extrapolation should be used when there are MOA data to indicate that the dose-response curve is expected to have a linear component below the POD. Agents that are generally considered to be linear in this region include:

- Agents that are DNA-reactive and have direct mutagenic activity, or
- Agents for which human exposures or body burdens are high and near doses associated with key precursor events in the carcinogenic process, so that background exposures to this and other agents operating through a common mode of action are in the increasing, approximately linear, portion of the dose-response curve.

When the weight of evidence evaluation of all available data are insufficient to establish the mode of action for a tumor site and when scientifically plausible based on the available data, linear extrapolation is used as a default approach, because linear extrapolation generally is considered to be a health-protective approach. Nonlinear approaches generally should not be used in cases where the mode of action has not been ascertained. Where alternative approaches with significant biological support are available for the same tumor response and no scientific consensus favors a single approach, an assessment may present results based on more than one approach.

A nonlinear approach should be selected when there are sufficient data to ascertain the mode of action and conclude that it is not linear at low doses *and* the agent does not demonstrate mutagenic or other activity consistent with linearity at low doses. Special attention is important when the data support a nonlinear mode of action but there is also a suggestion of mutagenicity. Depending on the strength of the suggestion of mutagenicity, the assessment may justify a conclusion that mutagenicity is not operative at low doses and focus on a nonlinear approach, or alternatively, the assessment may use both linear and nonlinear approaches.

Both linear and nonlinear approaches may be used when there are multiple modes of action. If there are multiple tumor sites, one with a linear and another with a nonlinear mode of action, then the corresponding approach is used at each site. If there are multiple modes of action at a single tumor site, one linear and another nonlinear, then both approaches are used to decouple and consider the respective contributions of each mode of action in different dose ranges. For example, an agent can act predominantly through cytotoxicity at high doses and through mutagenicity at lower doses where cytotoxicity does not occur. Modeling to a low response level can be useful for estimating the response at doses where the high-dose mode of action would be less important.

3.3.2. Extrapolation Using a Toxicodynamic Model

The preferred approach is to develop a toxicodynamic model of the agent's mode of action and use that model for extrapolation to lower doses (*see* Section 3.2.2). The extent of extrapolation is governed by an analysis of *model uncertainty,* where alternative models that fit similarly in the observed

range can diverge below that range (*see* Section 3.6). Substantial divergence is likely when model parameters are estimated from tumor incidence data, so that different combinations of parameter estimates yield similar fits in the observed range but have different implications at lower doses. An analysis of model uncertainty can be used to determine the range where extrapolation using the toxicodynamic model is supported and where further extrapolation would be based on either a linear or a nonlinear default, as appropriate (*see* Sections 3.3.3, 3.3.4).

3.3.3. Extrapolation Using a Low-Dose, Linear Model

Linear extrapolation should be used in two distinct circumstances: (1) When there are data to indicate that the dose-response curve has a linear component below the POD, or (2) as a default for a tumor site where the mode of action is not established (*see* Section 3.3.1). For linear extrapolation, a line should be drawn from the POD to the origin, corrected for background. This implies a proportional (linear) relationship between risk and dose at low doses. (**Note** that the dose-response curve generally is not linear at higher doses.)

The slope of this line, known as the *slope factor,* is an upper-bound estimate of risk per increment of dose that can be used to estimate risk probabilities for different exposure levels. The slope factor is equal to $0.01/LED_{01}$ if the LED_{01} is used as the POD.

Unit risk estimates express the slope in terms of μg/L drinking water or μg/m^3 or ppm air. In general, the drinking water unit risk is derived by converting a slope factor from units of mg/kg-d to units of μg/L, whereas an inhalation unit risk is developed directly from a dose-response analysis using equivalent human concentrations already expressed in units of μg/m^3. Unit risk estimates often assume a standard intake rate (L/day drinking water or m^3/day air) and body weight (kg), which may need to be reconciled with the exposure factors for the population of interest in an exposure assessment (*see* Section 4.4). Alternatively, when the slope factor for inhalation is in units of ppm, it may sometimes be termed the inhalation unit risk. Although unit risks have not been calculated in the past for dermal exposures, both exposures that are absorbed into the systemic circulation and those that remain in contact with the skin are also important.

Risk-specific doses are derived from the slope factor or unit risk to estimate the dose associated with a specific risk level, for example, a one-in-a-million increased lifetime risk.

3.3.4. Nonlinear Extrapolation to Lower Doses

A nonlinear extrapolation method can be used for cases with sufficient data to ascertain the mode of action and to conclude that it is not linear at low doses but with not enough data to support a toxicodynamic model that may be either nonlinear or linear at low doses. Nonlinear extrapolation having a significant biological support may be presented in addition to a linear approach when the available data and a weight of evidence evaluation support a nonlinear approach, but the data are not strong enough to ascertain the mode of action applying the Agency's mode of action framework. If the mode of action and other information can support chemical-specific modeling at low doses, it is preferable to default procedures.

For cases where the tumors arise through a nonlinear mode of action, an oral *reference dose* or an inhalation *reference concentration,* or both, should be developed in accordance with EPA's established practice for developing such values, taking into consideration the factors summarized in the characterization of the POD (*see* Section 3.2.5). This approach expands the past focus of such reference values (previously reserved for effects other than cancer) to include carcinogenic effects determined to have a nonlinear mode of action. As with other health effects of concern, it is important to put cancer in perspective with the overall health impact of an exposure by comparing reference value calculations for cancer with those for other health effects.

For effects other than cancer, reference values have been described as being based on the assumption of biological thresholds. The Agency's more current guidelines for these effects (U.S. EPA, 1996a, 1998b), however, do not use this assumption, citing the difficulty of empirically distinguishing a true threshold from a dose-response curve that is nonlinear at low doses.

Economic and policy analysts need to know how the probability of cancer varies at exposures above the reference value and whether, and to what extent, there are health benefits from reducing exposures below the reference value. The risk assessment community is working to develop better methods to provide more useful information to economic and policy analysts.

3.3.5. Comparing and Combining Multiple Extrapolations

When multiple estimates can be developed, all datasets should be considered and a judgment made about how best to represent the human cancer risk. Some options for presenting results include:

- Adding risk estimates derived from different tumor sites (NRC, 1994),
- Combining data from different datasets in a joint analysis (Putzrath and Ginevan, 1991; Stiteler *et al.*, 1993; Vater *et al.*, 1993),
- Combining responses that operate through a common mode of action,
- Representing the overall response in each experiment by counting animals with any tumor showing a statistically significant increase,
- Presenting a range of results from multiple datasets (in this case, the dose-response assessment includes guidance on how to choose an appropriate value from the range),
- Choosing a single dataset if it can be justified as most representative of the overall response in humans, or
- A combination of these options.

Cross-comparison of estimates from human and animal studies can provide a valuable risk perspective.

- Calculating an animal-derived slope factor and using it to estimate the risk expected in a human study can provide information with which to evaluate the human study design, for example, adequacy of exposure level and sample size.
- Calculating an upper-bound slope factor from a human study that does not show positive results but that has good exposure information, and comparing it to an animal-derived slope factor can indicate whether the animal and humans studies are consistent.

3.4. Extrapolation to Different Human Exposure Scenarios

As described in the previous cancer guidelines, special problems arise when the human exposure situation of concern suggests exposure regimens, *e.g.*, route and dosing schedule, that are substantially different from those used in the relevant animal studies. Unless there is evidence to the contrary in a particular case, the cumulative dose received over a lifetime, expressed as average daily exposure prorated over a lifetime, is recommended as an appropriate measure of exposure to a carcinogen. That is, the assumption is made that a high dose of a carcinogen received over a short period of time is equivalent to a corresponding low dose spread over a lifetime. This approach becomes more problematical as the exposures in question become more intense but less frequent, especially when there is evidence that the agent has shown dose-rate effects (U.S. EPA 1986a).

Accordingly, *for lifetime human exposure scenarios* that involve intermittent or varying levels of exposure, the prevailing practice has been to assess exposure by calculating *a lifetime average daily exposure or dose* (U.S. EPA, 1992a).

For less-than-lifetime human exposure scenarios, too, the lifetime average daily exposure or dose has often been used. The use of these lifetime average exposure metrics was adopted with low-dose linear cancer assessments in mind. The lifetime averaging implies that less-than-lifetime exposure is associated with a linearly proportional reduction of the lifetime risk, regardless of when exposures occur. Such averaging may be problematic in some situations. This can be illustrated using both the multistage model and the two-stage clonal expansion model that predict that short-duration risks are not necessarily proportional to exposure duration and can depend on the nature of the carcinogen and the timing of exposure (Goddard *et al.*, 1995; Murdoch *et al.*, 1992). These examples indicate some circumstances in which use of a lifetime average daily dose (LADD) would underestimate cancer risk by two-to fivefold, and others in which it might overestimate risk (Murdoch *et al.*, 1992). Thus, averaging over the duration of a lifestage or a critical window of exposure may be appropriate. As methodological research focuses on new approaches for estimating risks from less-than-lifetime exposures, methods and defaults can be expected to change.

This highlights the importance for each dose-response assessment to critically evaluate all information pertaining to less-than-lifetime exposure. For example, detailed stop-exposure studies can provide information about the relationship between exposure duration, precursor effects, potential for reversibility, and tumor development. Toxicokinetic modeling can investigate differences in internal dose between short-term and long-term exposure or between intermittent and constant exposure. Persistence in the body can be useful in explaining long-term effects resulting from shorter-term exposures.

For nonlinear cancer analyses, it may be appropriate to assess exposure by calculating a *daily dose* that is averaged over the exposure duration for the study (see Section 3.1.1). For example, when the analysis is based on precursor effects that result from less than a lifetime exposure, that exposure period may be used. This reflects an expectation that the precursor effects on which the analysis is based can result from less-than-lifetime exposure, bringing consistency to the methods used for dose-response assessment and exposure assessment in such cases. The dose-response assessment can provide a recommendation to exposure assessors about the averaging time that is appropriate to the mode of action and to the exposure duration of the scenario.

3.5. Extrapolation to Susceptible Populations and Lifestages

The dose-response assessment strives to derive separate estimates for susceptible populations and lifestages so that these risks can be explicitly characterized. For a susceptible population, higher risks can be expected from exposures anytime during life, but this applies to only a portion of the general population (*e.g.*, those bearing a particular genetic susceptibility). In contrast, for a susceptible lifestage, higher risks can be expected from exposures during only a portion of a lifetime, but everyone in the population may pass through those lifestages. Effects of exposures during a susceptible period are not equivalent to effects of exposures at other times; consequently, it is useful to estimate the risk attributable to exposures during each period.

Depending on the data available, a tiered approach should be used to address susceptible populations and lifestages.

- When there is an epidemiologic study or an animal bioassay that reports quantitative results for susceptible individuals, the data should be analyzed to provide a separate risk estimate for those who are susceptible. If susceptibility pertains to a lifestage, it is useful to characterize the portion of the lifetime risk that can be attributed to the susceptible lifestage.
- When there are data on some risk-related parameters that allow comparison of the general population and susceptible individuals, the data should be analyzed with an eye toward adjusting the general population estimate for susceptible individuals. This analysis can range from toxicokinetic modeling that uses parameter values representative of susceptible individuals to more simply adjusting a general population estimate to reflect differences in important rate-governing parameters. Care is taken to not make parameter adjustments in isolation, as the appropriate adjustment can depend on the interactions of several parameters; for example, the ratio of metabolic activation and clearance rates can be more appropriate than the activation rate alone (U.S. EPA, 1992b).
- In the absence of such agent-specific data, there is some general information to indicate that childhood can be a susceptible lifestage for exposure to some carcinogens (U.S. EPA, 2005); this warrants explicit consideration in each assessment. The potential for susceptibility from early-life exposure is expected to vary among specific agents and chemical classes. In addition, the concern that the dose-averaging generally used for assessing less-than-lifetime exposure is more likely to understate than overstate risk (see Section 3.4) contributes to the suggestion that alternative approaches be considered for assessing risks from less-than-lifetime exposure that occurs during childhood. Accompanying these cancer guidelines is the Supplemental Guidance that the Agency will use to assess risks from early-life exposure to potential carcinogens (U.S. EPA, 2005). The Supplemental Guidance may be updated to reflect new data and new understanding that may become available in the future.

3.6. Uncertainty

The NRC (1983, 1994, 1996, 2002) has repeatedly advised that proper characterization of uncertainty is essential in risk assessment. An assessment that omits or underestimates uncertainty can leave decisionmakers with a false sense of confidence in estimates of risk. On the other hand, a high level of uncertainty does not imply that a risk assessment or a risk management action should be delayed (NRC, 2002). Uncertainty in dose-response assessment can be classified as either *model uncertainty* or *parameter uncertainty.* A related concept, *human variation,* is discussed below. Assessments should discuss the significant uncertainties encountered in the analysis, distinguishing, if possible, between model uncertainty, parameter uncertainty, and human variation. Origins of these uncertainties can span a range, from a single causal thread supported by sparse data, to abundant information that presents multiple possible conclusions or that does not coalesce. As described in Section 2.6 and in Section 5.1, all contributing features should be noted.

Model uncertainty refers to a lack of knowledge needed to determine which is the correct scientific theory on which to base a model. In risk assessment, model uncertainty is reflected in alternative choices for model structure, dose metrics, and extrapolation approaches. Other sources of model uncertainty concern whether surrogate data are appropriate, for example, using data on adults to make inferences about

children. The full extent of model uncertainty usually cannot be quantified; a partial characterization can be obtained by comparing the results of alternative models. Model uncertainty is expressed through comparison of separate analyses from each model, coupled with a subjective probability statement, where feasible and appropriate, of the likelihood that each model might be correct (NRC, 1994).

Some aspects of model uncertainty that should be addressed in an assessment include the use of animal models as a surrogate for humans, the influence of cross-species differences in metabolism and physiology, the use of effects observed at high doses as an indicator of the potential for effects at lower doses, the effect of using linear or nonlinear extrapolation to estimate risks, the use of using small samples and subgroups to make inferences about entire human populations or subpopulations with differential susceptibilities, and the use of experimental exposure regimens to make inferences about different human exposure scenarios (NRC, 2002).

Toxicokinetic and toxicodynamic models are generally premised on *site concordance* across species, modeling, for example, the relationship between administered dose and liver tissue concentrations to predict increased incidences of liver cancer. This relationship, which can be observed in animals, is typically only inferred for humans. There are, however, numerous examples of an agent causing different cancers in different species. The assessment should discuss the relevant data that bear on this form of model uncertainty.

Parameter uncertainty refers to a lack of knowledge about the values of a model's parameters. This leads to a distribution of values for each parameter. Common sources of parameter uncertainty include random measurement errors, systematic measurement errors, use of surrogate data instead of direct measurements, misclassification of exposure status, random sampling errors, and use of an unrepresentative sample. Most types of parameter uncertainty can be quantified by statistical analysis.

Human variation refers to person-to-person differences in biological susceptibility or in exposure. Although both human variation and uncertainty can be characterized as ranges or distributions, they are fundamentally different concepts. Uncertainty can be reduced by further research that supports a model or improves a parameter estimate, but human variation is a reality that can be better characterized, but not reduced, by further research. Fields other than risk assessment use ''variation'' or ''variability'' to mean dispersion about a central value, including measurement errors and other random errors that risk assessors address as uncertainty.

Probabilistic risk assessment, informed by expert judgment, has been used in exposure assessment to estimate human variation and uncertainty in lifetime average daily exposure concentration or dose. Probabilistic methods can be used in this exposure assessment application because the pertinent variables (for example, concentration, intake rate, exposure duration, and body weight) have been identified, their distributions can be observed, and the formula for combining the variables to estimate the lifetime average daily dose is well defined (see U.S. EPA, 1992a). Similarly, probabilistic methods can be applied in dose-response assessment when there is an understanding of the important parameters and their relationships, such as identification of the key determinants of human variation (for example, metabolic polymorphisms, hormone levels, and cell replication rates), observation of the distributions of these variables, and valid models for combining these variables. With appropriate data and expert judgment, formal approaches to probabilistic risk assessment can be applied to provide insight into the overall extent and dominant sources of human variation and uncertainty. In doing this, it is important to note that analyses that omit or underestimate some principal sources of variation or uncertainty could provide a misleadingly narrow description of the true extent of variation and uncertainty and give decisionmakers a false sense of confidence in estimates of risk. Specification of joint probability distributions is appropriate when variables are not independent of each other. In each case, the assessment should carefully consider the questions of uncertainty and human variation and discuss the extent to which there are data to address them.

Probabilistic risk assessment has also been used in dose-response assessment to determine and distinguish the degree of uncertainty and variability in toxicokinetic and toxicodynamic modeling. Although this field is less advanced that probabilistic exposure assessment, progress is being made and these cancer guidelines are flexible enough to accommodate continuing advances in these approaches.

Advances in uncertainty analysis are expected as the field develops. The cancer guidelines are intended to be flexible enough to incorporate additional approaches for characterizing uncertainty that have less commonly been used by regulatory agencies. In all scientific and engineering fields, data and research limitations often limit the application of established methods. A dearth of data is a particular problem when quantifying the *probability distribution* of model outputs. In many of these scientific and engineering disciplines, researchers have used rigorous expert elicitation methods to overcome the lack of peer-reviewed methods and data. Although expert elicitation has not been widely used in environmental risk assessment, several studies have applied this methodology as a tool for understanding quantitative risk. For example, expert elicitation has been used in chemical risk assessment and its associated uncertainty (*e.g.*, Richmond, 1981; Renn, 1999; Florig *et al.*, 2001; Morgan *et al.*, 2001; Willis *et al.*, 2004), components of risk assessment such as hazard assessment and dose-response evaluation (*e.g.*, Hawkins and Graham 1988; Jelovsek *et al.*, 1990; Evans *et al.*, 1994; IEc, 2004; U.S. EPA 2004) and exposure assessment (*e.g.*, Whitfield and Wallsten, 1989; Hawkins and Evans, 1989; Winkler *et al.*, 1995; Stiber *et al.*, 1999; Walker *et al.*, 2001, 2003; Van Der Fels-Klerx *et al.*, 2002), and for evaluating other types of risks (*e.g.*, North and Merkhofer, 1976; Fos and McLin, 1990). These cancer guidelines are flexible enough to accommodate the use of expert elicitation to characterize cancer risks, as a complement to the methods presented in the cancer guidelines. According to NRC (NRC, 2002), the rigorous use of expert elicitation for the analyses of risks is considered to be quality science.

3.7. Dose-Response Characterization

A *dose-response characterization* extracts the dose-response information needed in a full risk characterization (U.S. EPA, 2000b), including:

- Presentation of the recommended estimates (slope factors, reference doses, reference concentrations) and alternatives with significant biological support,
- A summary of the data supporting these estimates,
- A summary and explanation of the modeling approaches used,
- A description of any special features such as the development and consolidation of multiple estimates as detailed in Section 3.3.5,
- The POD narrative (see Section 3.2.5),

• A summary of the key defaults invoked,

• Identification of susceptible populations or lifestages and quantification of their differential susceptibility, and

• A discussion of the strengths and limitations of the dose-response assessment, highlighting significant issues in developing risk estimates, alternative approaches considered equally plausible, and how these issues were resolved.

All estimates should be accompanied by the weight of evidence descriptor and its narrative (see Section 2.5) to convey a sense of the qualitative uncertainty about whether the agent may or may not be carcinogenic.

Slope factors generally represent an upper bound on the average risk in a population or the risk for a randomly selected individual but not the risk for a highly susceptible individual or group. Some individuals face a higher risk and some face a lower risk. The use of upper bounds generally is considered to be a health-protective approach for covering the risk to susceptible individuals, although the calculation of upper bounds is not based on susceptibility data. Similarly, exposure during some lifestages can contribute more or less to the total lifetime risk than do similar exposures at other times. The dose-response assessment characterizes, to the extent possible, the extent of these variations.

Depending on the supporting data and modeling approach, a slope factor can have a mix of traits that tend to either estimate, overestimate, or underestimate risk.

Some examples of traits that tend to overestimate risk include the following.

• The slope factor is derived from data on a highly susceptible animal strain.

• Linear extrapolation is used as a default and extends over several orders of magnitude.

• The largest of several slope factors is chosen.

Some examples of traits that tend to underestimate risk include the following.

• Several tumor types were observed, but the slope factor is based on a subset of them.

• The study design does not include exposure during a susceptible lifestage, for example, perinatal exposure.

• The study population is of less-than-average susceptibility, for example, healthy adult workers.

• There is random exposure misclassification or random exposure measurement error in the study from which the slope factor is derived.

Some examples of traits that inherently neither overestimate nor underestimate risk include the following.

• The slope factor is derived from data in humans or in an animal strain that responds like humans.

• Linear extrapolation is appropriate for the agent's mode of action.

• Environmental exposures are close to the observed data.

• Several slope factors for the same tumor are averaged or a slope factor is derived from pooled data from several studies.

• The slope factor is derived from the only suitable study.

BILLING CODE 6560–50–P

Figure 3-1. Compatibility of alternative points of departure with observed and modeled tumor incidences

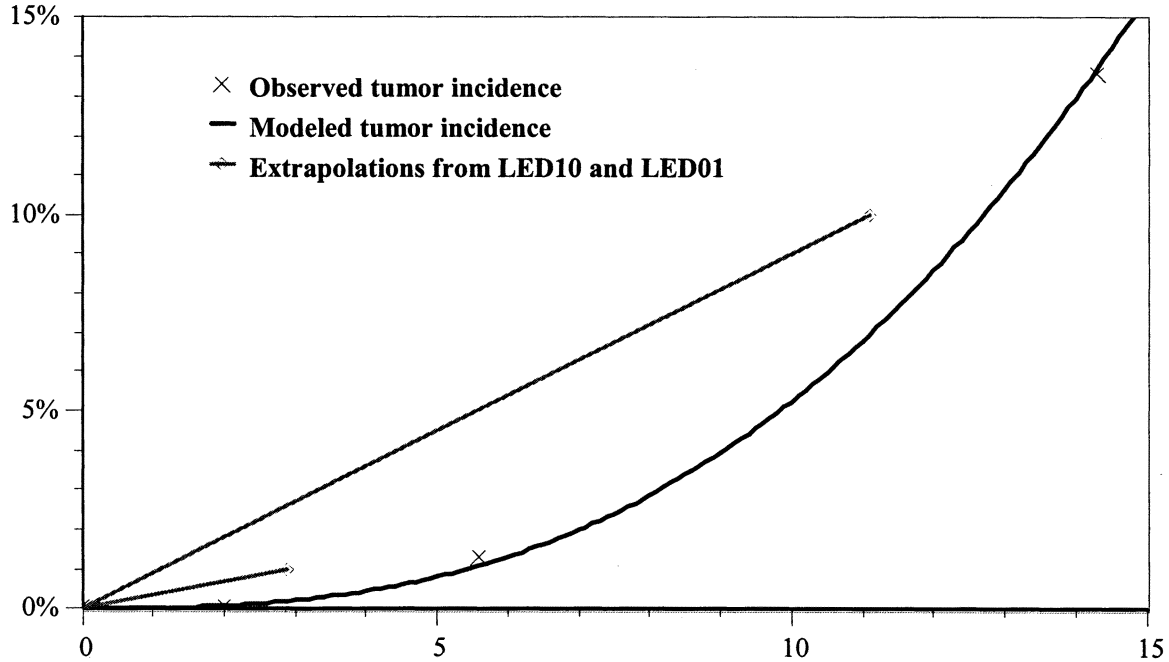
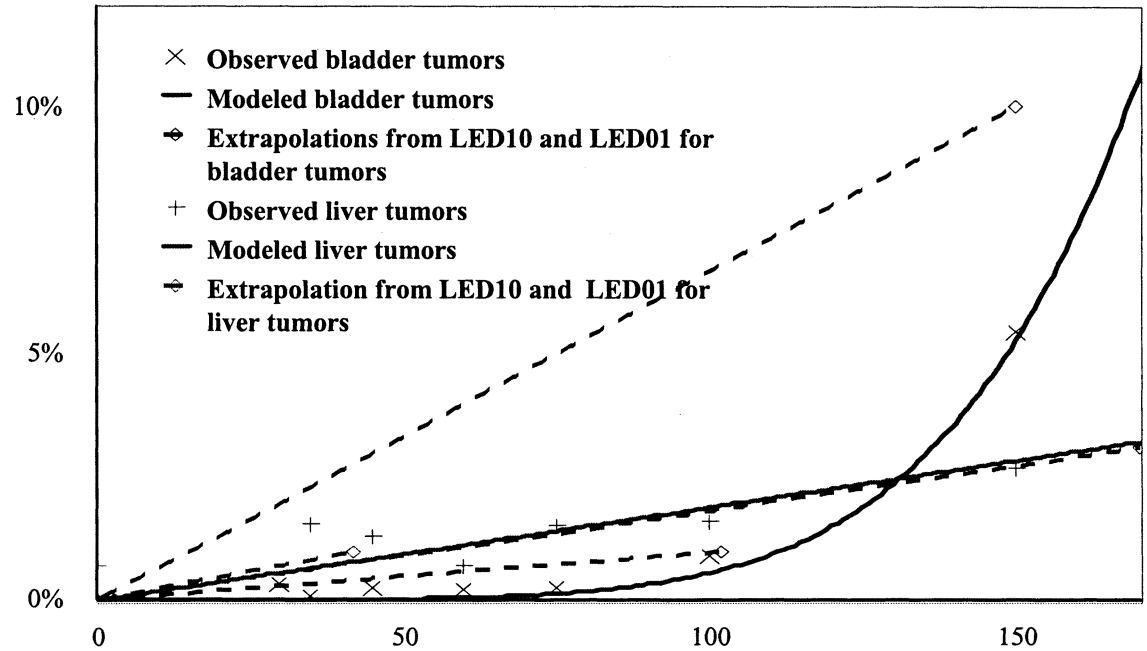


Figure 3-2. Crossing--between 10% and 1%--of dose-response curves for bladder carcinomas and liver carcinomas induced by 2-AAF



BILLING CODE 6560–50–C

4. Exposure Assessment

Exposure assessment is the determination (qualitative and quantitative) of the magnitude, frequency, and duration of exposure and internal dose (U.S. EPA, 1992a). This section provides a brief overview of exposure assessment principles, with an emphasis on issues related to carcinogenic risk assessment. The information presented here should be used in conjunction with other guidance documents, including *Guidelines for Exposure Assessment* (U.S. EPA, 1992a), *Science Policy Council Handbook: Risk Characterization* (U.S. EPA, 2000b), *Exposure Factors Handbook* (U.S. EPA, 1997c), the 1997 *Policy for Use of Probabilistic Analysis in Risk Assessments* (U.S. EPA, 1997d), and the 1997 *Guiding Principles for Monte Carlo Analysis* (U.S. EPA, 1997e). In addition, program-specific guidelines for exposure assessment should be consulted.

Exposure assessment generally consists of four major steps: defining the assessment questions, selecting or developing the conceptual and mathematical models, collecting data or selecting and evaluating available data, and exposure characterization. Each of these steps is briefly described below.

4.1. Defining the Assessment Questions

In providing a clear and unambiguous statement of the purpose and scope of the exposure assessment (U.S. EPA, 1997e), consider the following.

• The management objectives of the assessment will determine whether deterministic screening level analyses are adequate or whether full probabilistic exposure characterization is needed.

• Identify and include all important sources (*e.g.*, pesticide applications), pathways (*e.g.*, food or water), and routes (*e.g.*, ingestion, inhalation, and dermal) of exposure in the assessment. If a particular source, pathway, or route is omitted, a clear and transparent explanation should be provided.

• Separate analyses should be conducted for each definable subgroup within the population of interest. In particular, subpopulations or lifestages that are believed to be highly exposed or susceptible to a particular health effect should be studied. These include people with certain diseases or genetic susceptibilities and others whose behavior or physiology may lead to higher exposure or susceptibility. Consider the following examples:

—Physiological differences between men and women (*e.g.*, body weight and inhalation rate) may lead to important differences in exposures. See, for example, the discussion in *Exposure Factors Handbook* (U.S. EPA, 1997c, Appendix 1A).

—Pregnant and lactating women may have exposures that differ from the general population (*e.g.*, slightly higher water consumption) (U.S. EPA, 1997c). Further, exposure to pregnant women may result in exposure to the developing fetus (NRC, 1993b).

—Children consume more food per body weight than do adults while consuming fewer types of foods, *i.e.*, have a more limited diet (ILSI, 1992; NRC, 1993b; U.S. EPA, 1997c). In addition, children engage in crawling and mouthing (*i.e.*, putting hands and objects in the mouth) behaviors, which can increase their exposures.

—The elderly and disabled may have important differences in their exposures due to a more sedentary lifestyle (U.S. EPA, 1997c). In addition, the health status of this group may affect their susceptibility to the detrimental effects of exposure.

For further guidance, see *Guidelines for Exposure Assessment* (U.S. EPA, 1992a, § 3).

4.2. Selecting or Developing the Conceptual and Mathematical Models

Carcinogen risk assessment models have generally been based on the premise that risk is proportional to cumulative lifetime dose. For lifetime human exposure scenarios, therefore, the exposure metric used for carcinogenic risk assessment has been the lifetime average daily dose (LADD) or, in the case of inhalation exposure, the lifetime average exposure concentration. These metrics are typically used in conjunction with the corresponding slope factor to calculate individual excess cancer risk. The LADD is typically an estimate of the daily intake of a carcinogenic agent throughout the entire life of an individual, while the lifetime average exposure concentration is the corresponding estimate of average exposure concentration for the carcinogenic agent over the entire life of an individual. Depending on the objectives of the assessment, the LADD or lifetime average exposure concentration may be calculated deterministically (using point estimates for each factor to derive a point estimate of the exposure) or stochastically (using probability distributions to represent each factor and such techniques as Monte Carlo analysis to derive a distribution of the LADD) (U.S. EPA, 1997e). Stochastic analyses may help to identify certain population segments or lifestages that are highly exposed and may need to be assessed as a special subgroup. For further guidance, see *Guidelines for Exposure Assessment* (U.S. EPA, 1992a, § 5.3.5.2). As methodological research focuses on new approaches for estimating risks from less-than-lifetime exposures, methods and defaults can be expected to change.

There may be cases where the mode of action indicates that dose rates are important in the carcinogenic process. In these cases, short-term, less-than-lifetime exposure estimates may be more appropriate than the LADD for risk assessment. This may be the case when a nonlinear dose-response approach is used (*see* Section 3.3.4).

4.3. Collecting Data or Selecting and Evaluating Available Data

After the assessment questions have been defined and the conceptual and mathematical models have been developed, it is important to compile and evaluate existing data or, if necessary, to collect new data. Depending on the exposure scenario under consideration, data on a wide variety of exposure factors may be needed. EPA's *Exposure Factors Handbook* (U.S. EPA, 1997c) contains a large compilation of exposure data, with some analysis and recommendations. Some of these data are organized by age groups to assist with assessing such subgroups as children. See, for example, *Exposure Factors Handbook* (U.S. EPA, 1997c, Volume 1, Chapter 3). When using these existing data, it is important to evaluate the quality of the data and the extent to which the data are representative of the population under consideration. EPA's (U.S. EPA, 2000d) and OMB's (OMB 2002) guidance on information quality, as well as program-specific guidances can provide further assistance for evaluating existing data.

When existing data fail to provide an adequate surrogate for the needs of a particular assessment, it is important to collect new data. Such data collection efforts should be guided by the references listed above (*e.g.*, *Guidance for Data Quality Assessment* and program-specific guidance). Once again, subpopulations or lifestages of concern are an important consideration in any data collection effort.

4.3.1. Adjusting Unit Risks for Highly Exposed Populations and Lifestages

Unit risk estimates that have been developed in the dose-response assessment often assumed standard adult intake rates. When an exposure assessment focuses on a population or lifestage with differential exposure, good exposure assessment practice would replace the standard intake rates

with values representative of the exposed population. Small changes in exposure assessments can be approximated by using linearly proportional adjustments of exposure parameters, but a more accurate integrative analysis may require an analysis stratified by exposure duration (see Section 5.1).

For example, to adjust the drinking water unit risk for an active population that drinks 4 L/day (instead of 2 L/day), multiply the unit risk by 2.

Because children drink more water relative to their body weight than do adults (U.S. EPA, 2002d), adjustments to unit risk estimates are warranted whenever they are applied in an assessment of childhood exposure.

For example, to adjust the drinking water unit risk for a 9-kg infant who drinks 1 L/day (instead of a 70-kg adult who drinks 2 L/day), multiply the unit risk by [(1 L/day) / (9 kg)] / [(2 L/day) / (70 kg)] = 3.9.

Inhalation dosimetry is employed to derive the human equivalent exposure concentrations on which inhalation unit risks, and reference concentrations, are based (U.S. EPA, 1994). As described previously (see Sections 3.1.2, 3.1.3), different dosimetry methods may be employed depending on the availability of relevant data and chemical-specific characteristics of the pollutant. Consideration of lifestage-particular physiological characteristics in the dosimetry analysis may result in a refinement to the human equivalent concentration (HEC) to insure relevance in risk assessment across lifestages, or might conceivably conclude with multiple HECs, and corresponding inhalation unit risk values (*e.g.*, separate for childhood and adulthood).

The dose-response assessment discusses the key sources of uncertainty in estimating dosimetry, including any related to lifestage. Review of this discussion and of the dosimetric analysis performed in deriving the HEC and resultant unit risk will assist in the appropriate application of inhalation unit risk values to exposure across lifestages.

4.4. Exposure Characterization

The exposure characterization is a technical characterization that presents the assessment results and supports the risk characterization. It provides a statement of the purpose, scope, and approach used in the assessment, identifying the exposure scenarios and population subgroups covered. It provides estimates of the magnitude, frequency, duration, and distribution of exposures among members of the exposed population as the data permit. It identifies and compares the contribution of different sources, pathways, and routes of exposure. In particular, a qualitative discussion of the strengths and limitations (uncertainties) of the data and models are presented.

The discussion of uncertainties is a critical component of the exposure characterization. Uncertainties can arise out of problems with the conceptual and mathematical models. Uncertainties can also arise from poor data quality and data that are not quite representative of the population or scenario of interest. Consider the following examples of uncertainties.

- National data (*i.e.*, data collected to represent the entire U.S. population) may not be representative of exposures occurring within a regional or local population.
- Use of short-term data to infer chronic, lifetime exposures should be done with caution. Use of short-term data to estimate long-term exposures has the tendency to underestimate the number of people exposed while overestimating the exposure levels experienced by those in the upper end (*i.e.*, above the 90th percentile) of the exposure distribution. For further guidance, refer to *Guidelines for Exposure Assessment* (U.S. EPA, 1992a, § 5.3.1).
- Children's behavior, including their more limited diet, may lead to relatively high but intermittent exposures. This pattern of exposure, ''one that gradually declines over the developmental period and which remains relatively constant thereafter'' is not accounted for in the LADD model (ILSI, 1992). Further, the physiological characteristics of children may lead to important differences in exposure. Some of these differences can be accounted for in the LADD model. For further guidance, see *Guidelines for Exposure Assessment* (U.S. EPA, 1992a, § 5.3.5.2).

Overall, the exposure characterization should provide a full description of the sources, pathways, and routes of exposure. The characterization also should include a full description of the populations assessed. In particular, highly exposed or susceptible subpopulation or lifestage should be discussed. For further guidance on the exposure characterization, consult *Guidelines for Exposure Assessment* (U.S. EPA, 1992a), the *Policy and Guidance for Risk Characterization* (U.S. EPA, 2000b,1995) and EPA's *Rule Writer's Guide to Executive Order 13045* (especially Attachment C: Technical Support for Risk Assessors—Suggestions for Characterizing Risks to Children [U.S. EPA, 1998d]).

5. Risk Characterization

5.1. Purpose

EPA has developed general guidance on risk characterization for use in its risk assessment activities. The core of EPA's risk characterization policy (U.S. EPA, 2000b, 1995) includes the following.

Each risk assessment prepared in support of decision making at EPA should include a risk characterization that follows the principles and reflects the values outlined in this policy. A risk characterization should be prepared in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency. Further, discussion of risk in all EPA reports, presentations, decision packages, and other documents should be substantively consistent with the risk characterization. The nature of the risk characterization will depend upon the information available, the regulatory application of the risk information, and the resources (including time) available. In all cases, however, the assessment should identify and discuss all the major issues associated with determining the nature and extent of the risk and provide commentary on any constraints limiting fuller exposition.

Risk characterization should be carried out in accordance with the EPA (U.S. EPA, 2002a) and OMB (2002) information quality guidelines. EPA's risk characterization handbook (U.S. EPA, 2000b) provides detailed guidance to Agency staff. The discussion below does not attempt to duplicate this material, but it summarizes its applicability to carcinogen risk assessment.

The risk characterization includes a summary for the risk manager in a nontechnical discussion that minimizes the use of technical terms. It is an appraisal of the science that informs the risk manager in public health decisions, as do other decision-making analyses of economic, social, or technology issues. It also serves the needs of other interested readers. The summary is an information resource for preparing risk communication information, but being somewhat more technical than desired for communication with the general public, is not itself the usual vehicle for communication with every audience.

The risk characterization also brings together the assessments of hazard, dose response, and exposure to make risk estimates for the exposure scenarios of interest. This analysis that follows the summary is generally much more extensive. It typically will identify exposure scenarios of interest in decision making and present risk analyses associated with them. Some of the analyses may concern scenarios in

several media; others may examine, for example, only drinking water risks. As these cancer guidelines allow different hazard characterizations and different potencies for specified conditions, *e.g.*, exposure level, route of exposure, or lifestage, some of the integrative analyses may need to be stratified to accommodate the appropriate combinations of parameters across relevant exposure durations.

In constructing high end estimates of risk, the assessor should bear in mind that the high-end risk is a plausible estimate of the risk for those persons at the upper end of the risk distribution (U.S. EPA, 1992a). The intent of this approach is to convey an estimate of risk in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Overly conservative assumptions, when combined, can lead to unrealistic estimates of risk. This means that when constructing estimates from a series of factors (*e.g.*, emissions, exposure, and unit risk estimates) not all factors should be set to values that maximize exposure, dose, or effect, since this will almost always lead to an estimate that is above the 99th-percentile confidence level and may be of limited use to decisionmakers. This is particularly problematic when using unbounded lognormal factor distributions.

While it is an appropriate aim to assure protection of health and the environment in the face of scientific uncertainty, common sense, reasonable applications of assumptions and policy, and transparency are essential to avoid unrealistically high estimates. It is also important to inform risk managers of the final distribution of risk estimates (U.S. EPA, 2000b; 1995). Otherwise, risk management decisions may be made on varying levels of conservatism, leading to misplaced risk priorities and potentially higher overall risks. (Nichols and Zeckhauser,1986; Zeckhauser and Viscusi,1990).

The risk characterization presents an integrated and balanced picture of the analysis of the hazard, dose-response, and exposure. The risk analyst should provide summaries of the evidence and results and describe the quality of available data and the degree of confidence to be placed in the risk estimates. Important features include the constraints of available data and the state of knowledge, significant scientific issues, and significant science and science policy choices that were made when alternative interpretations of data exist (U.S. EPA, 1995, 2000b). Choices made about using data or default options in the assessment are explicitly discussed in the course of analysis, and if a choice is a significant issue, it is highlighted in the summary. In situations where there are alternative approaches for a risk assessment that have significant biological support, the decisionmaker can be informed by the presentation of these alternatives along with their strengths and uncertainties.

5.2. Application

Risk characterization is a necessary part of generating any Agency report on risk, whether the report is preliminary—to support allocation of resources toward further study—or comprehensive—to support regulatory decisions. In the former case, the detail and sophistication of the characterization are appropriately small in scale; in the latter case, appropriately extensive. Even if a document covers only parts of a risk assessment (hazard and dose-response analyses, for instance), the results of these are characterized.

Risk assessment is an iterative process that grows in depth and scope in stages from screening for priority making to preliminary estimation to fuller examination in support of complex regulatory decision making. Default options may be used at any stage, but they are predominant at screening stages and are used less as more data are gathered and incorporated at later stages. Various provisions in EPA-administered statutes require decisions based on differing findings for which differing degrees of analysis are appropriate. There are close to 30 provisions within the major statutes that require decisions based on risk, hazard, or exposure assessment. For example, Agency review of pre-manufacture notices under Section 5 of the Toxic Substances Control Act relies on screening analyses, whereas requirements for industry testing under Section 4 of that Act rely on preliminary analyses of risk or simply of exposure. In comparison, air quality criteria under the Clean Air Act rest on a rich data collection and are required by statute to undergo periodic reassessment. There are provisions that require ranking of hazards of numerous pollutants—which may be addressed through a screening level of analysis—and other provisions for which a full assessment of risk is more appropriate.

Given this range in the scope and depth of analyses, not all risk characterizations can or should be equal in coverage or depth. The risk assessor should carefully decide which issues in a particular assessment are important to present, choosing those that are noteworthy in their impact on results. For example, health effect assessments typically rely on animal data because human data are rarely available. The objective of characterization of the use of animal data is not to recount generic issues about interpreting and using animal data; Agency guidance documents cover these issues. Rather, the objective is to highlight any significant issues that arose within the particular assessment being characterized and inform the reader about significant uncertainties that affect conclusions.

5.3. Presentation of the Risk Characterization Summary

The presentation is a nontechnical discussion of important conclusions, issues, and uncertainties that uses the hazard, dose response, exposure, and integrative analyses for technical support. The primary technical supports within the risk assessment are the hazard characterization, dose-response characterization, and exposure characterization described in these cancer guidelines. The risk characterization is derived from these. The presentation should fulfill the aims outlined in the purpose section above.

5.4. Content of the Risk Characterization Summary

Specific guidance on hazard, dose-response, and exposure characterization appears in previous sections. Overall, the risk characterization routinely includes the following, capturing the important items covered in hazard, dose response, and exposure characterization:

- Primary conclusions about hazard, dose response, and exposure, including alternatives with significant biological support;
- Nature of key supporting information and analytic methods;
- Risk estimates and their attendant uncertainties, including key uses of default options when data are missing or uncertain.

—With linear extrapolations, risk below the POD is typically approximated by multiplying the slope factor by an estimate of exposure, *i.e.*, Risk = Slope Factor × Exposure. For exposure levels above the POD, the dose-response model is used instead of this approximation.

—With nonlinear extrapolations, the method of risk assessment depends on the procedure used. If a nonlinear dose-response function has been determined, it can be used with the expected exposure to estimate a risk. If an RfD or RfC was calculated, the hazard can be expressed as a *hazard quotient* (HQ), defined as the ratio of an exposure estimate over the

reference dose (RfD) or reference concentration (RfC), *i.e.*, HQ = Exposure / (RfD or RfC). From the hazard quotient, it can generally be inferred whether the nonlinear mode of action is relevant at the environmental exposure level in question;

• Statement of the extent of extrapolation of risk estimates from observed data to exposure levels of interest and its implications for certainty or uncertainty in quantifying risk. The extent of extrapolation can be expressed as a *margin of exposure* (MOE), defined as the ratio of the POD over an exposure estimate (MOE = POD / Exposure);

• Significant strengths and limitations of the data and analyses, including any major peer review issues;

• Appropriate comparison with similar EPA risk analyses or common risks with which people may be familiar; and

• Comparison with all appropriate assessments of the same problem by others.

It is often difficult to know a *priori* when or how different results of a cancer risk assessment are likely to be used by Agency economists, policy analysts, and decisionmakers, so it is important that the resulting characterizations include the necessary information for these analyses to the extent practicable. OMB and EPA guidelines for benefit-cost analysis require expected or central estimates of risk and information on the uncertainty of the estimate when it is possible or practicable. The extent of the uncertainty information needed for analysis depends, in part, on the scale of the policy being considered, with formal quantitative analysis of uncertainty being required in some cases.[6] OMB Circular A–4 (OMB, 2003) emphasizes that agencies ''should try to provide some estimate of the probability distribution of regulatory benefits and costs.'' These OMB guidelines note, ''Whenever it is possible to characterize quantitatively the probability distribution, some estimates of expected value * * * must be provided in addition to ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.'' The risk characterization should therefore include, where practicable, expected or central estimates of risk, as well as upper and lower bounds, *e.g.,* confidence limits, based on the POD, if not a full characterization of uncertainty of the risk. As discussed in EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (Appendix B), statutory mandates, such as the Safe Drinking Water Act, the Food Quality Protection Act, and the Clean Air Act, call for the Agency to generate specific kinds of risk information, and thus these updated cancer assessment guidelines should be read in conjunction with the Agency's statutory mandates regarding risk assessment.

[6] Specifically, OMB guidelines state: ''For rules that exceed the $1 billion annual [economic effects] threshold, a formal quantitative analysis of uncertainty is required. For rules with annual benefits and/or costs in the range from 100 million to $1 billion, you should seek to use more rigorous approaches with higher consequence rules.'' (OMB, 2003, page 158)

Appendix A: Major Default Options

This discussion covers the major default options commonly employed when data are missing or sufficiently uncertain in a cancer risk assessment, as adopted in these cancer guidelines. These options are predominantly inferences that help use the data observed under empirical conditions in order to estimate events and outcomes under environmental conditions. Several inferential issues arise when effects seen in a subpopulation of humans or animals are used to infer potential effects in the population of environmentally exposed humans. Several more inferential issues arise in extrapolating the exposure-effect relationship observed empirically to lower-exposure environmental conditions. The following issues cover the major default areas.

• Is the presence or absence of effects observed in a human population predictive of effects in another exposed human population?

• Is the presence or absence of effects observed in an animal population predictive of effects in exposed humans?

• How do metabolic pathways relate across species and among different age groups and between sexes in humans?

• How do toxicokinetic processes relate across species and among different age groups and between sexes in humans?

• What is the relationship between the observed dose-response relationship to the relationship at lower doses?

Is the Presence or Absence of Effects Observed in a Human Population Predictive of Effects in Another Exposed Human Population?

When cancer effects in exposed humans are attributed to exposure to an agent, the default option is that the resulting data are predictive of cancer in any other exposed human population. Most studies investigating cancer outcomes in humans from exposure to agents are often studies of occupationally exposed humans. By sex, age, and general health, workers may not be representative of the general population exposed environmentally to the same agents. In such studies there is no opportunity to observe subpopulations who are likely to be under represented, such as fetuses, infants and children, women, or people in poor health, who may respond differently from healthy workers. Therefore, it is understood that this option could still underestimate the response of certain human subpopulations (NRC, 1993b, 1994).

When cancer effects are not found in an exposed human population, this information by itself is not generally sufficient to conclude that the agent poses no carcinogenic hazard to this or other populations of potentially exposed humans, including susceptible subpopulations or lifestages. This is because epidemiologic studies often have low power to detect and attribute responses and typically evaluate cancer potential in a restricted population (*e.g.,* by age, healthy workers). The topic of susceptibility and variation is addressed further in the discussion below of quantitative default options about dose-response relationships. Well-conducted studies that fail to detect a statistically significant positive association, however, may have value and should be judged on their merits, including population size, duration of the study, the quality of the exposure characterization and measures of outcome, and the magnitude and duration of the exposure.

There is not yet enough knowledge to form a basis for any generally applicable qualitative or quantitative inference to compensate for the gap in knowledge concerning other populations. In these cancer guidelines, this problem is left to analysis in individual cases, to be attended to with further general guidance as future research and information allow. When information on a susceptible subpopulation or lifestage exists, it will be used. For example, an agent such as diethylstilbestrol (DES) causes a rare form of vaginal cancer (clear-cell adenocarcinoma) (Herbst *et al.,* 1971) in about 1 per 1000 of adult women whose mothers were exposed during pregnancy (Hatch *et al.*, 1998).

Is the Presence or Absence of Effects Observed in an Animal Population Predictive of Effects in Exposed Humans?

The default option is that positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans. Thus, if no adequate human or mode of action data are present, positive effects in animal cancer studies are a basis for assessing the carcinogenic hazard to humans. This option is a public health-protective policy, and it is both appropriate and necessary, given that we do not test for carcinogenicity in humans. The option is supported by the fact that nearly all of the agents known to cause cancer in humans are carcinogenic in animals in tests that have adequate protocols (IARC, 1994; Tomatis *et al.,* 1989; Huff, 1994). Moreover, almost one-third of human carcinogens were identified subsequent to animal testing (Huff, 1993). Further support is provided by research on the molecular biology of cancer processes, which has shown that the mechanisms of control of cell growth and differentiation are remarkably homologous among species and highly conserved in evolution. Nevertheless, the same research tools that have enabled recognition of the nature and commonality of cancer processes at the molecular level also have the power to reveal differences and instances in which animal responses are not relevant to humans (Lijinsky, 1993; U.S. EPA, 1991b). Under these cancer guidelines, available mode of action information is studied for its implications in both hazard and dose-response assessment and its ability to obviate default options.

There may be instances in which the use of an animal model would identify a hazard in animals that is not truly a hazard in humans (*e.g.,* the alpha-2u-globulin association with renal neoplasia in male rats [U.S. EPA, 1991b]). The extent to which animal studies may yield false positive indications for humans is a matter of scientific debate. To demonstrate that a response in animals is not relevant to any human situation, adequate data to assess the relevancy issue are important.

In general, while effects seen at the highest dose tested are assumed to be appropriate for assessment, it is necessary that the experimental conditions be scrutinized. Animal studies are conducted at high doses in order to provide statistical power, the highest dose being one that is minimally toxic (maximum tolerated dose or MTD). Consequently, the question often arises of whether a carcinogenic effect at the highest dose may be a consequence of cell killing with compensatory cell replication or of general physiological disruption rather than inherent carcinogenicity of the tested agent. There is little doubt that this may happen in some cases, but skepticism exists among some scientists that it is a pervasive problem (Ames and Gold, 1990; Melnick *et al.,* 1993; Barrett, 1993). If adequate data demonstrate that the effects are solely the result of excessive toxicity rather than carcinogenicity of the tested agent *per se,* then the effects may be regarded as not appropriate to include in assessment of the potential for human carcinogenicity of the agent. This is a matter of expert judgment, with consideration given to all of the data available about the agent, including effects in other toxicity studies, structure-activity relationships, and effects on growth control and differentiation.

When cancer effects are not found in well-conducted animal cancer studies in two or more appropriate species and other information does not support the carcinogenic potential of the agent, these data provide a basis for concluding that the agent is not likely to possess human carcinogenic potential, in the absence of human data to the contrary. This default option about lack of cancer effects has limitations. It is recognized that animal studies (and epidemiologic studies as well) have very low power to detect cancer effects. Detection of a 10% tumor incidence is generally the limit of power with standard protocols for animal studies (with the exception of rare tumors that are virtually markers for a particular agent, *e.g.*, angiosarcoma caused by vinyl chloride). In some situations, the tested animal species may not be predictive of effects in humans; for example, arsenic shows only minimal or no effect in animals, whereas it is clearly positive in humans. Therefore, it is important to consider other information as well; absence of mutagenic activity or absence of carcinogenic activity among structural analogues can increase the confidence that negative results in animal studies indicate a lack of human hazard.

Another limitation is that standard animal study protocols are not yet available for effectively studying perinatal effects. The potential for effects on the very young generally should be considered separately. Under existing Agency policy (U.S. EPA, 1997a, b), perinatal studies accomplished by modification of existing adult bioassay protocols are important in special circumstances.

Target organ concordance is not a prerequisite for evaluating the implications of animal study results for humans. Target organs of carcinogenesis for agents that cause cancer in both animals and humans are most often concordant at one or more sites (Tomatis *et al.,* 1989; Huff, 1994). However, concordance by site is not uniform. The mechanisms of control of cell growth and differentiation are concordant among species, but there are marked differences among species in the way control is managed in various tissues. For example, in humans, mutations of the tumor suppressor genes p53 and retinoblastoma are frequently observed genetic changes in tumors. These tumor-suppressor genes are also observed to be operating in some rodent tissues, but other growth control mechanisms predominate in other rodent tissues. Thus, an animal response may be due to changes in a control that are relevant to humans but appear in animals in a different way.

However, it is appropriate under these cancer guidelines to consider the influences of route of exposure, metabolism, and, particularly, some modes of action that may either support or not support target organ concordance between animals and humans. When data allow, these influences are considered in deciding whether agent-, species-, or organ-specific situations are appropriate to use in preference to this default assumption (NRC, 1994). In contrast, use of toxicokinetic modeling inherently assumes site concordance, as these models are used to estimate delivered dose to a particular tissue or organ in humans on the basis of the same tissue or organ from animal data.

The default is to include benign tumors observed in animal studies in the assessment of animal tumor incidence, if such tumors have the capacity to progress to the malignancies with which they are associated. This default is consistent with the approach of the National Toxicology Program and the International Agency for Research on Cancer and is more protective of public health than not including benign tumors in the assessment; benign and malignant tumors are treated as representative of related responses to the test agent (McConnell *et al.,* 1986), which is scientifically appropriate. Nonetheless, in assessing findings from animal studies, a greater proportion of malignancy is weighed more heavily than is a response with a greater proportion of benign tumors. Greater frequency of malignancy of a particular tumor type in comparison with other tumor responses observed in an animal study is also a factor to be considered

in selecting the response to be used in dose-response assessment.

Benign tumors that are not observed to progress to malignancy are assessed on a case-by-case basis. There is a range of possibilities for the overall significance of benign tumors. They may deserve attention because they are serious health problems even though they are not malignant; for instance, benign tumors may be a health risk because of their effect on the function of a target tissue, such as the brain. They may be significant indicators of the need for further testing of an agent if they are observed in a short-term test protocol, or such an observation may add to the overall weight of evidence if the same agent causes malignancies in a long-term study. Knowledge of the mode of action associated with a benign tumor response may aid in the interpretation of other tumor responses associated with the same agent.

How Do Metabolic Pathways Relate Across Species and Among Different Age Groups and Between Sexes in Humans?

The default option is that there is a similarity of the basic pathways of metabolism and the occurrence of metabolites in tissues in regard to the species-to-species extrapolation of cancer hazard and risk. If comparative metabolism studies were to show no similarity between the tested species and humans and a metabolite(s) was the active form, there would be less support for an inference that the animal response(s) relates to humans. In other cases, parameters of metabolism may vary quantitatively between species; this becomes a factor in deciding on an appropriate human-equivalent dose based on animal studies, optimally in the context of a toxicokinetic model. Although the basic pathways are assumed to be the same among humans, the presence of polymorphisms in the general population and factors such as the maturation of the pathways in infants should be considered. The active form of an agent may be present to differing degrees, or it may be completely absent, which may result in greater or lesser risk for subpopulations.

How Do Toxicokinetic Processes Relate Across Species and Among Different Age Groups and Between Sexes in Humans?

A major issue is how to estimate human-equivalent doses in extrapolating from animal studies. *As a default for oral exposure, a human equivalent dose for adults is estimated from data on another species by an adjustment of animal applied oral dose by a scaling factor based on body weight to the ¾ power. The same factor is used for children because it is slightly more protective than using children's body weight (see Section 3.1.3).* This adjustment factor is used because it represents scaling of metabolic rate across animals of different size. Because the factor adjusts for a parameter that can be improved on and brought into more sophisticated toxicokinetic modeling when such data become available, they are usually preferable to the default option.

For inhalation exposure, a human equivalent dose for adults is estimated by default methodologies that provide estimates of lung deposition and internal dose (U.S. EPA, 1994). The methodologies can be refined to more sophisticated forms with data on toxicokinetic and metabolic parameters of the specific agent. This default option, like the one for oral exposure, is selected in part because it lays a foundation for incorporating better data. The use of information to improve dose estimation from applied to internal to delivered dose is encouraged, including use of toxicokinetic modeling instead of any default, where data are available.

There are important differences between infants, adults, and older adults in the processes of absorption, distribution, and elimination; for example, infants tend to absorb metals through the gut more rapidly and more efficiently than do older children or adults (Calabrese, 1986). Renal elimination is also not as efficient in infants. Although these processes reach adult competency at about the time of weaning, they may have important implications, particularly when the dose-response relationship for an agent is considered to be nonlinear and there is an exposure scenario disproportionately affecting infants, because in these cases the magnitude of dose is more pertinent than the usual approach in linear extrapolation of averaging dose across a lifetime. Efficiency of intestinal absorption in older adults tends to be generally less overall for most chemicals. Another notable difference is that, post-weaning (about 1 year), children have a higher metabolic rate than do adults (Renwick, 1998), and they may toxify or detoxify agents at a correspondingly higher rate.

For a route-to-route exposure extrapolation, *the default option is that an agent that causes internal tumors by one route of exposure will be carcinogenic by another route if it is absorbed by the second route to give an internal dose.* This is a qualitative option and is considered to be public-health protective. The rationale is that for internal tumors an internal dose is significant no matter what the route of exposure. Additionally, the metabolism of the agent will be qualitatively the same for an internal dose. The issue of quantitative extrapolation of the dose-response relationship from one route to another is addressed case by case. Quantitative extrapolation is complicated by considerations such as first-pass metabolism.

What Is the Correlation of the Observed Dose-Response Relationship to the Relationship at Lower Doses?

If sufficient data are available, a biologically based model for both the observed range and extrapolation below that range may be used. Although no standard biologically based models are in existence, an agent-specific model may be developed if extensive data exist in a particular case and the purpose of the assessment justifies the investment of the resources needed. *The default procedure for the observed range of data when a biologically based model is not used is to use a curve-fitting model for incidence data.*

In the absence of data supporting a biologically based model for extrapolation outside of the observed range, the choice of approach is based on the view of mode of action of the agent arrived at in the hazard assessment. If more than one approach (*e.g.*, both a nonlinear and linear approach) are supported by the data, they should be used and presented to the decisionmaker.

A linear extrapolation approach is used when the mode of action information is supportive of linearity or mode of action is not understood. The linear approach is used when a view of the mode of action indicates a linear response, for example, when a conclusion is made that an agent directly causes alterations in DNA, a kind of interaction that not only theoretically requires one reaction but also is likely to be additive to ongoing, spontaneous gene mutation. Other kinds of activity may have linear implications, for example, linear rate-limiting steps would also support a linear procedure. The linear approach is to draw a straight line between a point of departure from observed data, generally as a default, an LED chosen to be representative of the lower end of the observed range, and the origin (zero incremental dose, zero incremental response). This approach is generally considered to be public-health protective.

The linear default is thought to generally provide an upper-bound calculation of potential risk at low doses, for example, a

1/100,000 to 1/1,000,000 risk. This upper bound is thought to be public-health protective at low doses for the range of human variation, considering the typical Agency target range for risk management of 1/1,000,000 to 1/10,000, although it may not completely be so (Bois *et al.*, 1995) if pre-existing disease or genetic constitution place a percentage of the population at greater risk from exposure to carcinogens. The question of what may be the actual variation in human susceptibility is one that was discussed in general in the NRC (1994) report, as well as the NRC report on pesticides in children and infants (NRC, 1993b). NRC has recommended research on the question, and EPA and other agencies are conducting such research. Given the current state of knowledge, EPA will assume that the linear default procedure adequately accounts for human variation unless there is case-specific information for a given agent or mode of action that indicates a particularly susceptible subpopulation or lifestage, in which case the special information will be used.

When adequate data on mode of action provide sufficient evidence to support a nonlinear mode of action for the general population and/or any subpopulations of concern, a different approach—a reference dose/reference concentration that assumes that nonlinearity—is used. The POD is again generally an BMDL when incidence data are modeled. A sufficient basis to support this nonlinear procedure is likely to include data on responses that are key events integral to the carcinogenic process. This means that the POD may be based on these precursor response data, for example, hormone levels or mitogenic effects rather than tumor incidence data.

When the mode of action information indicates that the dose-response function may be adequately described by both a linear and a nonlinear approach, then the results of both the linear and the nonlinear analyses are presented. An assessment may use both linear and nonlinear approaches if different responses are thought to result from different modes of action or a response appears to be very different at high and low doses due to influence of separate modes of action. The results may be needed for assessment of combined risk from agents that have common modes of action.

Absent data to the contrary, the default assumption is that the cumulative dose received over a lifetime, expressed as a lifetime average daily dose or lifetime average daily exposure, is an appropriate measure of dose or exposure. This assumes that a high dose of such an agent received over a shorter period of time is equivalent to a low dose spread over a lifetime. This is thought to be a relatively public-health-protective option and has some empirical support (Monro, 1992). A counter example, *i.e.*, effects of short-term, high exposure levels that result in subsequent cancer development, is treatment of cancer patients with certain chemotherapeutic agents. When sufficient information is available to support a different approach, it can be used. For example, short-term exposure estimates (several days to several months) may be more appropriate than the lifetime average daily dose. In these cases, both agent concentration and duration are likely to be important, because such effects may be reversible at cessation of very short-term exposures.

Appendix B: EPA's Guidance for Data Quality Assessment

U.S. EPA (U.S. Environmental Protection Agency). (2000d) Guidance for data quality assessment: practical methods for data analysis. Office of Environmental Information, Washington, DC. EPA/600/R–96/084. Available from: *http://www.epa.gov/quality/qs-docs/g9-final.pdf.*

References

Allen, BC; Crump, KS; Shipp, AM. (1988) Correlation between carcinogenic potency of chemicals in animals and humans. Risk Anal 8:531–544.

Ames, BN; Gold, LS. (1990) Too many rodent carcinogens: mitogenesis increases mutagenesis. Science 249:970–971.

Anderson, LM; Diwan, BA; Fear, NT; *et al.* (2000) Critical windows of exposure for children's health: cancer in human epidemiological studies and neoplasms in experimental animal models. Environ Health Perspect 108(Suppl 3):573–594.

Ashby, J; Tennant, RW. (1991) Definitive relationships among chemical structure, carcinogenicity and mutagenicity for 301 chemicals tested by the U.S. NTP. Mutat Res 257:229–306.

Ashby, J; Tennant, RW. (1994) Prediction of rodent carcinogenicity for 44 chemicals: results. Mutagenesis 9:7–15.

Ashby, J; Doerrer, NG; Flamm, FG; *et al.* (1990) A scheme for classifying carcinogens. Regul Toxicol Pharmacol 12:270–295.

Ashby, J; Brady, A; Elcombe, CR; *et al.* (1994) Mechanistically based human hazard assessment of peroxisome proliferator-induced hepatocarcinogenesis. Hum Exper Toxicol 13:1–117.

Barrett, JC. (1992) Mechanisms of action of known human carcinogens. In: Mechanisms of carcinogenesis in risk identification. IARC Sci Pubs No. 116, 115–134. International Agency for Research on Cancer, Lyon, France.

Barrett, JC. (1993) Mechanisms of multistep carcinogenesis and carcinogen risk assessment. Environ Health Perspect 100:9–20.

Barrett, JC; Lee, TC. (1992) Mechanisms of arsenic-induced gene amplification. In: Kellems, RE, ed. Gene amplification in mammalian cells: a comprehensive guide. New York: Marcel Dekker.

Baylin, S; Bestor, TH. (2002) Altered methylation patterns in cancer cell genomes: causes or consequence? Cancer Cell 1:299–305.

Bellamy, CO; Malcomson, RD; Harrison, DJ; *et al.* (1995) Cell death in health and disease: the biology and regulation of apoptosis. Seminars in Cancer Biology, Apoptosis in Oncogenesis and Chemotherapy 6:3–16.

Biggs, PJ; Warren, W; Venitt, S; *et al.* (1993) Does a genotoxic carcinogen contribute to human breast cancer? The value of mutational spectra in unraveling the etiology of cancer. Mutagenesis 8:275–283.

Birnbaum, LS; Fenton, SE. (2003) Cancer and developmental exposure to endocrine disruptors. Environ Health Perspect 111:389–394.

Birner, G; Albrecht, W; Neumann, HG. (1990) Biomonitoring of aromatic amines. III: hemoglobin binding and benzidine and some benzidine congeners. Arch Toxicol 64(2):97–102.

Blair, A; Burg, J; Foran, J; *et al.* (1995) Guidelines for application of meta-analysis in environmental epidemiology. Regul Toxicol Pharmacol 22:189–197.

Bois, FY; Krowech, G; Zeise, L. (1995) Modeling human interindividual variability in metabolism and risk: the example of 4-aminobiphenyl. Risk Anal 15:205–213.

Calabrese, EJ. (1986) Age and susceptibility to toxic substances. New York: Winter-Interscience Publication, John Wiley and Sons, Inc.

Callemen, CJ; Ehrenberg, L; Jansson, B; *et al.* (1978) Monitoring and risk assessment by means of alkyl groups in hemoglobin in persons occupationally exposed to ethylene oxide. J Environ Pathol Toxicol 2:427–442.

Caporaso, N; Hayes, RB; Dosemeci, M; *et al.* (1989) Lung cancer risk, occupational exposure, and the debrisoquine metabolic phenotype. Cancer Res 49:3675–3679.

Cavenee, WK; Koufos, A; Hansen, MF. (1986) Recessive mutant genes predisposing to human cancer. Mutat Res 168:3–14.

CDC (Centers for Disease Control and Prevention). (2004) The health consequences of smoking: a report of the surgeon general. Dept. of Health and Human Services, Washington, DC. Available from: *http://www.cdc.gov/tobacco/sgr/sgr_2004/index.htm.*

Chang, CC; Jone, C; Trosko, JE; *et al.* (1988) Effect of cholesterol epoxides on the inhibition of intercellular communication and on mutation induction in Chinese hamster V79 cells. Mutat Res 206:471–478.

Chuang, LS; Ng, HH; Chia, JN; Li, BF. (1996) Characterisation of independent DNA and multiple Zn-binding domains at the N terminus of human DNA-(cytosine-5)

methyltransferase: modulating the property of a DNA-binding domain by contiguous Zn-binding motifs. J Mol Biol 257(5):935–48.
Chen, C; Farland, W. (1991) Incorporating cell proliferation in quantitative cancer risk assessment: approaches, issues, and uncertainties. In: Butterworth, B., Slaga, T., Farland, W., *et al.*, eds. Chemical induced cell proliferation: implications for risk assessment. New York: Wiley-Liss, pp. 481–499.
Chhabra, RE; Huff, JE; Schwetz, BS; Selkirk, J. (1990) An overview of prechronic and chronic toxicity/carcinogenicity experimental study designs and criteria used by the National Toxicology Program. Environ. Health Perspect. 86:313–321.
Choy, WN. (1993) A review of the dose-response induction of DNA adducts by aflatoxin B_2 and its implications to quantitative cancer-risk assessment. Mutat Res 296:181–198.
Clayson, DB; Mehta, R; Iverson, F. (1994) Oxidative DNA damage—the effects of certain genotoxic and operationally non-genotoxic carcinogens. Mutat Res 317:25–42.
Cohen, SM. (1995) Role of urinary physiology and chemistry in bladder carcinogenesis. Fd Chem Toxicol 33:715–30.
Cohen, SW; Ellwein, LB. (1990) Cell proliferation in carcinogenesis. Science 249:1007–1011.
Cohen, SM; Ellwein, LB. (1991) Genetic errors, cell proliferation and carcinogenesis. Cancer Res 51:6493–6505.
Cohen, SM; Purtilo, DT; Ellwein, LB. (1991) Pivotal role of increased cell proliferation in human carcinogenesis. Mod Pathol 4:371–375.
Conolly, RB; Andersen, ME. (1991) Biologically based pharmacodynamic models: tools for toxicological research and risk assessment. Ann Rev Pharmacol Toxicol 31:503–523.
Contrera, JF; Matthews, EJ; Benz, RD. (2003) Predicting the carcinogenic potential of pharmaceuticals in rodents using molecular structural similarity and E-state indices. Regul. Toxicol. Pharmacol. 38:243–259.
Cresteil, T. (1998) Onset of xenobiotic metabolism in children: toxicological implications. Food Addit Contam 15, Supplement 45–51.
Dearfield, K. L.; Auletta, A. E.; Cimino, M. C., *et al.* (1991) Considerations in the U.S. Environmental Protection Agency's testing approach for mutagenicity. Mutat. Res. 258:259–283.
D'Souza, RW; Francis, WR; Bruce, RD; *et al.* (1987) Physiologically based pharmacokinetic model for ethylene chloride and its application in risk assessment. In: Pharmacokinetics in risk assessment: drinking water and health. Vol. 8. Washington, DC: National Academy Press.
Enterline, PE; Henderson, VL; Marsh, GM. (1987) Exposure to arsenic. Amer J Epidemiol 125:929–938.
Evans, JS; Gray, GM; Sielken, RL Jr; Smith, AE; Valdez-Flores, C; Graham, JD. (1994) Use of probabilistic expert judgment in uncertainty analysis of carcinogenic potency. Regul Toxicol Pharmacol. 2:15–36.
Executive Order 13045 (1997) Protection of children from environmental health risks and safety risks, issued April 21, 1997.
Fearon, E; Vogelstein, B. (1990) A genetic model for colorectal tumorigenesis. Cell 61:959–967.
Fenton, SE; Davis, CC. (2002) Atrazine exposure in utero increases dimethylbenz a anthracene-induced mammary tumor incidence in long evans offspring. Toxicol Sci 66(1–2):185. ''The Toxicologist, Abstracts of the 41st Annual Meeting of the Society of Toxicology.'' (Abstract 903)
Fisher, RA. (1950) Statistical methods for research workers. Edinburgh, Scotland: Oliver and Boyd.
Florig, HK; Morgan, MG; Morgan, KM; Jenni, KE; Fischhoff, B; Fischbeck, PS; DeKay, ML. (2001) A deliberative method for ranking risks (I): Overview and test bed development. Risk Anal. 21:913–21.
Flynn, GL. (1990) Physicochemical determinants of skin absorption. In: Gerrity, TR, Henry, CJ, eds. Principles of route to route extrapolation for risk assessment. New York: Elsevier Science; pp. 93–127.
Fos, PJ; McLin, CL. (1990) The risk of falling in the elderly: a subjective approach. Med Decis Making 10:195–200.
Garfinkel, L; Silverberg, E. (1991) Lung cancer and smoking trends in the United States over the past 25 years. Cancer 41:137–145.
Gaylor, DW; Zheng, Q. (1996) Risk assessment of nongenotoxic carcinogens based on cell proliferation/death rates in rodents. Risk Anal 16(2):221–225.
Gaylor, DW; Kodell, RL; Chen, JJ; *et al.* (1994) Point estimates of cancer risk at low doses. Risk Anal 14(5):843–850.
Gibson, DP; Aardema, MJ; Kerckaert, GA; *et al.* (1995) Detection of aneuploidy-inducing carcinogens in the Syrian hamster embryo (SHE) cell transformation assay. Mutat Res 343:7–24.
Ginsberg, GL. (2003) Assessing cancer risks from short-term exposures in children. Risk Anal 23(1):19–34.
Goddard, MJ; Murdoch, DJ; Krewski, D. (1995). Temporal aspects of risk characterization. Inhal Toxicol 7:1005–1018.
Goldsworthy, TL; Hanigan, MH; Pitot, HC. (1986) Models of hepatocarcinogenesis in the rat-contrasts and comparisons. CRC Crit Rev Toxicol 17:61–89.
Goodman, JI; Counts, JL. (1993) Hypomethylation of DNA: A possible nongenotoxic mechanism underlying the role of cell proliferation in carcinogenesis. Environ Health Perspect 101 Supp. 5:169–172.
Greenland, S. (1987) Quantitative methods in the review of epidemiologic literature. Epidemiol Rev 9:1–29.
Gulezian, D; Jacobson-Kram, D; McCullough, CB; *et al.* (2000) Use of transgenic animals for carcinogenicity testing: considerations and implications for risk assessment. Toxicol Pathol 28:482–499.
Hammand, EC. (1966) Smoking in relation to the death rates of one million men and women. In: Haenxzel, W, ed. Epidemiological approaches to the study of cancer and other chronic diseases. National Cancer Institute Monograph No. 19. Washington, DC.
Hanahan, D; Weinberg, RA. (2000) The hallmarks of cancer. Cell 100:57–70.
Harris, CC; Hollstein, M. (1993) Clinical implications of the p53 tumor suppressor gene. N Engl J Med 329:1318–1327.
Haseman, JK. (1983) Issues: a reexamination of false-positive rates for carcinogenesis studies. Fundam Appl Toxicol 3:334–339.
Haseman, JK. (1984) Statistical issues in the design, analysis and interpretation of animal carcinogenicity studies. Environ Health Perspect 58:385–392.
Haseman, JK. (1985) Issues in carcinogenicity testing: dose selection. Fundam Appl Toxicol 5:66–78.
Haseman, JK. (1990) Use of statistical decision rules for evaluating laboratory animal carcinogenicity studies. Fundam Appl Toxicol 14:637–648.
Haseman, JK. (1995) Data analysis: Statistical analysis and use of historical control data. Regul Toxicol Pharmacol 21:52–59.
Hatch, EE; Palmer, JR; Titus-Ernstoff, L; Noller, KL *et al.* (1998) Cancer risk in women exposed to diethylstilbestrol in utero. JAMA 280:630–634.
Hattis, D. (1990) Pharmacokinetic principles for dose-rate extrapolation of carcinogenic risk from genetically active agents. Risk Anal 10:303–316.
Hawkins, NC; Evans, JS. (1989) Subjective estimation of toluene exposures: a calibration study of industrial hygienists, Applied Industrial Hygiene, 4:61–68.
Hawkins, NC; Graham, JD. (1988) Expert scientific judgment and cancer risk assessment: a pilot study of pharmacokinetic data, Risk Anal. 8:615–25.
Hayward, JJ; Shane, BS; Tindall, KR; *et al.* (1995) Differential in vivo mutagenicity of the carcinogen-noncarcinogen pair 2,4- and 2,6-diaminotoluene. Carcinogenesis 10:2429–2433.
Heddle, JA; Swiger, RR. (1996) Risk estimation from somatic mutation assays. Mutat Res 365(1–3):107–17.
Herbst, AL, Ulfelder, H, Poskanzer, DC. (1971) Adenocarcinoma of the vagina: association of maternal stilbestrol therapy with tumor appearance in young women. N Engl J Med 284:878–881.
Hill, AB. (1965) The environment and disease: association or causation? Proc R Soc Med 58:295–300.
Hoel, DG; Kaplan, NL; Anderson, MW. (1983) Implication of nonlinear kinetics on risk estimation in carcinogenesis. Science 219:1032–1037.
Holliday, R. (1987) DNA methylation and epigenetic defects in carcinogenesis. Mutat Res 181:215–217.
Holladay SD, Smialowicz RJ. 2000. Development of the murine and human immune system: differential effects of immunotoxicants depend on time of exposure. Environ Health Perspect 108

Suppl 3:463–473.
Holsapple MP, West LJ, Landreth KS. 2003. Species comparison of anatomical and functional immune system development. Birth Defects Res B Dev Reprod Toxicol 68(4):321–334.
Huff, JE. (1993) Chemicals and cancer in humans: first evidence in experimental animals. Environ Health Perspect 100:201–210.
Huff, JE. (1994) Chemicals causally associated with cancers in humans and laboratory animals. A perfect concordance. In: Carcinogenesis. Waalkes, MP, Ward, JM, eds., New York: Raven Press; pp. 25–37.
Huff J, Cirvello J, Haseman J, Bucher J (1991) Chemicals associated with site-specific neoplasia in 1394 long-term carcinogenesis experiments in laboratory rodents. Environ Health Perspect 93:247–70. Erratum in: Environ Health Perspect 1991 Nov; 95:213.
Hulka, BS; Margolin, BH. (1992) Methodological issues in epidemiologic studies using biological markers. Am J Epidemiol 135:122–129.
IARC (International Agency for Research on Cancer). (1994) IARC monographs on the evaluation of carcinogenic risks to humans. Vol. 60. Some industrial chemicals. Lyon, France: IARC; pp. 13–33.
IARC. (International Agency for Research on Cancer) (1999) The use of short- and medium-term tests for carcinogens and data on genetic effects in carcinogenic hazard evaluation. Lyon, France.
IEc (Industrial Economics, Incorporated). 2004. ''An Expert Judgment Study of the Concentration-Response Relationship Between PM2.5 Exposure and Mortality,'' Available at: *http://www.epa.gov/ttn/ecas/benefits.html.*
ILSI (International Life Sciences Institute). (1992) Similarities and differences between children and adults; implications for risk assessment. Washington, DC: ILSI Press.
ILSI (International Life Sciences Institute). (1997) Principles for the selection of doses in chronic rodent bioassays. Foran, JA, ed. Washington, DC: ILSI Press.
ILSI (International Life Sciences Institute). (2001) Proceedings of workshop on the evaluation of alternative methods for carcinogenesis testing. Toxicol Pathol 29:1–351.
IPCS (International Programme on Chemical Safety). (1999) IPCS workshop on developing a conceptual framework for cancer risk assessment, February 16–18, 1999, Lyon, France. IPCS/99.6. World Health Organization, Geneva.
Ito, N; Shirai, T; Hasegawa, R. (1992) Medium-term bioassays for carcinogens. In: Vainio, H, Magee, PN, McGregor, DB, *et al.*, eds. Mechanisms of carcinogenesis in risk identifications. International Agency for Research on Cancer, Lyon, France; pp. 353–388.
Jelovsek, FR; Mattison, DR; Young, JF. (1990) Eliciting principles of hazard identification from experts. Teratology 42:521–533.
Jones, PA. (1986) DNA methylation and cancer. Cancer Res 46:461–466.
Kehrer, JP. (1993) Free radicals as mediators of tissue injury and disease. Crit Rev Toxicol 23:21–48.
Kelsey, JL; Whittemore, AS; Evans, AS; Thompson, WD. (1996) Methods in observational epidemiology. New York: Oxford University Press.
Kimbell, JS; Subramaniam, RP; Gross, EA; Schlosser, PM; Morgan, KT. (2001) Dosimetry modeling of inhaled formaldehyde: comparisons of local flux predictions in the rat, monkey and human nasal passages. Toxicol Sci 64(1):100–110.
Kinzler, KW; Vogelstein, B. (2002) Colorectal tumors. In: Vogelstein, B; Kinzler, KW, eds. The genetic basis of human cancer. New York: McGraw-Hill.
Kinzler, KW; Nilbert, MC; Su, L–K; *et al.* (1991) Identification of FAP locus genes from chromosome 5q21. Science 253:661–665.
Kraus, AL; Munro, IC; Orr, JC; *et al.* (1995) Benzoyl peroxide: an integrated human safety assessment for carcinogenicity. Regul Toxicol Pharmacol 21:87–107.
Krewski, D; Van Ryzin, J. (1981) Dose response models for quantal response toxicity data. In: Csorgo; Dawson; Rao; *et al.*, eds. Statistics and related topics. Amsterdam: North-Holland, pp. 201–231.
Krewski, D; Murdoch, DJ; Withey, JR. (1987) The application of pharmacokinetic data in carcinogenic risk assessment. In: Pharmacokinetics in risk assessment: drinking water and health. Vol. 8. Washington, DC: National Academy Press; pp. 441–468.
La, DK; Swenberg, JA. (1996) DNA adducts: biological markers of exposure and potential applications to risk assessment. Mutat Res 365(1–3):129–46.
Levine, AJ; Perry, ME; Chang, A; *et al.* (1994) The 1993 Walter Hubert lecture: the role of the p53 tumor-suppressor gene in tumorigenesis. Br J Cancer 69:409–416.
Lijinsky, W. (1993) Species differences in carcinogenesis. In Vivo 7:65–72.
Lilienfeld, AM; Lilienfeld, D. (1979) Foundations of epidemiology, 2nd ed. New York: Oxford University Press.
Littlefield, NA; Farmer, JH; Gaylor, DW. (1980) ED01 study. J Environ Pathol Toxicol 3:17.
Maltoni, C; Lefemine, G; Ciliberti, A; *et al.* (1981) Carcinogenicity bioassay of vinyl chloride monomer: a model of risk assessment on an experimental basis. Environ Health Perspect 41:3–29.
Maronpot, RR; Shimkin, MB; Witschi, HP; *et al.* (1986) Strain A mouse pulmonary tumor test results for chemicals previously tested in National Cancer Institute carcinogenicity test. J Natl Cancer Inst 76:1101–1112.
Marsman, DS; Popp, JA. (1994) Biological potential of basophilic hepatocellular foci and hepatic adenoma induced by the peroxisome proliferator, Wy-14,643. Carcinogenesis 15:111–117.
Mausner, JS; Kramer, S. (1985) Epidemiology, 2nd ed. Philadelphia: W.B. Saunders.
McConnell, EE. (1992) Comparative response in carcinogenesis bioassay as a function of age at first exposure. In: Guzelian, P; Henry, CJ; Olin, SS, eds. Similarities and difference between children and adults: implications for risk assessment. Washington, DC: ILSI Press; pp. 66–78.
McConnell, EE; Solleveld, HA; Swenberg, JA; *et al.* (1986) Guidelines for combining neoplasms for evaluation of rodent carcinogenesis studies. J Natl Cancer Inst 76:283–289.
Meek, ME; Bucher, JR; Chohen, SM; Dellarco, V; Hill, RN; Lehman-McKeeman, LD; Longfellow, DG; Pastoor, T; Seed, J.; and Patton, DE. (2003) A framework for humand relevance analysis of information on carcinogenic modes of action. Crit Rev Toxicol 33:591–653.
Melnick, RL, Huff, JE, Barrett, JC, Maronpot, RR, Lucier, G, Portier, CJ. (1993) Cell proliferation and chemical carcinogenesis: A symposium overview. Mol Carcinog 7:135–138.
Miller, RW. (1995) Special susceptibility of the child to certain radiation-induced cancers. Environ Health Perspect 103(suppl 6):41–44.
Miller, MD; Marty, MA; Arcus, A; *et al.* (2002) Differences between children and adults: implications for risk assessment at California EPA. Int J Toxicol 21:403–418.
Monro, A. (1992) What is an appropriate measure of exposure when testing drugs for carcinogenicity in rodents? Toxicol Appl Pharmacol 112:171–181.
Moolgavkar, SH. (1986) Carcinogenesis Modelin: From Molecular Biology to Epidemiology. Am Rev Public Health 7:151–169.
Moolgavkar, SH; Knudson, AG. (1981) Mutation and cancer: a model for human carcinogenesis. J Natl Cancer Inst 66:1037–1052.
Morgan, KM; DeKay, ML; Fischbeck, PS; Morgan, MG; Fischhoff, B; Florig, HK. (2001) A deliberative method for ranking risks (II): Evaluation of validity and agreement among risk managers. Risk Anal. 21:923–37.
Morrison, V; Ashby, J. (1994) A preliminary evaluation of the performance of the muta™ mouse (lacZ) and Big Blue™ (lacI) transgenic mouse mutation assays. Mutagenesis 9:367–375.
Murdoch, DJ; Krewski, D; Wargo, J. (1992) Cancer risk assessment with intermittent exposure. Risk Anal 12(4):569–577.
Murrell, JA; Portier, CJ; Morris, RW. (1998) Characterizing dose-response I: critical assessment of the benchmark dose concept. Risk Anal 18(1):13–25.
NRC (National Research Council). (1983) Risk assessment in the federal government: managing the process. Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences, NRC. Washington, DC: National Academy Press.
NRC (National Research Council). (1990) Health effects of exposure to low levels of ionizing radiation (BEIR V). Washington, DC: National Academy Press.
NRC (National Research Council). (1993a) Issues in risk assessment. Committee on Risk Assessment Methodology.

Washington, DC: National Academy Press.
NRC (National Research Council). (1993b) Pesticides in the diets of infants and children. Washington, DC: National Academy Press.
NRC (National Research Council). (1994) Science and judgment in risk assessment. Washington, DC: National Academy Press.
NRC (National Research Council). (1996) Understanding risk: informing decisions in a democratic society. Washington, DC: National Academy Press.
NRC (National Research Council). (2002) Estimating the public health benefits of proposed air pollution regulations. Washington, DC: National Academy Press.
NTP (National Toxicology Program). (1984) Report of the ad hoc panel on chemical carcinogenesis testing and evaluation of the National Toxicology Program, Board of Scientific Counselors. Washington, DC: U.S. Government Printing Office. 1984–421–132:4726.
Nichols, AL; Zeckhauser, RJ. (1986). The dangers of caution: Conservatism in the assessment and the mismanagement of risk. In: Smith, VK, ed., Advances in Applied Micro-Economics: Risk, Uncertainty, and the Valuation of Benefits and Costs, Vol. 4, Greenwich, Conn.: JAI Press, pp. 55–82.
North, DW ; Merkhofer, MW. (1976). A methodology for analyzing emission control strategies. Comput Oper Res 3:187–207.
OECD (Organization for Economic Cooperation and Development). (1981) Guidelines for testing of chemicals. Carcinogenicity studies. No. 451. Paris, France.
OMB (Office of Management and Budget). (2002) Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies. **Federal Register** 67(36):8451–8460. Available from: *http://www.epa.gov/oei/qualityguidelines/fr22fe02–117.htm.*
OMB (Office of Management and Budget). (2003) Circular A–4: Regulatory Analysis. September 17. Available from: *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.*
OMB (Office of Management and Budget). (2004) Revised information quality bulletin for peer review. April 15. Available from: *http://www.whitehouse.gov/omb/inforeg/peer_review041404.pdf.*
OSTP (Office of Science and Technology Policy). (1985) Chemical carcinogens: review of the science and its associated principles. **Federal Register** 50:10372–10442.
Peltoṁaki, P; Aaltonen, LA; Sisonen, P; *et al.* (1993) Genetic mapping of a locus predisposing human colorectal cancer. Science 260:810–812.
Peto, J. (1992) Meta-analysis of epidemiological studies of carcinogenesis. In: Mechanisms of carcinogenesis in risk assessment. IARC Sci. Pubs. No. 116, Lyon, France; pp. 571–577.
Peto, J; Darby, S. (1994) Radon risk reassessed. Nature 368:97–98.
Peto, R; Gray, R; Brantom, P; *et al.* (1984) Nitrosamine carcinogenesis in 5120 rodents: chronic administration of sixteen different concentrations of NDEA, NDMA, NPYR and NPIP in the water of 4440 inbred rats, with parallel studies on NDEA alone of the effect of age of starting (3,6, or 20 weeks) and of species (rats, mice or hamsters). IARC Sci Publ 57:627–665.
Pinkerton, KE; Joad, J. (2000) The mammalian respiratory system and critical windows of exposure for children's health. Environ Health Perspect 108(suppl):457–462.
Portier, C. (1987) Statistical properties of a two-stage model of carcinogenesis. Environ Health Perspect 76:125–131.
Putzrath, RM; Ginevan, ME (1991) Meta-analysis: Methods for combining data to improve quantitative risk assessment. Regul Toxicol Pharmacol 14:178–188.
Rall, DP. (1991) Carcinogens and human health: part 2. Science 251:10–11.
Renn, O. (1999) Model for an analytic-deliberative process in risk management. Environ Sci Technol 33:3049–3055.
Renwick, AG. (1998) Toxicokinetics in infants and children in relation to the ADI and TDI. Food Addit Contam 15, Suppl 17–35.
Rice, JM. (1979) Problems and perspective in perinatal carcinogenesis: a summary of the conference. NCI Monogr 51:271–278.
Richard, AM. (1998a) Structure-based methods for predicting mutagenicity and carcinogenicity: are we there yet? Mutat Res 400:493–507.
Richard, AM, (1998b) Commercial toxicology prediction systems: A regulatory perspective. Toxicol. Lett. 102–103:611–616.
Richard, AM; Williams, CR. (2002) Distributed structure-searchable toxicity (DSSTox) public database network: a proposal: Mutat. Res. 499:27–52.
Richmond, HM. (1981). A framework for assessment of health risks associated with national ambient air quality standards. Environ Prof 3:225–234.
Rothman, KJ; Greenland, S. (1998) Modern Epidemiology. Philadelphia: Lippincott Williams and Wilkins Publishers.
Rouse, J; Jackson, SP. (2002) Interfaces between the detection, signaling, and repair of DNA damage. Science 297:547–551.
Samet, JM; Schnatter, R; Gibb, H. (1998) Invited Commentary: Epidemiology and risk assessment. Am J Epidemiol 148:929–936.
Scheuplein, R; Charnley, G; Dourson, M. (2002) Differential sensitivity of children and adults to chemical toxicity. I: biological basis. Regul Toxicol Pharmacol 35:429–447.
SAB (Science Advisory Board). (1997) An SAB report: guidelines for cancer risk assessment. Washington DC: U.S. Environmental Protection Agency, September. EPA–SAB–EHC–97–010. Available from: *http://www.epa.gov/sab/pdf/ehc9710.pdf.*
Shelby, MD; Zeiger, E. (1990) Activity of human carcinogens in the *Salmonella* and rodent bone-marrow cytogenetics tests. Mutat Res 234:257–261.
Silberstein, GB. (2001) Tumour-stromal interactions: role of the stroma in mammary development. Breast Cancer Res 3:218–223.
Slikker W, 3rd, Mei N, Chen T. 2004. N-ethyl-N-nitrosourea (ENU) increased brain mutations in prenatal and neonatal mice but not in the adults. Toxicol Sci 81(1):112–120. Sisk, SC; Pluta, LJ; Bond, JA; *et al.* (1994) Molecular analysis of lacI mutants from bone marrow of B6C3F1 transgenic mice following inhalation exposure to 1,3-butadiene. Carcinogenesis 15(3):471–477.
Snedecor, GW; Cochran, WG. (1967) Statistical methods, 6th ed. Ames, Iowa: Iowa State University Press.
Sonich-Mullin, C; Fielder, R; Wiltse, J; Baetcke, K; Dempsey. K; Fenner-Crisp, P; Grant, D; Hartley, M; Knaap, A; Kroese, D; Mangelsdorf, I; Meek, E; Rice, JM; and Yones, M. (2001) IPCS conceptual framework for evaluating a mode of action for chemical carcinogenesis. Regul Toxicol Phamacol 34:146–152.
Spalding, JW; French, JE; Stasiewicz, S; Furedi-Machacek, M; Conner, F; Tice, RR; Tennant, RW. (2000) Responses of transgenic mouse lines p53(+/−) and Tg.AC to agents tested in conventional carcinogenicity bioassays. Toxicol Sci 53(2)213–223.
Stiber, NA; Pantazidou, M; Small, MJ. (1999) Expert system methodology for evaluating reductive dechlorination at TCE sites. Environ Sci Technol 33:3012–3020.
Stiteler, WH; Knauf, LA; Hertzberg, RC; *et al.* (1993) A statistical test of compatibility of data sets to a common dose-response model. Regul Toxicol Pharmacol 18:392–402.
Subramaniam, RP; Asgharian, B; Freijer, JI; Miller, FJ; Anjilvel, S. (2003) Analysis of differences in particle deposition in the human lung. Inhal Toxicol 15:1–21.
Swierenga, SHH; Yamasaki, H. (1992) Performance of tests for cell transformation and gap junction intercellular communication for detecting nongenotoxic carcinogenic activity. In: Mechanisms of carcinogenesis in risk identification. IARC Sci. Pubs. No. 116, Lyon, France; pp. 165–193.
Szklo, M; Nieto, FJ. (2000): Epidemiology Beyond the Basics. Gaithersburg, MD: Aspen Publishers, Inc.
Tarone, RE. (1982) The use of historical control information in testing for a trend in proportions. Biometrics 38:215–220.
Taylor, JH; Watson, MA; Devereux, TR; *et al.* (1994) p53 mutation hotspot in radon-associated lung cancer. Lancet 343:86–87.
Tennant, RW. (1993) Stratification of rodent carcinogenicity bioassay results to reflect relative human hazard. Mutat Res 286:111–118.
Tennant, RW; French, JE; Spalding, JW. (1995) Identifying chemical carcinogens and assessing potential risk in short-term

bioassays using transgenic mouse models. Environ Health Perspect 103:942–950.

Tennant, RW; Stasiewicz, S; Mennear, J; *et al.* (1999) Genetically altered mouse models for identifying carcinogens. In: McGregor, DB; Rice, JM; Venitt, S, eds. The use of short- and medium-term tests for carcinogens and data on genetic effects in carcinogenic hazard evaluation. Lyon, France: International Agency for Research on Cancer.

Tinwell, H; Ashby, J. (1991) Activity of the human carcinogen MeCCNU in the mouse bone marrow mironucleus test. Environ Molec Mutagen 17:152–154.

Todd, GC. (1986) Induction of reversibility of thyroid proliferative changes in rats given an antithyroid compound. Vet Pathol 23:110–117.

Tomatis, L; Aitio, A; Wilbourn, J; *et al.* (1989) Human carcinogens so far identified. Jpn J Cancer Res 80:795–807.

Tucker, JD; Preston, RJ. (1996) Chromosome aberrations, micronuclei, aneuploidy, sister chromatid exchanges, and cancer risk assessment. Mutat Res 365(1–3):147–59. Review.

U.S. EPA (U.S. Environmental Protection Agency). (1986a) Guidelines for carcinogen risk assessment. **Federal Register** 51(185):33992–34003. Available from: *http://www.epa.gov/ncea/raf/*.

U.S. EPA (U.S. Environmental Protection Agency). (1986b) Guidelines for mutagenicity risk assessment. **Federal Register** 51(185):34006–34012. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=23160*.

U.S. EPA (U.S. Environmental Protection Agency). (1989) Summary of the second workshop carcinogenesis bioassay with the dermal route. May 18–19, 1988, Research Triangle Park, NC. EPA/560/6–89/003. Available from NTIS, Springfield, VA 22161.

U.S. EPA (U.S. Environmental Protection Agency). (1991a) Guidelines for developmental toxicity risk assessment. **Federal Register** 56(234):63798–63826. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=23162*.

U.S. EPA (U.S. Environmental Protection Agency). (1991b) Alpha-2u-globulin: association with chemically induced renal toxicity and neoplasia in the male rat. Risk Assessment Forum, Washington, DC. EPA/625/3–91/019F.

U.S. EPA (U.S. Environmental Protection Agency). (1992a) Guidelines for exposure assessment. **Federal Register** 57(104):22888–22938. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=15263*.

U.S. EPA (U.S. Environmental Protection Agency). (1992b) Draft report: a cross-species scaling factor for carcinogen risk assessment based on equivalence of mg/kg¾/day. **Federal Register** 57(109):24152–24173.

U.S. EPA (U.S. Environmental Protection Agency). (1994) Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Research Triangle Park, NC. EPA/600/8–90/066F.

U.S. EPA (U.S. Environmental Protection Agency). (1995) Policy for risk characterization. Memorandum of Carol M. Browner, Administrator, March 21, 1995, Washington, DC. Available from: *http://www.epa.gov/osp/spc/2riskchr.htm*.

U.S. EPA (U.S. Environmental Protection Agency). (1996a) Guidelines for reproductive toxicity risk assessment. **Federal Register** 61(212):56274–56322. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=2838*.

U.S. EPA (U.S. Environmental Protection Agency). (1996b) Comparison of the effects of chemicals with combined perinatal and adult exposure vs. Adult only exposure in carcinogenesis studies. Office of Pesticide Programs. Washington, DC.

U.S. EPA (U.S. Environmental Protection Agency). (1997a) A proposed OPP policy on determining the need for perinatal carcinogenicity testing on a pesticide. Office of Pesticide Programs. Washington, DC.

U.S. EPA (U.S. Environmental Protection Agency). (1997b) A set of scientific issues being considered by the Agency in connection with the criteria for requiring in-utero cancer studies. Office of Pesticide Programs. FIFRA Scientific Advisory Panel. September 1997 meeting report. Available from: *http://www.epa.gov/pesticides/SAP/archive/september/finalsep.htm*.

U.S. EPA (U.S. Environmental Protection Agency). (1997c) Exposure factors handbook. National Center for Environmental Assessment, Washington, DC. EPA/600/P–95/002F. Available from: *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12464*.

U.S. EPA (U.S. Environmental Protection Agency). (1997d) Policy for use of probabilistic analysis in risk assessment. Memorandum of Fred Hansen, Deputy Administrator, May 15, 1997. Available from: *http://www.epa.gov/osp/spc/probpol.htm*.

U.S. EPA (U.S. Environmental Protection Agency). (1997e) Guiding principles for Monte Carlo analysis. Risk Assessment Forum, Washington, DC. EPA/630/R–97/001. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=29596*.

U.S. EPA (U.S. Environmental Protection Agency). (1998a) Assessment of thyroid follicular cell tumors. Risk Assessment Forum, Washington, DC. EPA/630/R–97/002. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=13102*.

U.S. EPA (U.S. Environmental Protection Agency). (1998b) Guidelines for neurotoxicity risk assessment. **Federal Register** 63(93):26926–26954. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=12479*.

U.S. EPA (U.S. Environmental Protection Agency). (1998c) Health effects test guidelines: OPPTS 870.4300 combined chronic toxicity/carcinogenicity. Office of Prevention, Pesticides and Toxic Substances, Washington, DC. EPA/712/C–98/212. Available from: *http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/*.

U.S. EPA (U.S. Environmental Protection Agency). (1998d) EPA's rule writer's guide to Executive Order 13045. Available from: *http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_regulate.htm*.

U.S. EPA (U.S. Environmental Protection Agency). (1999a) Guidelines for carcinogen risk assessment (review draft). Risk Assessment Forum, Washington, DC. NCEA–F–0644. Available from: *http://www.epa.gov/ncea/raf/cancer.htm*.

U.S. EPA (U.S. Environmental Protection Agency). (1999b) Review of revised sections of the proposed guidelines for carcinogen risk assessment. Science Advisory Board, Washington, DC. EPA/SAB/EC–99/015. Available from: *http://www.epa.gov/ncea/raf/cancer.htm*.

U.S. EPA (U.S. Environmental Protection Agency). (1999c) Cancer risk coefficients for environmental exposure to radionuclides: Federal guidance report no. 13. Office of Air and Radiation. EPA/402/R–99/001. Available from: *http://www.epa.gov/radiation/federal*.

U.S. EPA (U.S. Environmental Protection Agency). (2000a) Science Policy Council handbook: peer review. Office of Research and Development, Office of Science Policy, Washington, DC. EPA/100/B–98/001. Available from: *http://www.epa.gov/osp/spc/prhandbk.pdf*.

U.S. EPA (U.S. Environmental Protection Agency). (2000b) U.S. EPA. Science Policy Council handbook: risk characterization. EPA Science Policy Council, Washington, DC. EPA/100/B–00/002. Available from: *http://www.epa.gov/osp/spc/rchandbk.pdf*.

U.S. EPA (U.S. Environmental Protection Agency). (2000c) Supplementary guidance for conducting health risk assessments of chemical mixtures. Risk Assessment Forum, Washington, DC. EPA/630/R–00/002. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=20533*.

U.S. EPA (U.S. Environmental Protection Agency). (2000d) Guidance for data quality assessment: practical methods for data analysis. Office of Environmental Information, Washington, DC. EPA/600/R–96/084. Available from: *http://www.epa.gov/quality/qs-docs/g9-final.pdf*.

U.S. EPA (U.S. Environmental Protection Agency). (2000e) EPA quality manual for environmental programs 5360 A1. Available from: *http://www.epa.gov/quality/qs-docs/5360.pdf*.

U.S. EPA (U.S. Environmental Protection Agency). (2001a) Health effects test guidelines. Combined chronic toxicity/carcinogenicty testing of respirable fibrous particles. OPPTS 870.8355. Available from: *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

U.S. EPA (U.S. Environmental Protection Agency). (2001b) Notice of opportunity to provide additional information and comment. FR 66:59593–59594. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55868.*

U.S. EPA (U.S. Environmental Protection Agency). (2002a) Guidelines for ensuring and maximizing the quality, objectivity, utility and integrity for information disseminated by the Environmental Protection Agency. Office of Environmental Information, Washington, DC. EPA/260/R–02/008. Available from: *http://www.epa.gov/oei/qualityguidelines/index.html.*

U.S. EPA (U.S. Environmental Protection Agency). (2002b) A review of the reference dose and reference concentration process. Risk Assessment Forum, Washington, DC. EPA/630/P–02/002F. Available from: *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55365.*

U.S. EPA (U.S. Environmental Protection Agency). (2002c) Workshop on the benefits of reductions in exposure to hazardous air pollutants: developing best estimates of dose-response functions. Science Advisory Board, Washington, DC. EPA/SAB–EC/WKSHP/02/001. Available from: *http://www.epa.gov/science1/fiscal02.htm.*

U.S. EPA (U.S. Environmental Protection Agency). (2002d) Child-specific exposure factors handbook (interim report). EPA/600/P–00/002B. Office of Research and Development, National Center for Environmental Assessment, Washington, DC, 448 pp. Available from: *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55145.*

U.S. EPA (U.S. Environmental Protection Agency). (2003) A summary of general assessment factors for evaluating the quality of scientific and technical information. Science Policy Council, Washington, DC. EPA 100/B–03/001. Available from: *http://www.epa.gov/osa/spc/htm/assess2.pdf.*

U.S. EPA (U.S. Environmental Protection Agency). (2004). Final Regulatory Analysis: Control of Emissions from Nonroad Diesel Engines. Prepared by U.S. EPA, Office of Transportation and Air Quality, Washington, DC, May; EPA report no. EPA420–R–04–007. See chapter 9 and Appendix B. Available from: *http://www.epa.gov/nonroad-diesel/2004fr.htm#ria.*

U.S. EPA (U.S. Environmental Protection Agency). (2005) Supplemental guidance for assessing cancer susceptibility from early-life exposure to carcinogens. Risk Assessment Forum, Washington, DC. Available from: *http://www.epa.gov/ncea/raf.*

Vainio, H; Magee, P; McGregor, D; *et al.* (1992) Mechanisms of carcinogenesis in risk identification. IARC Sci. Pubs. No. 116. Lyon, France: IARC.

Van Der Fels-Klerx, IHJ; Goossens, LHJ; Saatkamp, HW; Horst, SHS. (2002) Elicitation of quantitative data from a heterogeneous expert panel: formal process and application in animal health. Risk Anal.22:67–81.

Van Sittert, NJ; De Jong, G; Clare, MG; *et al.* (1985) Cytogenetic, immunological, and hematological effects in workers in an ethylene oxide manufacturing plant. Br J Indust Med 42:19–26.

Vater, ST; McGinnis, PM; Schoeny, RS; *et al.* (1993) Biological considerations for combining carcinogenicity data for quantitative risk assessment. Regul. Toxicol Pharmacol 18:403–418.

Vesselinovitch, SD; Rao, KVN; Mihailovich, N. (1979) Neoplastic response of mouse tissues during perinatal age periods and its significance in chemical carcinogenesis. NCI Monogr 51:239.

Vogelstein, B; Fearon, ER; Hamilton, SR; *et al.* (1988) Genetic alterations during colorectal-tumor development. N Eng J Med 319:525–532.

Walker, KD; MacIntosh, D; Evans, JS. (2001) Use of expert judgment in exposure assessment. Part I. Characterization of personal exposure to benzene. J Exposure Environ Epidemiol 11:308–322.

Walker, KD; Catalano, P; Hammitt, JK; Evans, JS. (2003) Use of expert judgment in exposure assessment: part 2. Calibration of expert judgments about personal exposures to benzene. J Expo Anal Environ Epidemiol. 13:1–16.

Waters, MD; Stack, H; F. Jackson, MA. (1999) Short-term tests for defining mutagenic carcinogens. In: McGregor, DB; Rice, JM; Venitt, S, eds. The use of short term tests for carcinogens and data on genetic effects in carcinogenic hazard evaluation. Lyon, France: International Agency for Research on Cancer. IARC Sci. Publ. No. 146, pp.499–536.

Whitfield, RG; Wallsten, TS. (1989). A risk assessment for selected lead-induced health effects: an example of a general methodology. Risk Anal. 9:197–208.

Whysner, J; Williams, GM. (1996) Saccharin mechanistic data and risk assessment: urine composition, enhanced cell proliferation, and tumor promotion. Pharmacol Ther 71:225:252.

Willis, HH; DeKay, ML; Morgan, MG; Florig, HK; Fischbeck, PS. (2004) Ecological risk ranking: development and evaluation of a method for improving public participation in environmental decision making, Risk Anal. 24:363–78.

Winkler, RL; Wallsten, TS; Whitfield, RG; Richmond, HM; Rosenbaum, AS. (1995). An assessment of the risk of chronic lung injury attributable to long-term ozone exposure. Operations Research 43:19–28.

Woo, YT; Arcos, JC. (1989) Role of structure-activity relationship analysis in evaluation of pesticides for potential carcinogenicity. In: Ragsdale, NN; Menzer, RE, eds. Carcinogenicity and pesticides: principles, issues, and relationship. ACS Symposium Series No. 414. San Diego: Academic Press; pp. 175–200.

Yamasaki, H. (1995) Non-genotoxic mechanisms of carcinogenesis: Studies of cell transformation and gap junctional intercellular communication. Toxicol Lett 77:55–61.

Zeckhauser, RJ; Viscusi, WK. (1990). Risk Within Reason, Science 248:559–564.

[FR Doc. 05–6642 Filed 4–6–05; 8:45 am]

BILLING CODE 6560–50–C

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7895–1]

Notice of Availability of the Document Entitled Supplemental Guidance for Assessing Susceptibility From Early-Life Exposure to Carcinogens

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of availability of final document.

SUMMARY: This Notice announces the availability of the final document entitled *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, hereafter referred to as Supplemental Guidance.

DATES: The Supplemental Guidance is available for use by EPA risk assessors as of March 29, 2005.

ADDRESSES: The Supplemental Guidance document is available electronically through the EPA Web site at *http://www.epa.gov/cancerguidelines*. A limited number of paper and CDROM copies will be available from the EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: (800) 490–9198 or (513) 489–8190; facsimile: (513) 489–8695. Please provide your name, mailing address, the title and the EPA number of the requested publication (EPA/630/R–03/003F). Additionally, copies of the Supplemental Guidance will be available for inspection at EPA headquarters and regional libraries, through the U.S. Government Depository Library program.

FOR FURTHER INFORMATION CONTACT: Dr. William P. Wood, Risk Assessment Forum, National Center for Environmental Assessment (8601D), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: (202) 564–3361; facsimile: (202) 565–0062; or e-mail: *risk.forum@epa.gov*.

SUPPLEMENTARY INFORMATION:

Background

In another notice in today's **Federal Register**, EPA has announced the availability of final *Guidelines for Carcinogen Risk Assessment* (EPA/630/P–03/001F), hereafter referred to as the Guidelines. The background and scope of the Guidelines are explained in that notice. The Guidelines explicitly call for

consideration of possible sensitive subpopulations and/or lifestages (such as childhood). The consideration of childhood risks in the final Guidelines has been augmented by the development of the Supplemental Guidance document announced in this Notice. The Supplemental Guidance is issued separately from the Guidelines so that it may be more easily updated in a timely manner given the expected rapid evolution of scientific understanding about the effects of early-life exposures.

A draft of the Supplemental Guidance was subjected to public comment and was peer reviewed by the Agency's Science Advisory Board (SAB) in May 2003. In response to one of the SAB's recommendations EPA developed additional analyses of the available data. This analysis is included in the Supplemental Guidance and has been accepted for publication in the National Institute of Environmental Health Sciences journal, *Environmental Health Perspectives*. A separate peer review of the analysis also was conducted earlier in 2005.

Scope of the Supplement

The Supplemental Guidance recommends consideration of all studies on the effects of early-life exposures. For the common case where there are no early-life studies on a potential carcinogen, the Guidelines suggest consideration of the carcinogen's mode of action. The Supplemental Guidance addresses a number of issues pertaining to cancer risks associated with early-life exposures generally, but provides specific guidance on suggested actions only for carcinogens acting through a mutagenic mode of action. The Supplemental Guidance addresses carcinogens with a mutagenic mode of action because the currently available early-life studies are generally for carcinogens with a mutagenic mode of action. This Supplemental Guidance recommends for such agents, a default approach using estimates from chronic studies (*i.e.*, cancer slope factors) with appropriate modifications to address the potential for differential risk of early-lifestage exposure. As new research leads to more conclusive evidence, EPA intends to update this Supplemental Guidance to address other modes of action. The Agency expects to produce additional guidance documents for other modes of action, as data from new research and toxicity testing indicate it is warranted. EPA intends to focus its research, and work collaboratively with its federal partners, to improve understanding of the implications of early life exposure to carcinogens.

EPA intends to use, to the extent practicable and consistent with Agency statutes and regulations, the best available science in its risk assessments and regulatory actions, and this Supplemental Guidance is not intended to provide any substantive or procedural obstacle in achieving that goal. Therefore, the Supplemental Guidance has no binding effect on EPA or on any regulated entity. EPA expects its risk assessments to reflect emerging science even if the Supplemental Guidance has not been updated to reflect it. EPA intends to use the approaches in the Supplemental Guidance to develop risk assessments, when EPA has determined the approaches are suitable and appropriate. Thus, EPA is not establishing any substantive, binding ''rules'' under the Administrative Procedure Act or any other law in publishing this Supplemental Guidance, but is issuing the Supplemental Guidance as a non-binding statement of policy.

Dated: March 29, 2005.

Stephen L. Johnson,

Acting Administrator.

[FR Doc. 05–6641 Filed 4–6–05; 8:45 am]

BILLING CODE 6560–50–P

Federal Register

Thursday,
April 7, 2005

Part III

Department of Homeland Security

Bureau of Customs and Border Protection

8 CFR Parts 217, 231 and 251

19 CFR Parts 4, 122 and 178

Electronic Transmission of Passenger and Crew Manifests for Vessels and Aircraft; Final Rule

Privacy Impact Assessment and Privacy Policy; No

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

8 CFR Parts 217, 231 and 251

19 CFR Parts 4, 122 and 178

[CBP Decision 05–12]

RIN 1651–AA37

Electronic Transmission of Passenger and Crew Manifests for Vessels and Aircraft

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This document amends the Bureau of Customs and Border Protection regulations pertaining to the filing of commercial vessel and aircraft manifests for passengers and crew members. Collectively, the provisions of this final rule require the electronic transmission of manifest information for passengers and crew members onboard commercial vessels and aircraft, in advance of arrival in and departure from the United States, and for crew members and non-crew members onboard commercial aircraft that continue within (foreign air carriers only) and overfly the United States, in advance of the departure of those flights. Submission of this manifest information to the Bureau of Customs and Border Protection is a necessary component of the nation's continuing program of ensuring aviation and vessel safety and protecting national security. The required information also will assist in the efficient inspection and control of passengers and crew members and thus will facilitate the effective enforcement of the customs, immigration, and transportation security laws.

DATES: *Effective Date:* This final rule is effective on June 6, 2005.

FOR FURTHER INFORMATION CONTACT: Tricia Kennedy (202) 344–1229 or Charles G. Perez (202–344–2605), Office of Field Operations, Bureau of Customs and Border Protection.

SUPPLEMENTARY INFORMATION:

Background

Statement of Purpose

The Bureau of Customs and Border Protection (CBP) emphasizes that the primary impetus for this rulemaking and the provisions set forth in the regulatory text below is the increased terrorist threat facing the United States and international trade and transportation industries, particularly the commercial air and vessel carrier industries, since the September 11, 2001 terrorist attacks. To prevent future terrorist attacks, the Department of Homeland Security and its agencies, including CBP and the Transportation Security Administration (TSA), as well as the air and vessel carrier industries, must take the necessary steps to alleviate, to the greatest extent possible, the risk to these vital industries posed by the threat of terrorism, including implementing regulations under the Aviation and Transportation Security Act of 2001 and the Enhanced Border Security and Visa Reform Act of 2002.

The urgency of these efforts is underscored by the recent cancellation of flights to the United States, the terrorist attacks in Spain, and the continued operations of Al Qaeda and its affiliates throughout the world. The threat is serious and ongoing. It is important to note that the threat is not just to the lives of the innocent, but also to the economic well-being of the commercial aircraft and vessel industries. Given the importance of these industries to the United States and other economies, a terrorist attack involving a commercial airliner or an ocean-going vessel could substantially disrupt the global economy. Therefore, it is incumbent upon the government and private sector to take steps to prevent such an attack.

The provisions of this final rule impose on commercial air and vessel carriers electronic manifest transmission requirements relative to passengers, crew members, and non-crew members in several circumstances—those situations involving arrival in, departure from, or overflying the United States, as well as those involving a foreign air carrier arriving at a U.S. port and then continuing domestically within the United States to a second U.S. port. The manifest information required in these circumstances varies to some extent but uniformly includes certain travel itinerary data, aircraft/flight or vessel/voyage data, and personal identification information, including name, gender, date of birth, citizenship, travel document data, and status onboard the vessel or aircraft. These and other requirements are imposed for the purpose of meeting the collective objectives of the Aviation and Transportation Security Act (49 U.S.C. 44909), the Enhanced Border Security and Enhanced Visa Entry Reform Act of 2002 (8 U.S.C. 1221), and applicable aviation security laws and regulations enforced by the Transportation Security Administration (49 U.S.C. 114; 49 CFR parts 1544, 1546, and 1550): to secure the United States citizenry and economy, international travelers, and the international air and sea carrier industries from terrorist attack and from violations of various other laws, including other customs and immigration laws. The enforcement and administration of these requirements will provide that protection without unduly impacting upon international trade and travel.

Clarification of Agency Names

CBP notes that in this document (hereinafter, the final rule), references to U.S. Customs, the Customs Service, or Customs concern the former Customs Service or actions undertaken by the former Customs Service prior to its transfer to the Department of Homeland Security (DHS) under the Homeland Security Act (HS Act) and the Reorganization Plan Modification for DHS of January 30, 2003. References in this document to the Immigration & Naturalization Service (INS), the INS, or the Service concern the former INS or actions taken by the former INS prior to certain of its component functions being transferred to CBP under these authorities. (See section IV of this document, entitled ''Government Reorganization Pursuant to the Homeland Security Act of 2002'' for a more detailed presentation of this subject.)

Also, any references to the Secretary of the Treasury, the Commissioner of Customs, the Attorney General of the United States, or the Commissioner of the INS are retained in this document only when made in discussion of the governing statutes (which were amended in pertinent part prior to the creation of the DHS); these authorities are now vested in the Secretary of the Department of Homeland Security and his delegees.

Organization

This document is organized as follows:

I. The Customs Interim Rule—Summary of rule published in the **Federal Register** on December 31, 2001, (hereinafter, the Customs Interim Rule);
II. The INS NPRM—Summary of INS NPRM published on January 3, 2003 (hereinafter, the INS NPRM);
III. TSA Requirements—Provisions incorporated into this final rule in order to assist TSA in carrying out its aviation security responsibilities with respect to crew members and non-crew members of commercial aircraft;
IV. Governmental Reorganization Pursuant to the Homeland Security

Act—Discussion of the new Department of Homeland Security and its effect in combining the border security and inspectional functions of Customs and INS into one agency—''CBP;

V. Discussion of Comments—Discussion of comments received by CBP in response to the Customs Interim Rule and the INS NPRM;

VI. Changes to the Interim and Proposed Regulatory Texts—Summary of changes made to the Customs Interim Rule and the INS NPRM in this final rule, including changes made to assist TSA;

VII. Conclusion.

I. The Customs Interim Rule

Statutory Changes

On November 19, 2001, the President signed into law the Aviation and Transportation Security Act (ATSA), Public Law 107–71, 115 Stat. 597. Section 115 of the ATSA, amending 49 U.S.C. 44909, provides that, not later than 60 days after the date of enactment of the ATSA, each domestic air carrier and foreign air carrier operating a passenger flight in foreign air transportation to the United States must electronically transmit to the Customs Service a passenger and crew manifest containing specific identifying data elements and any other information determined to be reasonably necessary to ensure aviation safety.

The specific passenger and crew identifying information required consists of the following: (a) The full name of each passenger and crew member; (b) the date of birth and citizenship of each passenger and crew member; (c) the gender of each passenger and crew member; (d) the passport number and country of issuance for each passenger and crew member if a passport is required for travel; and (e) the United States visa number or resident alien card number of each passenger and crew member, as applicable.

Section 115 of ATSA further provides that: (i) The carriers may use the advanced passenger information system established under section 431 of the Tariff Act of 1930, as amended (19 U.S.C. 1431), to provide the required information; (ii) the carriers must make passenger name record (PNR) information available to the Customs Service upon request; (iii) the required passenger and crew manifest must be transmitted in advance of the aircraft landing in the United States in such manner, time, and form as the Customs Service prescribes; and (iv) the required information may, upon request, be shared with other Federal agencies for the purpose of protecting national security.

Interim Regulatory Amendments

On December 31, 2001, Customs published in the **Federal Register** (66 FR 67482), as T.D. 02–01, an interim rule (with request for comments) entitled ''Passenger and Crew Manifests Required for Passenger Flights in Foreign Air Transportation to the United States'' (the Customs Interim Rule). The Customs Interim Rule amended the Customs regulations (now CBP regulations) by adding a new § 122.49a (19 CFR 122.49a) to implement the new passenger and crew manifest reporting requirement discussed above. The Customs Interim Rule addresses all of the provisions of section 115 of ATSA except for the PNR provision which has been addressed separately as indicated below.

Section 122.49a of the Customs Interim Rule sets forth the general requirement that each foreign and domestic air carrier operating a passenger flight in foreign air transportation to the United States must transmit electronically to Customs a passenger manifest and a crew manifest containing the information set forth in section 115 of ATSA. The transmission must be effected through an electronic data interchange system approved by Customs and must go to the U.S. Customs Data Center, Customs Headquarters. The system in operation at the time ATSA was enacted is the Advance Passenger Information System (APIS), which was a voluntary program. It remains in operation, and many carriers have or will have this capability to comply with the requirements set forth in this final rule. There are alternative means available for those carriers without this capability, as discussed in the ''Discussion of Comments'' section (section V). Section 122.49a further provides that the manifest reporting requirement applies to flights where the passengers and crew have already been pre-inspected or pre-cleared at the foreign location for admission to the United States.

Section 122.49a of the Customs Interim Rule also provides that the air carrier for each flight must transmit the passenger manifest and the crew manifest separately. Furthermore, the crew manifest must be received by Customs electronically anytime prior to departure from the last foreign port or place, and the passenger manifest must be received by Customs no later than 15 minutes after the flight has departed from the last foreign port or place. Departure occurs after the wheels are up on the aircraft and the aircraft is en route directly to the United States.

Section 122.49a of the Customs Interim Rule specifies the following categories of information and related requirements that apply to each passenger manifest and crew manifest:

1. The following airline and flight information must be included in the transmission: (a) the airline International Air Transport Association (IATA) code; (b) the flight number, followed by the alpha character ''C'' in the case of a crew manifest; (c) the departure location IATA code; (d) the U.S. arrival location(s) IATA code(s); (e) the date of flight arrival in the United States; and (f) whether each passenger and crew member on the flight is destined for the United States or in transit through the United States.

2. The passenger and crew member identity data elements required in section 115 of ATSA must be included in the transmission.

3. Each air carrier must provide the passenger and crew member identity data elements specified in section 115 of ATSA by transmitting to Customs one, and only one, travel document per passenger or crew member, selected from the following list: U.S. Alien Registration Card; U.S. Border Crossing Card; U.S. non-immigrant visa; U.S. Refugee Travel Document or Re-entry Permit; U.S. Passport; or non-U.S. passport. Until notice is published in the **Federal Register** providing otherwise, timely receipt by Customs of the electronically transmitted preferred travel document will constitute full compliance with the informational requirements of section 115 of ATSA. (Transmission of the travel document means transmission of the information that is obtained from the travel document via the electronic document reader that scans the machine-readable zone of the travel document. In those instances where a travel document does not have a machine-readable zone, the data normally so obtained will be collected manually from the biographical page of the travel document.)

4. The Customs Interim Rule specifies that the following additional information must be included on each passenger and crew manifest: (a) The foreign airport where the passengers and crew members began their air transportation to the United States; (b) for passengers and crew members destined for the United States, the airport in the United States where the passenger will be processed through customs and immigration formalities; and (c) for passengers and crew members that are transiting through the

United States and not clearing customs and immigration formalities, the foreign airport of ultimate destination.

5. The Customs Interim Rule indicates that by a date that would be announced in the **Federal Register**, air carriers would be required to transmit additional elements which are not contained in the transmitted travel documents (*see* section 4 above). Thus, as of the date announced in the **Federal Register**, air carriers would no longer be excused from satisfying all informational requirements set out in section 115 of ATSA and the ''full compliance'' provision described above would no longer apply as of that published date.

Section 122.49a of the Customs Interim Rule also provides that the carrier collecting the required information is responsible for comparing this information with the related travel document to ensure that the information is correct, that the document appears to be valid for travel to the United States, and that the passenger or crew member is the person to whom the travel document was issued.

Section 122.49a of the Customs Interim Rule also provides that the information contained in passenger and crew manifests that were the subject of the Customs Interim Rule may, upon request, be shared with other Federal agencies for the purpose of protecting national security.

The Customs Interim Rule also included a conforming amendment to § 178.2 of the Customs regulations (19 CFR 178.2) which sets forth a list of information collection control numbers assigned by the Office of Management and Budget pursuant to the Paperwork Reduction Act.

Finally, the Customs Interim Rule document provides that the requirement in section 115 of ATSA that the carriers make PNR information available to the Customs Service upon request would be the subject of a separate document. (PNR information is data the carrier has in its reservation system regarding passengers. PNR data or information is not to be confused with the ''PNR locator number'' (also referred to as the PNR locator or PNR number) which is only the number that is associated with the passenger record.)

On June 25, 2002, Customs published in the **Federal Register** (67 FR 42710) as T.D. 02–33 an interim rule document (a new § 122.49b) setting forth the regulatory standards by which Customs will have electronic access to PNR information maintained by air carriers (that is, information contained in a carrier's automated reservation or departure control system). Although this § 122.49b is not the subject of, nor affected by (beyond being redesignated § 122.49d), this final rule, this interim rule also included a technical amendment to § 122.49a which reflects the passenger and crew information elements contained in section 115 of ATSA. The amendment involved the replacement of the words ''and the United States visa number'' with the words ''and the United States visa travel document number (located in the machine-readable zone of the visa document).'' This amendment was made in order to ensure that the requirement in the regulatory text is compatible with the existing reporting system that uses an electronic document reader to scan the travel document and transmit the information on it to Customs.

The Customs Interim Rule invited the submission of written public comments on new § 122.49a, and the public comment period closed on March 1, 2002. The submitted comments are summarized and responded to in section V (''Discussion of Comments'') set forth later in this document.

II. The INS NPRM

Statutory Changes

On May 14, 2002, the President signed into law the Enhanced Border Security and Visa Entry Reform Act of 2002 (EBSA), Public Law 107–173, 116 Stat. 543. Section 402 of the EBSA amended section 231 of the Immigration and Nationality Act (8 U.S.C. 1221). Section 402 of the EBSA provides that, for each commercial vessel or aircraft transporting any person to any seaport or airport of the United States from any place outside the United States, it shall be the duty of an appropriate official to provide to any United States border officer at that port manifest information concerning each passenger, crew member, and other occupant transported on such vessel or aircraft prior to arrival at that port.

Section 402 of the EBSA provides that, for each commercial vessel or aircraft taking passengers on board at any seaport or airport of the United States, who are destined to any place outside the United States, it shall be the duty of an appropriate official to provide to any United States border officer before departure from such port manifest information concerning each passenger, crew member, and other occupant to be transported.

Section 402 of the EBSA also provides that the information to be provided with respect to each person listed on a manifest covered by this section shall include the following information: (a) Complete name; (b) date of birth; (c) citizenship; (d) gender; (e) passport number and country of issuance; (f) travel document type and date of expiration; (g) country of residence; (h) United States visa number, date, and place of issuance; (i) alien registration number; (j) United States address while in the United States; and (k) such other information the Attorney General, in consultation with the Secretary of State, and the Secretary of the Treasury determine as being necessary for the identification of the persons transported, the enforcement of the immigration laws, and the protection of safety and national security. (This authority is now vested in the Secretary of DHS.)

Section 402 of the EBSA also provides that an ''appropriate official'' is the master or commanding officer, or authorized agent, owner, or consignee, of the commercial vessel or aircraft concerned.

Section 402 of the EBSA provides that, not later than January 1, 2003, manifest information required under this section shall be transmitted electronically by the appropriate official to an immigration officer.

Section 402 of the EBSA provides that no operator of any private or public carrier that is under a duty to provide manifest information shall be granted clearance papers until the appropriate official has complied with the requirements of this subsection, except that, in the case of commercial vessels or aircraft that the Attorney General determines are making regular trips to the United States, the Attorney General may, when expedient, arrange for the provision of manifest information of persons departing the United States at a later date.

In addition to other penalties and sanctions available under Federal law, section 402 of the EBSA further provides that, if it appears to the satisfaction of the Attorney General that an appropriate official, any public or private carrier, or the agent of any transportation line has refused or failed to provide required manifest information, or that the manifest information provided is not accurate and full based on information provided to the carrier, such official, carrier, or agent shall pay to the Commissioner of INS (now CBP) the sum of $1,000 for each person for whom such accurate and full manifest information is not provided, or for whom the manifest information is not prepared as prescribed. No commercial vessel or aircraft shall be granted clearance pending determination of the question of the liability to the payment of such

penalty, or while it remains unpaid, and no such penalty shall be remitted or refunded, except that clearance may be granted prior to the determination of such question upon the deposit with the Commissioner of a bond or undertaking approved by the Attorney General or a sum sufficient to cover such penalty.

Section 402 of the EBSA further provides that the Attorney General may waive the requirements for providing arrival or departure manifests upon such circumstances and conditions as the Attorney General may by regulation prescribe.

Finally, section 402 of the EBSA provides that the term ''United States border officer'' means, with respect to a particular port of entry into the United States, any United States official who is performing duties at that port of entry.

Proposed Regulatory Amendments

On January 3, 2003, the INS published in the **Federal Register** (68 FR 292), as INS No. 2182–01, a document entitled ''Manifest Requirements Under Section 231 of the Act'' (INS NPRM). This document set forth proposed amendments to the Immigration regulations in Title 8 of the Code of Federal Regulations to implement the statutory changes made by section 402 of the EBSA as described above. These proposed regulatory amendments involved the revision of § 217.7 (8 CFR 217.7), the revision of the heading for Part 231, the revision of § 231.1 (8 CFR 231.1), the revision of the heading for Part 251, the redesignation of § 251.5 as § 251.6 (8 CFR 251.6), the addition of a new § 251.5 (8 CFR 251.5), and the revision of newly redesignated § 251.6.

Proposed Revision of § 217.7

The proposed revision of § 217.7 involved changes to conform the text to the terms of revised § 231.1 discussed below. These conforming changes involved a non-substantive rewording of the text and the insertion of a cross-reference to the requirements of § 231.1, and (2) replacement of text regarding procedures and specific data elements for the electronic transmission of passenger arrival and departure information, with text describing the potential consequences for carriers that fail to submit electronic arrival and departure manifests.

Proposed Revision of § 231.1

The changes made in the proposed revision of § 231.1 involved (1) a revision of the section heading, (2) the addition of provisions to implement the terms of section 402 of the EBSA, (3) elimination of the manifest submission exception for in-transit passengers, (4) redesignation of paragraphs, and (5) elimination of the provision regarding the completion and presentation of Form I–94. Thus, the proposed revision of § 231.1 was intended to implement all of the principal operational requirements reflected in the statutory changes made by section 402(a) of the EBSA. The proposed terms of revised § 231.1 are discussed in detail below.

Paragraph (a) of revised § 231.1 is headed ''definitions'' and defines the following terms: ''appropriate official''; ''commercial aircraft''; ''commercial vessel''; ''crew member''; ''ferry''; ''passenger''; and ''United States.''

Paragraph (b) of revised § 231.1 is headed ''electronic arrival manifest'' and provides that (i) an appropriate official of every commercial vessel or aircraft arriving in the United States from any place outside of the United States shall transmit electronically to the Service a passenger arrival manifest and a crew member arrival manifest, and (ii) the electronic arrival manifest must contain the required data elements for each passenger and crew member.

Paragraph (b) also sets forth rules regarding the timing for transmission of aircraft arrival manifests. In the case of passenger arrival manifests, the appropriate official must transmit the manifest no later than 15 minutes after the flight has departed from the last foreign port or place. For crew member arrival manifests, the manifest must be transmitted in advance of departure from the last foreign port or place. Further, paragraph (b) sets forth rules regarding the timing for transmission of vessel arrival manifests. For passenger and crew member manifests, one of the following three alternative rules will be applied, depending on the length of the voyage: (i) At least 96 hours before entering the port or place of destination, for voyages of 96 hours or more; (ii) at least 24 hours before entering the port or place of destination, for voyages of less than 96 hours but not less than 24 hours; or (iii) prior to departing the port or place of departure, for voyages of less than 24 hours.

Paragraph (c) of revised § 231.1 is headed ''electronic departure manifest'' and provides that an appropriate official of every commercial vessel or aircraft departing from the United States to any place outside of the United States shall transmit electronically to the Service a passenger departure manifest and a crew member departure manifest. The electronic departure manifest must contain the required data elements for each passenger and crew member.

Paragraph (c) also provides that the appropriate official must transmit both the passenger departure manifest and the crew member departure manifest no later than 15 minutes before the flight or vessel departs from the United States. Further, paragraph (c) sets forth a special rule regarding the timing for transmission of vessel and aircraft departure manifests when passengers or crew members board or disembark after the original manifest has been submitted. In this case, the appropriate official must submit amended or updated passenger and crew member information electronically to the Service no later than 15 minutes after the flight or vessel has departed from the United States. The appropriate official must also notify the Service electronically if a flight or voyage has been cancelled after submission of a departure manifest.

Paragraph (d) of revised § 231.1 is headed ''electronic format'' and sets forth standards for the electronic transmission of the arrival and departure manifests for passengers and crew members. Manifests ''must be transmitted electronically to the Service via the USCS [U.S. Customs Service], by means of an electronic data interchange system that is approved by the Service.'' Passenger arrival and departure manifests must be transmitted separately from the crew member arrival and departure manifests and, to distinguish the two manifests transmitted for a given flight or vessel, the crew member arrival and departure manifests must have the alpha character ''C'' included in the transmission to denote that the manifest information pertains to the crew members for the flight or vessel.

Paragraph (e) of revised § 231.1 is headed ''contents of arrival and departure manifests'' and provides that each electronic arrival or departure manifest must contain certain information for all passengers or crew members of air and vessel carriers. Air carriers must provide the following information: (a) Complete name; (b) date of birth; (c) citizenship (country of document issuance); (d) gender; (e) passport number and country of issuance, if a passport is required; (f) country of residence; (g) United States visa number, date, and place of issuance (arrivals only); (h) alien registration number; (i) United States address while in the United States; (j) International Air Transport Association (IATA) arrival port code; (k) IATA departure port code; (l) flight number, date of flight arrival, date of flight departure; (m) airline carrier code; (n) document type (*e.g.*, passport; visa; alien registration); (o) date of document expiration; and (p) a unique passenger identifier, or

reservation number or Passenger Name Record (PNR) locator number.

Sea carriers must provide the following information: (a) Complete name; (b) date of birth; (c) citizenship (country of document issuance); (d) gender; (e) passport number and country of issuance, if a passport is required; (f) country of residence; (g) United States visa number, date, and place of issuance (arrivals only); (h) alien registration number; (i) United States address while in the United States; (j) arrival port code; (k) departure port code; (l) voyage number; (m) date of vessel arrival; (n) date of vessel departure; (o) country of registry/flag; (p) document type (*e.g.*, passport; visa; alien registration); (q) date of document expiration; (r) a unique passenger identifier, or reservation number or Passenger Name Record (PNR) locator; (s) vessel name; and (t) International Maritime Organization (IMO) number or the official number of the vessel.

Paragraph (f) of revised § 231.1 is headed ''ferries'' and provides that requirements relating to the transmission of electronic arrival and departure manifests ''shall not apply to a ferry (if the passengers are subject to a land-border inspection by the Service upon arrival in the United States).''

Finally, paragraph (g) of revised § 231.1 is headed ''progressive clearance'' and provides that the inspection of arriving passengers may be deferred at the request of the carrier to an onward port of debarkation, that authorization for this progressive clearance may be granted by the Regional Commissioner of the INS when both the initial port of entry and the onward port are within the same regional jurisdiction, and that, when the initial port of entry and onward port are located within different regions, requests for progressive clearance must be authorized by the Assistant Commissioner for Inspections. Paragraph (g) further provides that, when progressive clearance is requested, the carrier shall present Form I–92 in duplicate at the initial port of entry and that the original Form I–92 will be processed at the initial port of entry and the duplicate noted and returned to the carrier for presentation at the onward port of debarkation.

Proposed Revision of § 251.5

Proposed new § 251.5 is headed ''electronic arrival and departure manifest for crew member'' and provides that, in addition to submitting arrival and departure manifests in a paper format in accordance with §§ 251.1, 251.3, and 251.4, the master or commanding officer, or authorized agent, owner, or consignee of any aircraft or vessel transporting passengers to any airport or seaport of the United States from any place outside of the United States or from any airport or seaport of the United States to any place outside of the United States must submit electronic arrival and departure manifests for all crew members on board in accordance with 8 CFR 231.1.

Proposed Revision of § 251.6

The proposed revision of § 251.6 involved minor wording changes.

The INS NPRM invited the submission of written public comments on the 8 CFR changes, and the public comment period closed on February 3, 2003. The submitted comments are summarized and responded to in section V (''Discussion of Comments'') set forth later in this document.

III. TSA Requirements

TSA Security Directives and Emergency Amendments

This final rule contains several provisions that, in addition to implementing the authority of CBP, will assist TSA in carrying out its aviation security mission. TSA issues and administers Transportation Security regulations (TSRs) which are codified in Title 49 of the Code of Federal Regulations (49 CFR), Chapter XII, parts 1500 through 1699. The TSRs establish security requirements for, among others, certain U.S. aircraft operators (49 CFR part 1544) and foreign air carriers (49 CFR parts 1546 and 1550) that conduct passenger and all-cargo operations to, from, within, and overflying the United States. In addition to these public regulations published in the CFR, TSA issues non-public regulations in the form of security programs, Security Directives (SDs), and Emergency Amendments (EAs) that establish additional detailed security requirements for these regulated parties. (*See* 49 CFR 1544.305, 1546.105, 1550.5.)

As part of its security mission, TSA is responsible for assessing intelligence and other information in order to identify individuals who pose, or are suspected of posing, a threat to transportation or national security and to coordinate countermeasures with other Federal agencies to address such threats. (*See* 49 U.S.C. 114(f)(1)–(4).) Under this authority, which is held concurrently by the Under Secretary of Border and Transportation Security (BTS) of DHS, TSA may require aircraft operators and foreign air carriers conducting passenger or all-cargo flight operations to and from the United States, as well as certain air carriers conducting flights within (limited to foreign air carrier flights from the U.S. port of their arrival to a second U.S. port) and overflying the United States, to provide TSA, prior to departure, manifest information for those persons (other than passengers) onboard a flight. Under certain SDs and EAs now in effect, TSA requires the advance submission of certain manifest information for certain flights operating to, from, within, or overflying the United States. TSA uses this information, in coordination with CBP, to conduct security threat assessments for crew and non-crew members.

Because these requirements, which are already effective under security programs, EAs, and SDs issued to the air carriers by TSA, are similar to the provisions of the Customs Interim Rule and the INS NPRM in substance, effect, and purpose, the Under Secretary of BTS has determined to incorporate them into this final rule. As a result, the public now has access to all manifest requirements in a single source. In addition, these requirements (except for those affecting overflights) are also authorized under 49 U.S.C. 44909(c)(2)(F) and 8 U.S.C. 1221(c)(10), both of which provide that CBP may require that crew manifests include such information that CBP and TSA determine is reasonably necessary to ensure aviation safety.

IV. Governmental Reorganization Pursuant to the Homeland Security Act

On November 25, 2002, the President signed into law the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135 (HS Act), which involved, among other things, the creation of a new cabinet-level department, the Department of Homeland Security (DHS), the transfer to DHS of a number of Executive Branch agencies and offices, and the reorganization of a number of Executive Branch agencies and offices within existing cabinet-level departments. This legislation had a profound impact on the organization and operation of both the Customs Service and INS, with consequential implications (discussed below) for the Customs Interim Rule and the INS NPRM.

Section 401 of the HS Act established in DHS a Directorate of Border and Transportation Security (BTS) headed by an Under Secretary for BTS. Section 402 of the HS Act provides that the Secretary of DHS, acting through the Under Secretary for BTS, shall be responsible for, among other things, the following: (1) Securing the borders, territorial waters, ports, terminals,

waterways, and air, land, and sea transportation systems of the United States, including managing and coordinating those functions transferred to DHS at ports of entry; (2) carrying out the immigration enforcement functions vested by statute in, or performed by, the Commissioner of INS (or any officer, employee, or component of the INS) immediately before the date on which the transfer of functions specified under section 441 of the HS Act takes effect; (3) establishing and administering rules, in accordance with section 428 of the HS Act, governing the granting of visas or other forms of permission, including parole, to enter the United States to individuals who are not a citizen or an alien lawfully admitted for permanent residence in the United States; (4) establishing national immigration enforcement policies and priorities; and (5) with some exceptions, administering the customs laws of the United States.

With regard to the Customs Service, section 403(1) of the HS Act transferred the functions, personnel, assets, and liabilities of the Customs Service, including the functions of the Secretary of the Treasury relating to the Customs Service, to the Secretary of DHS. Section 411 of the HS Act established, in DHS, the United States Customs Service, under the authority of the Under Secretary for BTS, and provided for a Commissioner of Customs as its head.

Pursuant to section 1502 of the HS Act, the President submitted to Congress on November 25, 2002, a reorganization plan and, on January 30, 2003, a modification of that reorganization plan (collectively, The Reorganization Plan). The Reorganization Plan, among other things, renamed the ''Customs Service'' as the ''Bureau of Customs and Border Protection'' (CBP). The Reorganization Plan also provided (1) that CBP will inherit and have responsibility for, among other things, the resources and missions of the Customs Service and the INS (including the Border Patrol and the inspections program) relating to borders and ports of entry and (2) that the Commissioner of CBP will, among other things, establish and oversee the administration of the policies for performing the Border Patrol and inspection program functions that are transferred to the Under Secretary for BTS by section 441 of the HS Act (discussed below) and delegated to the Commissioner by the Under Secretary.

With regard to the INS, section 471(a) of the HS Act provided for the abolishment of the INS of the Department of Justice upon completion of all transfers from the INS as provided for by the HS Act. The transfers referred to in section 471(a) that affect DHS are as follows:

1. Section 441 of the HS Act transferred, from the Commissioner of INS to the Under Secretary for BTS, all functions performed under, and all personnel, assets, and liabilities pertaining to, the following programs: The Border Patrol; detention and removal; intelligence; investigations; and inspections.

2. Section 442 of the HS Act established in DHS a bureau to be known as the ''Bureau of Border Security'' and headed by an Assistant Secretary who reports directly to the Under Secretary for BTS. The functions of the Assistant Secretary include, among other things, the establishment of policies for performing functions transferred to the Under Secretary by section 441 of the HS Act and delegated to the Assistant Secretary by the Under Secretary. The Reorganization Plan renamed the ''Bureau of Border Security'' as the ''Bureau of Immigration and Customs Enforcement'' (ICE). It also provided that ICE would have responsibility for, among other things, the INS interior enforcement functions (including the detention and removal program, the intelligence program, and the investigations program) and the interior enforcement resources and mission of the Customs Service and thus would be responsible for the enforcement of the full range of immigration and customs laws within the interior of the United States. Subsequently, by Delegation Order 7030, the border search authority vested in the Under Secretary of BTS under section 402 was delegated to the Assistant Secretary of ICE; thus, ICE's responsibilities include a border enforcement component, as well.

3. Section 451 of the HS Act established in DHS a bureau to be known as the ''Bureau of Citizenship and Immigration Services'' (CIS) and headed by a Director who reports directly to the Deputy Secretary of Homeland Security. The Director's functions include, among other things, establishing and overseeing the administration of policies for performing functions transferred by section 451 from the Commissioner of INS to the Director. The functions (including all supporting personnel, infrastructure, and funding) transferred by section 451 consist of (1) adjudications of immigrant visa petitions, naturalization petitions, and asylum and refugee applications, (2) adjudications performed at service centers, and (3) all other adjudications performed by the INS immediately before the date on which the transfer of functions specified in section 441 of the HS Act takes effect.

Under section 1502 of the HS Act and the Reorganization Plan, the statutory transfers and Presidential agency redesignations and allocations of functions described above took effect on March 1, 2003. Accordingly, as of that date, the INS ceased to exist as a separate agency and the border inspection functions formerly performed by INS under the immigration laws were merged with the border functions historically performed by the Customs Service under the customs and related laws in one agency, CBP.

The statutory amendment made by the ATSA (which enabled publication of the Customs Interim Rule) and the statutory amendments made by the EBSA (which enabled publication of the INS NPRM) respectively involve only customs border arrival functions and immigration border arrival and departure inspection functions, all of which are now the exclusive responsibility of CBP. It is further noted that the Customs Interim Rule and the INS NPRM affect one or both of the same industry sectors (that is, the air carrier industry and the sea carrier industry) and that each of those statutory and regulatory regimes imposes separate but in some cases identical or similar information reporting requirements for the same carrier transaction. Finally, it is noted that the Customs Interim Rule and INS NPRM changes in question were published prior to the March 1, 2003, governmental reorganization under the HS Act and therefore reflected the agency organization and regulatory perspective that existed prior to that date, with the Customs Interim Rule amendments set forth in Title 19 of the CFR and the INS NPRM changes slated for inclusion in Title 8 of the CFR.

Based on the considerations set forth above, and in light of the similar provisions added to this final rule to assist TSA in its aviation security mission, the Secretary has determined that it would be preferable to consider the Customs Interim Rule and the INS NPRM as one regulatory initiative and to address the TSA requirements at the same time. Accordingly, the Secretary, after consultation with the Commissioner of CBP and the Assistant Secretary for TSA, and pursuant to the authority vested in him by law, including but not limited to 49 U.S.C. 44909, 8 U.S.C. 1221, 49 U.S.C. 114, and section 402 of the HS Act, has determined to incorporate the three above initiatives into this final rule amending 19 CFR in order to avoid a

duplication of reporting requirements, improve the organization and transparency of the regulatory texts, and facilitate administration of these important provisions that concern national security and the safety of commercial vessel transportation to and from the United States and commercial air transportation to, from, within, and over the United States.

V. Discussion of Comments

The comments submitted in response to the Customs Interim Rule and the INS NPRM are summarized and responded to below. Where a comment directed to a provision of the Customs Interim Rule or the INS NPRM raises an issue that is also relevant to the other rule or to a provision included in this final rule to assist TSA, all aspects of the comment will be addressed at that time; the full response to the comment will appear only once in the text of the final rule.

Comments on the Customs Interim Rule

Twelve commenters responded to the solicitation of comments on the Customs Interim Rule setting forth new § 122.49a to require the electronic transmission of passenger and crew manifests for flights in foreign air transportation to the United States.

Comment: One commenter contended that the § 122.49a requirements should not apply to a passenger flight in foreign air transportation that is not initially destined for the United States but rather is diverted in flight to a U.S. airport due to an emergency (for example, a mechanical problem, bad weather, a sick passenger).

Response: Initially, CBP notes that, due to a reorganization of the regulation based on the incorporation of TSA requirements into this final rule, § 122.49a of this final rule covers only passengers while crew members are covered in § 122.49b (whereas § 122.49a of the Customs Interim Rule covered both passengers and crew members on arriving commercial aircraft).

CBP does not agree that flights diverted to a U.S. port due to an emergency should be excepted from the passenger and crew manifest transmission requirement; however, CBP recognizes that the regulation should address emergency flight scenarios. Thus, an appropriate provision has been added to the regulatory texts in this final rule for emergency aircraft arrivals (§§ 122.49a(b)(2)(ii) (passenger manifests) and 122.49b(b)(2)(i)(B) (crew member manifests)).

CBP recognizes that an aircraft diverted to a U.S. port due to an emergency may not be able to transmit manifests in compliance with the time requirement of the regulation. CBP also recognizes that not all such aircraft will be equipped for making a transmission of manifest information through the APIS, whether by electronic US or UN EDIFACT transmission or by an approved alternative transmission medium. For these reasons, the regulation now provides an alternative manifest filing time requirement for these flights and an accommodation for non-equipped air carriers who fail to meet the requirements.

As the above discussion is also applicable to arriving vessels, this final rule also contains an emergency provision for these vessels (§ 4.7b(b)(2)(D)).

Comment: This comment discussion (regarding alternative means of electronic transmission) includes comments on both the Customs Interim Rule and the INS NPRM.

One commenter argued that § 122.49a should expressly provide for a separate electronic system by which small carriers could transmit passenger and crew manifest data to Customs. It was explained that Customs had allowed small carriers to transmit manifest data through an electronic mail (e-mail) system, and it was recommended that this system for transmitting the data be changed to a computer web-based medium, coupled with a telephonic or facsimile back-up system. Another commenter requested information on the alternative methods of submission such as e-mail and the web-based application. The commenter also requested that the effective date of the final rule be delayed until the web-based application is piloted.

Response: CBP does not believe that every electronic setup, along with its technological details and operational features, that is authorized for effecting the mandatory transmission of manifest data to CBP needs to be prescribed in the regulations. Consistent with the terms of 49 U.S.C. 44909(c)(1) and (c)(4), CBP believes that it is sufficient to use a general statement in the regulatory texts that the electronic transmission of manifest information to CBP must be effected through an electronic data interchange system that is approved by CBP. Also, as the statute requires electronic submission of data, and telephonic and facsimile reporting are not considered electronic, transmissions in this manner would not be in compliance with the requirements.

It is also noted that, in an effort to be more responsive to the needs of the affected industries, CBP has developed a computer web-based medium (eAPIS) to allow carriers to access the CBP Web site and thus transmit manifests directly to the data center via the Internet. This medium became operational at the end of January 2005. More information on eAPIS is available at *http://www.cbp.gov* (related links). All information on alternative methods for transmitting electronic manifest data for air and sea carriers, including e-mail and web-based applications, can be found at *http://www.cbp.gov* (related links).

Regarding a delayed effective date, CBP does not believe that the availability of the web-based application should be related to the implementation date of the manifesting requirements. As noted above, eAPIS is now operational, so this concern is moot (and there are other alternative methods of transmission currently available).

Comment: Two commenters cited an inability to install automated equipment that would enable them to transmit electronically the necessary manifest data for passenger flights from Cuba in accordance with § 122.49a. These commenters requested that Customs develop alternative procedures to deal with this situation.

Response: Since the publication of the Customs Interim Rule, carriers arriving from Cuba have demonstrated ability to comply with electronic manifest requirements. As such, we believe this concern is no longer an issue. It is clear under the express language of 49 U.S.C. 44909(c)(1) that CBP may require the transmission itself be by electronic means. Additionally, as noted previously, the manifest may be transmitted through the CBP Web site once operational.

Comment: Two commenters requested that Customs use account managers for the purpose of administering § 122.49a, as was originally done to administer the APIS system, which was then a voluntary program under which air carriers electronically transmitted passenger and crew manifest data to Customs.

Response: CBP believes the practice of using account managers is beneficial to the industry and therefore will continue to provide those services. Further information on APIS account managers (not necessary for this rule) is available at *http://www.cbp.gov* (related links).

Comment: Six commenters were concerned about the degree to which carriers would need to comply with the provisions of § 122.49a. These commenters referred to a Customs press release of March 1, 2002 (*http://www.cbp.gov/xp/cgov/* click on links to newsroom/press releases) indicating that penalties could be assessed if carriers failed to reach stated minimum levels of compliance by certain target

dates in transmitting to Customs error-free manifest data under § 122.49a. The commenters concluded that these target dates did not afford enough time for many carriers not yet online to achieve the stated levels of compliance. Also, it was asserted that a penalty of $5,000 for noncompliance with the requirements of § 122.49a was too harsh.

Response: Full compliance with the provisions of § 122.49a (§§ 122.49a for passengers and 122.49b for crew members in this final rule) was, of course, compulsory as of its effective date (December 31, 2001). However, the use of CBP penalty guidelines for determining the parameters under which CBP may assess a penalty for noncompliance with § 122.49a falls outside the scope of this rulemaking. Penalty guidelines are set forth in Part 171 of CBP's regulations and any changes will be published on the website and in the **Federal Register**. Furthermore, it is noted that a civil penalty of $5,000 is authorized by statute and regulation for each violation of § 122.49a (or § 122.49b for arriving crew members in this final rule) (see 19 U.S.C. 1644a(b)(1)(D) and (b)(2); 19 CFR 122.161; and 19 U.S.C. 1436).

Comment: This comment discussion (regarding the timing of manifest information submission) includes comments on both the Customs Interim Rule and the INS NPRM. These comments have been broken down into four subparts.

(1) Eleven commenters were of the opinion that the requirement regarding transmission of passenger manifest information to Customs no later than 15 minutes after the departure of the aircraft was difficult to meet and should be relaxed. It was instead suggested that the time period for transmitting the passenger manifest to Customs should be a flexible one and that it should be tied to the duration of the related flight.

(2) It was further suggested in this context that the crew manifest should be sent to Customs at the same time as the passenger manifest, rather than in advance of departure, in order to accommodate last minute crew changes.

(3) One commenter requested that any updates to the departure manifest be limited to only those records that need to be updated, not a complete transmission.

(4) Finally, one commenter asked for clarification of ''departure time.''

Response: (1) After careful review of the matter, including consideration of recent events involving the continuing threat of terrorism, CBP has determined that changing the time requirements in the manner recommended by the commenters for arriving and departing aircraft is not in the best interest of the international traveling public, the carrier industries, or national security. Such a change would be inimical to the security enhancing intent of the requirements as it would result in the completion of security checks later rather than sooner and leave less time for the taking of appropriate action. Thus, permitting variable submission times based on flight duration would be unacceptable. CBP continues to evaluate whether the transmission of APIS data for aircraft passengers and for passengers and crew onboard departing vessels, in accordance with the provisions of this final rule, allows CBP sufficient time to respond to identified threats.

However, as discussed previously, this final rule includes provisions designed to assist TSA in its aviation security mission. These provisions are set forth in security programs, EAs, and SDs already issued by TSA to the air carriers and address electronic manifest transmission requirements for crew members (on passenger and all-cargo flights) and non-crew members (all-cargo flights only) traveling onboard commercial aircraft arriving in, departing from, continuing within (foreign air carriers only), and overflying the United States. These provisions are authorized under TSA law and regulations (49 U.S.C. 114 and 49 CFR part 1500), and, with the exception of overflights, also fall within the authority of 49 U.S.C. 44909, as amended by the ATSA, and 8 U.S.C. 1221, as amended by the EBSA. These provisions require the advance transmission of crew manifest information no later than 60 minutes prior to departure of the aircraft and have been adopted for incorporation into this final rule in §§ 122.49b and 122.75b, pertaining respectively to crew and non-crew members on flights to, continuing within, and overflying the United States and to the same persons on flights departing from the United States. In this final rule, the 60-minute requirement is limited to crew and non-crew in these scenarios.

(2) With this final rule, as set forth in (1) above, crew member and non-crew member manifests are now required no later than 60 minutes prior to departure. Last minute crew changes (updating manifests within 60 minutes of departure) will be accommodated only upon approval by TSA. Failure to obtain timely approval may result in possible denial of flight clearance or diversion of the flight to another port, as appropriate. CBP notes that the updating manifest requirement in this final rule applies only to crew members and non-crew members. There is no manifest updating provision for passengers.

(3) CBP agrees with the commenter's preference regarding updating (amending) manifests. As such, where submission of updated information is provided for in this final rule, it is only the updated information that is required, although a complete manifest may be transmitted through APIS with updated information if the carrier desires. Further, while the INS NPRM provided for amendment of the departure manifests to reflect the disembarkation of passengers or crew members, the text of this final rule reflects that the amendment provisions apply only to additions to crew member and non-crew member manifests. The APIS system is not capable of deleting manifest information already transmitted, so reporting disembarkations is not required in the manifest amendment provisions of this final rule.

(4) Regarding the meaning of ''departure time,'' for aircraft, departure time is the moment at which the aircraft's wheels are up and off the runway and the aircraft is en route to its destination. The ''wheels up'' concept is the same for other scenarios covered in this final rule, such as flights continuing within and overflying the United States.

Comment: Two commenters stated that, while § 122.49a(b) required that Customs timely receive the electronic transmission of the passenger manifest and the crew manifest for a covered flight, air carriers could not guarantee receipt of the information by Customs, only its transmission by the carrier.

Response: Section 122.49a(b) regarding arriving passengers and § 122.49b(b) in this final rule regarding arriving crew members require both the transmission and the receipt of the requisite manifest information because transmission without receipt defeats the purpose behind the statutory requirement that the carrier ''provide'' the manifest by electronic transmission. The APIS application will provide an automatic confirmation procedure for notifying a registered sender that the transmitted manifest data was received by CBP.

Comment: This comment discussion (regarding the issue of privacy) includes comments on both the Customs Interim Rule and the INS NPRM.

Seven commenters remarked that requiring the disclosure to Customs of passenger manifest data might conflict with the requirements of foreign privacy laws. These commenters opined that the U.S. Government should engage in a dialogue with applicable foreign governments to resolve this issue. Also,

a large majority of the 328 commenters to the INS NPRM expressed concern with respect to the right to privacy of travelers and the protection of data by the agency.

Response: CBP has fully complied with, and will continue to ensure compliance with, all requirements of the Privacy Act of 1974, 5 U.S.C. 552a. APIS data is used primarily for law enforcement purposes and in accordance with all applicable laws of the United States. Those U.S. laws, and the measures taken by CBP to implement such laws, protect against misuse of, or unauthorized access to, the information in the system.

APIS data largely consists of information that appears on the biographical data page of travel documents, including passports issued by governments worldwide. The collection of this information is generally consistent with the recommended document standards and practices of the International Civil Aviation Organization (ICAO) set forth in ICAO Document 9303, ''A Passport with Machine Readable Capability.'' APIS data elements have been collected routinely over the years by governments of countries into which a traveler seeks entry (that is, by requiring the traveler to present a government-issued travel document). Moreover, CBP has the statutory authority to require presentation of the information by travelers upon their arrival at the U.S. border. Through APIS, CBP can efficiently and effectively conduct its necessary risk assessment of travelers, while substantially facilitating bona fide travel and avoiding substantial delays in the processing of travelers. Accordingly, CBP does not believe that APIS will give rise to any new or increased threats to personal privacy interests.

More detailed information regarding the collection and safeguarding of APIS data is available in the APIS Privacy Impact Assessment (PIA) published in conjunction with this final rule.

Comment: This comment discussion (regarding the right to travel) addresses comments made in response to both the Customs Interim Rule and the INS NPRM. Several commenters remarked that collection of information through APIS would infringe on the right to travel as recognized by the Supreme Court in *Kent* v. *Dulles,* 357 U.S. 116 (1958).

Response: CBP recognizes, as the Supreme Court has stated, that the right to travel is an important and long-cherished liberty. Although a passenger's refusal to supply the information required by the regulatory text will result in denying that person access to international travel on commercial vessels and aircraft, the new provisions will not violate a constitutional right to travel. The Supreme Court has recognized that the right to travel abroad is not an absolute right, and the Court has recognized that no government interest is more compelling than the security of the nation. *Haig* v. *Agee,* 453 U.S. 280, 307 (1981). The government may place reasonable restrictions on the right to travel in order to protect this compelling interest. Id.; see also *Eunique* v. *Powell,* 302 F. 3d 971, 974 (9th Cir. 2002); *Hutchins* v. *District of Columbia,* 188 F. 3d 531, 537 (D.C. Cir. 1999).

The restrictions this final rule places on certain modes of travel (here, by effectively denying access to certain international travel if a passenger or crew member refuses to provide the information required) are reasonable and narrowly drawn to ensure accurate identification of individuals. Moreover, the restrictions imposed through the required submission of information are far more likely to promote the ability to travel than to restrict it. In fact, as recent events have shown, the ability to travel can be severely restricted by terrorist threats to our means of transportation. *See* National Commission on Terrorist Attacks Upon the United States, Final Report 29 (Norton 2004) (noting FAA's September 11, 2001, instruction to all aircraft to land at the nearest airport). Congress, through legislation discussed throughout this document, has required certain safeguards involving the collection of information to protect our national security. The new regulatory text published today is designed to enhance the ability to travel, not to restrict it for law-abiding U.S. citizens, lawful permanent residents (LPRs), or foreign visitors. Some commenters argued that the proposed rule should not apply to U.S. citizens and LPRs. While requiring information from U.S. citizens and LPRs is a valid concern, the applicable statutes, 49 U.S.C. 44909(c) and 8 U.S.C. 1221, do not exempt these persons from their requirements. Nevertheless, CBP recognizes that certain U.S. citizens and LPRs could pose a risk to the transportation industry and the national security of the United States. CBP must have the ability to properly assess the level of risk of all persons and to respond accordingly.

Comment: Several commenters requested additional clarification as to the meaning of the terms ''full name'' and ''country of issuance of the passport'' as used in § 122.49a(c)(2). Also, it was asked why both the citizenship and the country of issuance of the passport for each passenger and crew member on a covered flight were required to be electronically transmitted to Customs as this information would, in almost all cases, be the same.

Response: The regulatory texts contained in this final rule (§ 122.49a(b)(3) for arriving passengers and § 122.49b(b)(3) for arriving crew members) specify the data element ''full name'' as meaning the first name, last name, and, if available, middle name. However, CBP will accept as the full name the name that appears in the machine-readable zone of the travel document. Carriers have the responsibility to ensure that the information in the machine-readable zone, including full name, is accurately transmitted to CBP.

Regarding the data element ''country of issuance of the passport,'' CBP defines this as the country that issued the passport, as opposed to the country where the document is issued (*i.e.*, if a passport is issued to a U.S. citizen by the U.S. embassy in Costa Rica, the country of passport issuance is the United States). In most instances, country of passport issuance will be the same as ''citizenship,'' and CBP, for the time being, will accept for both data element fields the country of passport issuance as obtained from the machine-readable zone of the passport. However, as CBP is interested in those instances when these data elements are not the same, in the longer term, under the UN EDIFACT transmission format for aircraft (required for aircraft manifest transmissions in place of US EDIFACT 180 days after publication of this document) and under the U.S. Coast Guard's (USCG) electronic Notice of Arrival/Departure (eNOA/D) transmission method or Extensible Markup Language (XML) transmission method for vessels (required 30 days after publication for cargo vessels; 180 days after publication for passenger vessels; explained more fully below), CBP will require the carrier to provide the appropriate data for each of these fields in all cases. As explained further below in the comment discussion, vessel carriers must use the eNOA/D or XML transmission methods to transmit required manifest information.

Finally, citizenship data is required even if a travel document is not required (under both US and UN EDIFACT and under either eNOA/D or XML).

Comment: Concerning § 122.49a(c)(3), which obliges carriers to use a preferred travel document to obtain the information that identifies the passengers and crew on a covered flight, eight commenters argued that Customs should only require the submission of information from the preferred travel

document, usually a passport, that is capable of being scanned through the use of an electronic document reader (in other words, only the electronic transmission of information that is contained in the machine-readable zone of the travel document should be required). For example, it was stated that the U.S. visa number that is required in § 122.49a(c)(2) for a U.S.-issued non-immigrant visa travel document was not located in the machine-readable zone of that document, and thus the visa number of this travel document as described in § 122.49a(c)(3) could not be electronically transmitted to Customs through the use of a machine reader.

Response: CBP disagrees that the electronic transmission of manifest data (in §§ 122.49a(b)(3) and 122.49b(b)(3) in this final rule) should be limited only to the information contained in the machine-readable zone of a preferred travel document. Even though the preamble of the Customs Interim Rule stated that the electronic transmission of the preferred travel document information for the time being would be considered as constituting full compliance with the requirements of 49 U.S.C. 44909(c)(2)(A)–(E), in the longer term, application of that more limited standard would result in the collection of less information than CBP believes is necessary for law enforcement and national security purposes. For example, neither the traveler's U.S. destination address nor his/her travel itinerary is obtainable from the machine-readable zone of the travel document. It was for this reason that the Customs Interim Rule stated that air carriers would be required to transmit any informational elements required by the statute and regulation that are not contained in transmitted travel documents by a date that would be announced in a future **Federal Register** document. That date is 180 days after publication of this document, as specified in the regulatory text of this final rule.

With regard specifically to submission of the U.S. visa number, CBP has determined that it will be able to electronically obtain this data from another source. Therefore, this data need not be transmitted by the carrier. The regulatory text of this final rule has been modified accordingly. This modification will reduce the manual data collection burden on carriers while ensuring that CBP receives the required data.

Comment: With reference to § 122.49a(c)(1) and (c)(4), which provide that certain travel itinerary information for each passenger and crew member must be electronically transmitted to Customs, several commenters observed that information on a passenger's travel itinerary is not always available through the air carrier's PNR (reservation) information system. These commenters suggested that Customs limit the requirement for submitting details on a passenger's travel itinerary to those cases where the carrier possesses this information in its PNR reservation system.

Response: The submission of information on the travel itinerary of each passenger and crew member, as provided in § 122.49a(c)(1) and (c)(4) (in §§ 122.49a(b)(3) and 122.49b(b)(3) in this final rule), has been determined to be important to the effort to ensure national safety and, therefore, such information should be submitted to the maximum extent possible. However, carriers will be expected to report a passenger's itinerary only to the extent that the carrier can determine the itinerary electronically. The statutory authority for requiring the submission of this information is 49 U.S.C. 44909(c)(2)(F) and 8 U.S.C. 1221(c)(10).

Comment: A number of commenters sought further clarification of the following words or phrases used in § 122.49a(c)(4): ''transiting'; ''destined for the United States'; and ''the foreign airport where they [each passenger and crew member] began their air transportation to the United States.''

Response: CBP believes that these words in § 122.49a(c)(4) (§§ 122.49a(b)(3) and 122.49b(b)(3) in this final rule) do not require special definitions regarding their meaning. They are not intended as terms of art and therefore should be accorded their generally accepted, ordinary meanings. Yet, clarification of the words pertaining to the airport where a passenger's or crew member's air transportation to the United States began is warranted. These words require identification of the airport where the passenger or crew member first boarded an aircraft on his/her journey to the United States; however, as mentioned above, the information required to be transmitted will depend on the responsible, transmitting carrier's knowledge of the traveler's itinerary. Thus, where, for example, the traveler first boards at Athens for travel to New York via Rome and London, and the responsible, transmitting carrier knows this itinerary, Athens will be the port/place where the traveler's journey to the United States began, regardless of any aircraft changes, air carrier changes, or overnight layovers along the way. However, if the responsible, transmitting carrier only knows of the traveler's itinerary beginning in Rome, because, *e.g.*, the traveler changed airlines there and the carrier is unaware that the traveler's journey began in Athens, then the carrier's identification of Rome as the port/place where the journey began will be acceptable. Setting forth all possible scenarios in this document is not feasible. The carrier is responsible for transmitting the required information based on its knowledge, obtained through reasonable effort, of the traveler's itinerary.

Comments on the INS NPRM

A total of 328 commenters responded to the solicitation of comments on the INS NPRM setting forth amendments to the immigration regulations in Title 8 of the CFR to require the electronic transmission of passenger and crew manifests for air and sea carriers in foreign transportation into and out of the United States. The submitted comments are summarized and responded to below. Again, similar comments received on both the Customs Interim Rule and the INS NPRM were addressed in the comment-response section for the Customs interim rule and will not be repeated in this section.

Comment: Ten commenters expressed their support for the proposed regulatory requirements. The commenters noted in particular that the requirements would increase the security of air travelers and the United States.

Response: CBP agrees and appreciates the support for this regulatory action.

Comment: Eleven commenters expressed concern over the requirement that the carriers submit the traveler's address while in the United States. The various concerns involve the following:

(1) The address requires manual input;

(2) The requirement applies to in-transit passengers who, by definition, are not entering the United States;

(3) The requirement applies to departure manifests;

(4) Whether a telephone number should be sufficient for passengers who cannot supply a specific address;

(5) Whether the carriers should be liable for the accuracy of the data;

(6) The requirement is not limited to visitors;

(7) That carriers should be allowed to send crew addresses via fax; and

(8) The requirement should not be applied to crew members of sea carriers.

Response: After serious consideration of the various concerns of the industry regarding the requirement to submit the U.S. destination address (primarily, additional processing time for manual entry of this data), CBP has significantly

modified this requirement to decrease the burden on the industry. Although CBP has determined that the submission of the U.S. destination address for certain persons is necessary for transportation and national security, CBP has modified the scope to focus more accurately the requirement on a subset of the traveling public. The following are the responses to the eight concerns summarized above:

(1) CBP recognizes that the manual entry of data will result in an additional burden on the carriers that collect and provide the information. As mentioned above, CBP has carefully weighed the importance of any information that requires manual entry to ensure that the burden is imposed only when the receipt of the information is necessary for transportation and national security purposes.

(2) CBP agrees that a U.S. address should not be required for in-transit passengers since they are only transiting through and are not destined to remain in the United States. Thus, CBP is waiving this requirement. The relevant regulatory texts set forth in this final rule document have been modified accordingly.

(3) CBP agrees that the U.S. address should not be included as part of the passenger departure manifest for either commercial vessels or aircraft. This information relative to non-immigrant travelers can be obtained from information collected upon arrival (as U.S. address is required for arriving non-immigrant passengers). Thus, CBP is waiving this data element requirement in the above scenarios. The regulatory texts set forth in this final rule document have been modified accordingly.

(4) Some travelers (as to whom the information is required) may indicate that they are not able to provide a specific U.S. address; however, CBP cannot accept a telephone number in lieu of the address. The U.S. destination address is required under the EBSA (8 U.S.C. 1221) and must be provided unless waived under the statute. The statute does not provide for transmission of a telephone number or anything else as an alternative. If the information is not submitted with the manifest, the carrier may be penalized for submitting an incomplete manifest, and CBP will be forced to elicit this information from the traveler upon arrival, which could impact CBP processing times.

(5) CBP agrees that the carriers should not be held liable for the accuracy of the U.S. address information provided by the traveler. However, a carrier may be held liable for a failure to provide the information or for providing information it knows or should have known was incorrect. An example of the latter kind of failure is not catching and correcting an address lacking credibility, such as one naming the White House or using a post office box which carriers should be made aware is unacceptable. CBP expects that carriers will make a reasonable effort to ensure that the address provided appears to be a valid address.

(6) CBP agrees that the U.S. address requirement should apply to arriving non-immigrant visitors and not to U.S. citizens or lawful permanent residents (LPRs). As this information, with respect to U.S. citizens and LPRs, can be obtained by other means, CBP is waiving this data requirement for these groups. The regulatory texts set forth in this final rule document have been appropriately modified to reflect this view.

(7) CBP does not agree that transmission of the U.S. address, where required, can be made via fax. This means of transmission is not in compliance with the ATSA and EBSA requirements for the electronic submission of manifest data.

(8) In preparing this final rule, CBP has decided to waive the requirement for U.S. address for crew members arriving in or departing from the United States onboard commercial vessels or aircraft. This information can be obtained from the carrier if necessary. The regulatory texts of this final rule have been modified accordingly. However, the data element ''address of permanent residence'' (which may be a U.S. address in some instances) has been added to the regulatory texts of this final rule for crew members and non-crew members onboard arriving and departing commercial aircraft. This data element (as well as two additional scenarios to which it applies for crew members and non-crew members: certain flights continuing within and overflying the United States) has been added to incorporate current TSA provisions into this rulemaking. Requiring this data element for arriving and departing aircraft is also authorized under the EBSA amendments to 8 U.S.C. 1221 (8 U.S.C. 1221(c)(10)) and, additionally for aircraft arrivals, under the ATSA amendments to 49 U.S.C. 44909 (49 U.S.C. 44909(c)(2)(F)). The regulatory texts of this final rule have been modified accordingly. Thus, where the crew member's or non-crew member's permanent residence is in the United States, that address will be required (and, per item (7) above, cannot be transmitted to CBP by fax) to meet this data element requirement.

Under ATSA, CBP may require additional information that it determines is reasonably necessary to ensure aviation safety, such as the address requirement for certain crew and non-crew members discussed above. Thus, for this reason, requiring the U.S. address as outlined above is authorized under the statute for aircraft arrivals; not requiring it in some circumstances is not contrary to the statute.

Under 8 U.S.C. 1221, as amended by EBSA, pertaining to manifests for aircraft and vessel arrivals and departures, the U.S. address is required (in paragraph (c)(9)). However, paragraph (h) of 8 U.S.C. 1221, as amended, provides CBP the authority to waive the requirements of paragraphs (a) and (b) of the statute relating to submission of arrival and departure manifest information. As CBP has the authority to waive submission of the manifest information altogether (such as for active duty U.S. military personnel on certain Department of Defense aircraft), its authority to waive submission of one or more data elements is reasonably implied. Thus, a manifest data element provided for under paragraph (c) of the statute may be excluded from the regulation (visa number) or limited in the regulation (U.S. address) under the waiver provision, provided that to do so does not present a security risk to vessel and air travel or shipments and is grounded in a reasonable need. Accordingly, the waiver of 8 U.S.C. 1221(h) provides the basis for not requiring, under this final rule, the U.S. destination address for U.S. citizens, LPRs, in-transit passengers, crew members, and all departing travelers in both the commercial vessel and air travel environments. CBP again notes, however, that it can obtain the U.S address by other means with respect to these groups (except in-transits). And CBP reiterates that, despite the foregoing waiver, the data element ''address of permanent residence'' (which may be a U.S. address in some instances) is required in this final rule for crew members and non-crew members on flights to, from, continuing within (foreign air carriers only), and overflying the United States.

Comment: Eight commenters commented on the conversion to the United Nations Electronic Data Interchange for Administration, Commerce, and Trade (UN EDIFACT). The comments involved the following specific issues:

(1) Estimates of the time required to convert to UN EDIFACT;

(2) Concern over the cost of conversion to UN EDIFACT;

(3) Concern over the availability of other methods of transmission for small carriers (e-mail and Web-based applications);

(4) Confusion over the statement in the preamble of the INS NPRM that conversion to UN EDIFACT is not required;

(5) Concern over the timeliness of the final publication of the UN EDIFACT Implementation Guide; and

(6) Concern that the increased transmission of data in blocks will increase the possibility of lost data.

Response: Although the carriers have specific concerns regarding UN EDIFACT, the use of this format for APIS transmissions serves several useful purposes for the air carrier industry. UN EDIFACT was approved as the global standard for APIS messaging by the World Customs Organization in March 2003. Therefore, although the air carriers must reprogram their systems to comply with this new format, they will not have to continue to reprogram to meet other governments' individual APIS requirements, other than possible minor programming changes. Also, UN EDIFACT is much more flexible than US EDIFACT and will allow the carriers to comply with the new data element requirements and make minor adjustments to accommodate modifications without major reprogramming.

The following are the specific responses to the six issues raised by the commenters:

(1) CBP considered all submitted estimates of time required to convert to UN EDIFACT. Industry estimates indicated that most air carriers would be able to convert by the end of December 2003 if the regulatory requirements were finalized by April 2003. CBP has modified the regulatory texts contained in this final rule document to set the requirement for transmission of all data in UN EDIFACT format at approximately 180 days from the date of publication of this final rule. In view of the ample period of time during which the industry has been aware of these impending requirements and has had access to the draft implementation guide to UN EDIFACT, CBP believes that this 180-day delay affords sufficient time for the carriers to complete the necessary programming. Prior to the publication of this final rule, five major carriers and two communication providers have completed programming for UN EDIFACT and 60 others are currently testing with CBP.

For the sea travel environment, CBP has decided to adopt the use of the USCG's eNOA/D transmission format or the XML transmission format for vessel carrier transmissions. The eNOA/D is a web-based application that has been developed by the USCG in cooperation with CBP. It became available to the vessel carrier industry at the end of January 2005. The XML format allows transmission of required information by attachment to an email message. CBP is adopting these methods in large part due to the comments received by the industry calling for USCG and CBP to consolidate duplicative manifesting requirements and provide the industry a ''single-window'' for manifest transmissions. USCG and CBP conducted an evaluation of their respective systems to determine the optimum way to consolidate their transmission requirements and be more responsive to the industry. It was determined that the eNOA/D and XML methods (not UN EDIFACT) are the most compatible and easy to implement methods for this purpose.

For cargo vessel carriers, using eNOA/D or XML will constitute transmission to CBP through an electronic data interchange system approved by CBP, as required under 8 U.S.C. 1221, as amended by EBSA. Cargo vessel carriers must make transmissions through one of these media 30 days after the date of publication of this document. Passenger vessel carriers must make transmissions through one of these media by a date that is 180 days after the date of publication of this document. Cargo vessel carriers are required to comply earlier than passenger vessels since they do not currently submit data and have not previously implemented the US EDIFACT transmission format. Passenger vessel carriers have been required to submit manifest data on Visa Waiver passengers in US EDIFACT since October 10, 2002, and therefore will require a period of time to convert to XML. This change has been made in cooperation with the USCG to facilitate transmission in the sea environment for the vessel carriers and is expected to be easily achieved.

(2) CBP recognizes that the conversion to UN EDIFACT will impose initial and subsequent operating expenses on the carriers. In fact, CBP itself has incurred considerable expense in programming its automated system to accept UN EDIFACT. See the economic impact analysis set forth in the ''Regulatory Assessment Under Executive Order (E.O.) 12866'' section of this document which concludes that this final rule constitutes a significant regulatory action because it requires the expenditure of over $100 million in any one year. However, CBP notes that UN EDIFACT was approved as the standard for transmission of Advance Passenger Information (API) data by the World Customs Organization in March 2003, and, thus, many air carriers would likely need to convert to UN EDIFACT (as many already have) to comply with the requirements of other countries, even if CBP APIS, and the requirements of this final rule, did not exist. Also, this final rule provides certain benefits to the carriers that are discussed in the E.O. 12866 analysis.

(3) In the air travel environment, although CBP will continue to accept e-mail transmissions for the foreseeable future, CBP may eventually phase out this method of transmission since it is generally considered to be less reliable. In the meantime, CBP will require the transmissions sent via email to be in UN EDIFACT format once UN EDIFACT becomes the operative format under the regulatory texts adopted in this final rule. Again, CBP has developed ''eAPIS'' (the web-based application located on the CBP web site) which became available to the carrier industry at the end of January 2005. Additional information on UN EDIFACT and points of contact for assistance can be accessed on the Internet at *http://www.cbp.gov* (related links).

Concerning the sea travel environment, the industry can access eNOA/D through the USCG's National Movement Vessel Center Web site (*http://www.nvmc.uscg.gov)*. The eNOA/D contains all information required to satisfy the USCG's Notice of Arrival (NOA) report requirements and CBP's electronic manifest requirements. Finally, for vessel carriers who do not have access to the Internet or do not wish to incur the On-line costs, they can either download the XML form provided on the USCG Web site or design their own XML form and e-mail it to the address provided on the USCG Web site above.

(4) Some of the commenters were confused with the statement in the preamble of the INS NPRM regarding conversion to UN EDIFACT not being required. To clarify, in order to comply with the statutory and regulatory requirements, conversion to UN EDIFACT will be necessary for air carriers. As already noted, UN EDIFACT is the API messaging format endorsed by the World Customs Organization, and, therefore, most air carriers would likely have to convert to UN EDIFACT to satisfy other government requirements regardless of this final rule.

(5) CBP published a draft UN EDIFACT Implementation Guide in March 2003 which was updated in March 2004. CBP will publish a final

UN EDIFACT Implementation Guide at *http://www.cbp.gov* (related links) as soon as practicable following publication of this final rule document.

(6) CBP assures the industry that it will work to ensure that the increased transmissions will not increase the risk of lost data. CBP has implemented specific programming to address the initial loss of data experienced after the publication of the Customs Interim Rule.

Comment: Three commenters asked for clarification on whether the electronic manifest requirement applies to carriers that transport crew only.

Response: For the national and aviation security reasons set forth in the governing statutes, as amended, CBP will require carriers (vessel and air) transporting only crew members to transmit arrival and departure manifests in accordance with the regulatory texts of this final rule. The provisions incorporated into this final rule to assist the TSA aviation security mission, which serve the same purposes, also require crew member and non-crew member manifest transmissions for cargo-only flights arriving in or departing from the United States (as well as for cargo-only flights continuing within (foreign air carriers only) and overflying the United States).

Comment: One commenter requested that the government match APIS manifest data through the passport number at the time of arrival only and thus not require the alien registration number, country of residence, or the U.S. address on the outbound manifest. Five commenters argued that the alien registration number requirement should be omitted from the final rule altogether (for inbound and outbound) since it can be retrieved by (legacy) INS systems. One commenter also alleged that it is difficult for an airline to know if a traveler has an alien registration card.

Response: Regarding the alien registration number, which must be submitted ''where applicable'' under 8 U.S.C. 1221(c)(9), as amended, and ''as appropriate'' under 49 U.S.C. 44909(c)(2)(E), as amended, CBP has determined that providing this information with respect to any LPR to whom an alien registration card has been issued, whether or not the card is required for travel, is an ''applicable'' and ''appropriate'' requirement. In other words, where a traveler is an LPR to whom an alien registration card has been issued, it is appropriate in, and applicable to, the situation at issue (international travel—arrival in and departure from the United States) to require that information, particularly given the national security, aviation security, and law enforcement purposes upon which the amendments to the laws predicating this regulatory action are based. Thus, under the circumstances, waiving this data element is not warranted.

Regarding the commenters' suggestion that the requirement to submit the alien registration card number can be removed from the regulation because this information can be obtained elsewhere, after looking into the possibility of automated retrieval of the alien registration number from other sources, CBP has concluded that the electronic manifest transmission systems required to comply with the amendments of this document currently lack this capability. Accordingly, the alien registration number requirement must be retained.

Comment: Five commenters expressed concern that the visa number, issuance country, and date of issuance data elements require manual input and thus will significantly delay processing times. The commenters also asserted that, with the transmission of the passport number, the visa information could be retrieved from the State Department database.

Response: CBP concurs. Regarding the U.S. visa number and date and place of visa issuance, CBP has determined that submission of this information under 8 U.S.C. 1221(c)(7) by the carrier is subject to the waiver of paragraph (h) of the statute. Because CBP will be able to obtain this information electronically from another source and does not wish to delay processing times unnecessarily, these elements have not been included in the regulatory texts set forth in this final rule document. The waiver of this requirement reduces the burden on carriers supplying information under these regulations, since these data elements would have required manual entry by carrier representatives.

Comment: Two commenters referred to the proposed requirement that the crew manifest be transmitted separately with an indicator ''C'' after the flight number to distinguish it as a crew manifest. These commenters noted that the new UN EDIFACT will require each traveler's status to be indicated, thus making the ''C'' designation requirement unnecessary.

Response: The proposed use of the indicator ''C'' (in the INS NPRM) was for manifest transmissions in US EDIFACT format only, to distinguish passenger manifests from crew manifests. This final rule does not require a ''C'' indicator under the UN EDIFACT format; however, TSA may require certain air carriers to add specific suffixes to the flight number to distinguish crew manifests. TSA will advise the affected air carriers accordingly.

Comment: One commenter sought clarification on the requirement for the transmission of a passenger's citizenship vis-a-vis the country of document issuance.

Response: As stated in a previous response to a comment relative to the regulatory text of the Customs Interim Rule that concerned the country of issuance of the passport, CBP will accept the country of travel document issuance data, contained in the machine-readable zone of the travel document, as the citizenship data. However, after commencement of transmission of aircraft manifest information in UN EDIFACT format, both data elements will be required separately. It should also be noted that citizenship data is required even if a travel document is not.

Comment: Four commenters requested omission of the country of residence requirement from the final rule since it requires manual entry and can only be determined through interview of the passenger.

Response: Notwithstanding the fact that this requirement will add to processing times, CBP believes that the requirement should be retained for arrivals. CBP routinely collects this data upon entry into the United States and all foreign nationals are required to provide this data on the I–94 form. Electronic submission of the country of residence, in advance, assists CBP in facilitating travelers' entry and evaluating risk assessments. However, CBP has determined that this data element need not be required for outbound passenger or crew manifests since this information is captured on the inbound manifests (subject to the caveat noted previously for crew and non-crew members who must provide the address of permanent residence).

Comment: One commenter asked that the Passenger Name Record (PNR) locator number requirement not be effective until December 15, 2003, so that the capability to satisfy this requirement can be developed. Eight commenters stated that a PNR locator number may not always be available and may, at times, be different for inbound and outbound manifests. Three commenters requested that the final regulation not require the creation of a unique identifier.

Response: This final rule does not require carriers to provide CBP access to a passenger's reservation data. The regulatory requirements for access to PNR information was published under a separate interim regulation, under 19

CFR 122.49b, which has been redesignated 19 CFR 122.49d in this final rule. This rule only requires submission of the PNR locator number. The locator number will be used by CBP to locate a passenger's passenger name record (PNR; reservation data) when available. A carrier will be responsible for transmission of the PNR locator only when UN EDIFACT becomes the required transmission format—180 days after publication of this final rule, well after the December 15, 2003 date mentioned by the commenter. With regard to the second comment, CBP recognizes that a PNR locator number may not always be available and may be different for inbound and outbound manifests. Therefore, CBP has determined that, for the time being, if the carrier's system does not contain PNR locator numbers, the carrier may leave this data element blank. The regulatory texts set forth in this final rule document have been modified to require the PNR locator only ''if available.'' Also, CBP will not require the transmission of a unique identifier number.

Comment: One commenter requested that sea carriers be allowed to transmit ''traveling manifests'' via APIS and be exempted from submitting the paper I–418, thus permitting full replacement of the paper I–418 by the APIS transmission. Two commenters similarly asked for elimination of the Form I–94.

Response: CBP's APIS system cannot currently accommodate the filing of traveling manifests. CBP believes that this capacity is beyond the scope and intent of the APIS system. With regard to the I–418 and I–94 forms, CBP intends to study whether, and if so to what extent, the transmission of APIS data can replace the submission of these paper forms. Preliminary analysis indicates that these documents can be significantly reduced, if not eliminated. However, this evaluation will not be completed by the effective date of this final rule and, therefore, the I–418 and I–94 will continue to be required. If CBP ultimately determines that these two paper forms can be eliminated entirely or in some circumstances, an appropriate regulatory change document will be published in the **Federal Register** for public comment at a future date.

Comment: One commenter requested that CBP work with the USCG to consolidate requirements and thus allow the data submitted to CBP to satisfy the passenger and crew manifesting requirements of the USCG.

Response: CBP and USCG have consolidated requirements to every extent possible. For instance, the INS NPRM's provision for submitting a vessel arrival manifest, in certain circumstances, less than 24 hours in advance of entry at a U.S. port (in proposed § 231.1(b)(2)(iii)) was removed from the regulatory text in this final rule and replaced with a submission time requirement acceptable to USCG. This modification was done to maintain consistency with USCG requirements. However, it is noted that the USCG has other manifesting requirements that cannot be addressed in an APIS regulatory context.

As mentioned in a previous comment response, CBP has adopted the use of the eNOA/D and XML in order to eliminate the duplicate reporting requirements and provide a ''single window'' for filing manifest information. For this purpose, commercial vessel carriers will utilize either of these methods to satisfy both USCG's and CBP's passenger and crew manifest submission requirements.

Comment: Five commenters expressed concern that the ''date of document expiration'' requires manual input for some travel documents. They suggested for this reason that this data requirement should be omitted from the regulation.

Response: CBP has determined that the ''date of document expiration'' data element is necessary for advance risk assessment. However, the date of expiration is also contained in the machine-readable zone of the passport. Therefore, manual input of this data element should be minimal.

Comment: One commenter asked for clarification as to whether the carrier will be liable if a traveler, due to dual citizenship, presents different travel documents when traveling into or out of the United States.

Response: CBP will not hold the carrier liable if the traveler, due to dual citizenship, presents different valid travel documents while traveling into or out of the United States. The carrier's responsibility, and liability for failure to meet it, relates to the proper transmission of travel document information provided by the traveler and a reasonable effort to obtain correct information.

Comment: Three commenters requested that Visa Waiver Program passengers not be refused entry due to inaccurate APIS transmissions.

Response: Upon arrival of a VWP passenger, the passport will be scanned and the inspector will be alerted to discrepant information. When resolved by the inspector as an incorrect transmission, the VWP passenger will be admitted. CBP does not intend to deny entry of a Visa Waiver Program passenger based solely on an incorrect APIS transmission.

Comment: Four commenters expressed concern regarding the penalties for non-compliance with the APIS regulatory requirements. The concerns were as follows:

(1) Whether the carriers will be penalized for the accuracy of those data elements that rely solely on the verbal declaration of the passengers (country of residence and U.S. destination address);

(2) Whether compliance with data element requirements under the regulations will affect a carrier's APIS compliance rate (previously calculated by the Customs Service);

(3) Whether notices of potential penalties should be e-mailed or faxed rather than mailed;

(4) Whether penalties should be waived if the carrier's compliance rate exceeds a certain level over a 1-year period; and

(5) Whether carriers will be penalized for discrepancies between the I–94 and the APIS transmission.

Response: (1) As addressed in a previous comment response, carriers must make a reasonable effort to ensure the information on the manifest appears valid.

(2) An APIS compliance rate will still be calculated and may encompass all elements of this regulation.

(3) Notices of penalties will be emailed or faxed when practicable. All carriers should ensure that local APIS port coordinators have current email addresses and fax numbers.

(4) Compliance with the provisions of this rule is necessary in order for CBP to facilitate the processing of travelers and properly conduct advance risk assessments. Therefore, CBP will not waive enforcement of these provisions simply because a carrier has demonstrated compliance for one year.

(5) CBP does not intend to penalize carriers for discrepancies between the I–94 and the APIS transmission. Passenger information is submitted to the carrier at check in. If it is apparently valid, carriers cannot be held accountable if a passenger later puts different information on the I–94 that is submitted at the time of arrival.

Comment: One commenter asked that air carriers be exempt from transmitting APIS manifest information from flights departing pre-inspection locations.

Response: APIS manifest information must be transmitted for pre-inspection location departures in order to perform law enforcement and national security checks that are not completed during the pre-inspection process. Also, the APIS transmissions are necessary to

satisfy United States Visitor and Immigrant Status Indicator Technology (US VISIT) requirements that were the subject of a rulemaking document published in the **Federal Register** (69 FR 468) on January 5, 2004.

Comment: One commenter asked for clarification of the process by which a carrier should cancel APIS manifests for a flight that was canceled after transmission.

Response: There is currently no method for a carrier to cancel a manifest after transmission. Accordingly, all references to reports of cancelled voyages or flights have been removed from the regulatory texts set forth in this final rule. Carriers should continue to follow current practices of notifying CBP of cancellations as soon as practicable.

VI. Changes to the Interim and Proposed Regulatory Texts

This final rule incorporates a few organizational changes and a number of textual changes from what was set forth in the regulatory texts of the Customs Interim Rule and the INS NPRM, including changes to assist TSA in its aviation security mission. All substantive changes are addressed below.

Organizational Changes

The principal organizational change involves a transfer of the operative manifest provisions contained in the INS NPRM (that is, the substance of the proposed revision of 8 CFR 231.1, which set forth the new passenger and crew manifest requirements for arriving and departing vessels and aircraft) to 19 CFR parts 4 and 122. This change is based on the following considerations: (1) As pointed out earlier in this document, the new manifest requirements will now be administered by one government agency, CBP; (2) the existing CBP regulations in Chapter I of Title 19 of the CFR already contain detailed requirements regarding the arrival and clearance for departure of commercial vessels and aircraft, including manifest reporting requirements covering incoming and outgoing cargo and electronic manifest requirements for passengers and crew members on arriving aircraft; and (3) use of the regulations by the affected industry sectors will be facilitated if the various provisions that apply to the same arrival or departure transaction are found in one place within the CFR.

Thus, with this transfer of the manifest provisions from 8 CFR to 19 CFR, the requirements for submitting manifest information relative to passengers and crew members arriving in and departing from the United States on board commercial vessels and aircraft will not be found in 8 CFR 231.1, as proposed in the NPRM. Instead, vessel manifest requirements will be found in 19 CFR 4.7b (arrivals) and 4.64 (departures), and aircraft manifest requirements will be found in 19 CFR 122.49a (passenger arrivals), 122.49b (crew member and non-crew member arrivals), 122.75a (passenger departures), and 122.75b (crew and non-crew departures), as set forth in the regulatory texts below.

Other organizational changes, made to accommodate the incorporation into this final rule of certain provisions to assist TSA in carrying out its aviation security responsibilities, include limiting the manifest requirement of 19 CFR 122.49a to arriving passengers (aircraft) and placing this requirement for arriving crew members in a new 19 CFR 122.49b. Manifest requirements for crew members and non-crew members on foreign flights continuing within and overflying the United States also have been placed in the new 19 CFR 122.49b. This change regarding new 19 CFR 122.49b necessitated redesignating former 19 CFR 122.49b pertaining to PNR information as 19 CFR 122.49d. New 19 CFR 122.49c pertaining to master crew member and non-crew member lists has been added. Manifest transmission requirements for departing passengers have been added in new 19 CFR 122.75a and, for departing crew members, new 19 CFR 122.75b.

Textual Changes to the Provisions of the Customs Interim Rule and the INS NPRM

(1) Conforming Amendments:

(a) Appropriate conforming changes have been made to proposed 8 CFR 217.7 regarding the Visa Waiver Program (VWP). In this final rule, this section now references 19 CFR 4.7b and 122.49a for electronic manifest requirements for aliens arriving in the United States as applicants under the VWP and 19 CFR 4.64 and 122.75a for electronic manifest requirements for aliens admitted under the VWP who are departing from the United States.

(b) The INS NPRM did not contain a proposed amendment to 8 CFR 231.2. In this final rule, appropriate conforming changes have been made to 8 CFR 231.2 to reflect that the electronic departure manifest requirements for passengers and crew are now found in 19 CFR 4.64, 122.75a, and 122.75b. Language regarding the I–94 has been retained in 8 CFR 231.2.

(2) Definitions: The definitions of proposed 8 CFR 231.1(a) of the INS NPRM have been removed from that section. These definitions, some of which have been revised, have been placed, as appropriate, in 19 CFR 4.7b(a), 4.64(a), 122.49a(a), 122.49b(a), 122.75a(a), and 122.75b(a) of this final rule. In addition, definitions for the following terms have been added, as appropriate, to these 19 CFR sections: ''carrier''; ''departure'' relative to aircraft (this term is defined for vessels in 19 CFR 4.0(g)); ''emergency''; ''flight continuing within the United States''; ''flight overflying the United States''; ''non-crew member''; and ''territorial airspace of the United States.'' Some of these definitions have been added due to the incorporation in this final rule of provisions that assist TSA in meeting its aviation security responsibilities. CBP notes that, for purposes of consistency (given that the electronic manifest filing provisions subject of this rulemaking are now contained in 19 CFR), the INS NPRM definition of ''ferry'' (now contained in 19 CFR 4.7b(a)) has been modified to be consistent with the definition of ''ferry'' found in 19 CFR 24.22(a)(4). The definition of ''crew member'' has been revised to encompass certain elements of 8 U.S.C. 1101(a)(10) and (a)(15)(D) (under which sections the term ''crewman'' is used) to reflect more accurately factors established by case law (alien crew members must further meet all additional requirements for such persons set forth in subparagraph (a)(15)(D)). In some instances, due to incorporation in this final rule of provisions related to the TSA aviation security mission, the definition includes ''relief crew'' (also known as ''deadheading crew'') and airline management personnel authorized to travel in the cockpit. However, CBP notes that, for all other purposes of immigration law and documentary evidence required under the Immigration and Nationality Act (8 U.S.C. 1101, *et seq.*), the term ''crew member'' (or ''crewman'') does not include relief crew or airline management personnel authorized to travel in the cockpit unless such persons otherwise fall within the definition of ''crewman'' as set forth in 8 U.S.C. 1101(a)(10) and (a)(15)(D), as applicable. CBP further notes that the definitions of ''crew member'' found in the amended texts of 19 CFR set forth in this document should not be applied in the context of other customs laws, to the extent these definitions differ from the meaning of ''crew member'' contemplated in such other customs laws.

(3) I–94 Form: Requirements concerning submission of the Form I–94 (Arrival/Departure Record), removal of

which from 8 CFR 231.1 was proposed in the INS NPRM, have been retained in this final rule. CBP has determined that, until further study of the matter is concluded, the I–94 requirement must be retained.

(4) Air Ambulances: Based on concerns from the industry, CBP has determined that an accommodation is warranted for flights by air ambulances, *i.e.*, aircraft operating for the purpose of servicing a medical emergency. (An air ambulance, or aircraft in service of a medical emergency, is not an aircraft experiencing a medical emergency on board; it is one that has been put in service for the specific purpose of attending to a medical emergency situation.) Therefore, the regulatory texts of this final rule, for arrivals and departures, reflect a relaxation of the passenger and crew manifest transmission requirement for such aircraft by providing that these carriers have up to 30 minutes prior to arrival to transmit arrival manifests and up to 30 minutes after departure to transmit departure manifests. In the departure context, this ''30 minutes after departure'' requirement does not comport with the ''before departure'' requirement of the statute, 8 U.S.C. 1221(b), as amended by the EBSA. However, in these narrow circumstances, the statutory requirement can be relaxed under the waiver of paragraph (h) of the statute.

(5) Emergencies: Based on comments received, CBP has determined that an accommodation is necessary for commercial aircraft and vessels diverted to a U.S. port due to an emergency. In cases of non-compliance, CBP will take into consideration that the carrier was not equipped to make the transmission and the circumstances of the emergency situation.

Thus, for flights not originally destined to the U.S., but diverted to a U.S. port due to an emergency, manifests are required to be submitted no later than 30 minutes prior to arrival. In the case of a vessel that was not destined to the United States but was diverted to a U.S. port due to an emergency, manifests are required to be submitted before the vessel enters the U.S. port or place to which diverted.

(6) Vessel manifest filing times: Based on comments received, the manifest filing (transmission) requirement for arriving vessels (found in proposed 8 CFR 231.1(b)(2) of the INS NPRM but placed in 19 CFR 4.7b(b)(2) in this final rule) has been changed in this final rule to provide that (i) for voyages of 96 hours or more, the manifest must be transmitted to CBP at least 96 hours before the vessel's entry at the first U.S. port or place of destination; (ii) for voyages of 24 hours but less than 96 hours, the manifest must be transmitted to CBP prior to the vessel's departure and (iii) for voyages of less than 24 hours, the transmission must be made 24 hours prior to the vessel's entry at the first U.S. port or place of destination. This requirement was modified to be consistent with USCG requirements.

(7) Departure port code: The departure port code data element contained in the Customs Interim Rule for arriving aircraft and in the INS NPRM for arriving vessels and aircraft has not been carried over into this final rule, as the APIS system can accommodate the transmission of only three location identifiers. The departure port code would be the fourth location identifier for passengers on arriving vessels and aircraft, and CBP has decided to remove it from the regulation. This data element is still required for vessel and aircraft departures.

(8) Passenger updates: While the INS NPRM provided for updates to departure passenger manifests, CBP has taken into consideration the aviation, transportation, and national security purposes this rule serves and has decided that passenger updates for departure manifests will not be included in the regulation.

(9) Timing of crew updates: Based on comments received, crew manifest updates relative to vessel arrivals (not provided for in the INS NPRM) must be transmitted at least 12 hours, and up to 24 hours, before the vessel enters a U.S. port. For vessel departures, manifest updates will be accepted up to 12 hours after departure from the U.S. port. Crew manifest updates relative to aircraft arrivals and departures require TSA approval if sought to be made within 60 minutes of departure. (See item (17) below regarding the content of crew and non-crew manifest updates which are required under the regulation.)

(10) DOD Exception: Based on specific concerns expressed by the Department of Defense (DOD), an exception to the electronic passenger manifest filing requirement for arrivals and departures has been added in this final rule document (in paragraph (c) of 19 CFR 4.7b, 4.64, 122.49a, and 122.75a) to apply to active duty U.S. military personnel traveling as passengers on board DOD vessels and aircraft. Neither the INS NPRM nor the Customs Interim Rule provided this exception. This exception applies to DOD aircraft and vessels as well as DOD controlled commercial chartered aircraft and vessels. Appropriate manifests will be required for crew members, non-active duty U.S. military personnel, and non-military personnel.

(11) Pre-inspected flights: The language found in 19 CFR 122.49a(a) of the Customs Interim Rule that refers to arriving flights with pre-inspected or pre-cleared passengers and crew being subject to the electronic manifest transmission requirement has not been carried over to the regulatory text of this final rule. (CBP notes that arriving crew members are covered in 19 CFR 122.49b of this final rule.) Although the transmission requirement still applies to flights with pre-inspected or pre-cleared passengers and crew, it is not necessary to explicitly state so in the regulation, which is sufficiently clear and unambiguous without it.

(12) U.S. Visa: Based on comments received, CBP will no longer require commercial air and vessel carriers to submit visa number, date, and place of visa issuance. This information will be obtained through other means.

(13) U.S. destination address: Based on comments received, the following exceptions have been made to the requirement to supply the U.S. destination address for passengers and crew members on commercial sea and air carriers:

(a) For arriving carriers, U.S. citizens, LPRs, crew members, and in-transit passengers are not required to provide a U.S. destination address (but note address of permanent residence requirement for crew and non-crew members in item (26) of this listing).

(b) For departing carriers, no passengers or crew members are required to provide a U.S. destination address (again, see item (26)).

(14) Conversion date to UN EDIFACT: Based on comments received, CBP has designated a conversion date of 180 days from publication of this final rule.

(15) eNOA/D and XML: Based on comments received, CBP adopted the use of USCG's eNOA/D and XML in order to eliminate duplicative manifest reporting requirements and provide the industry with a single window for electronic transmission of manifests.

(16) Country of residence: Based on comments received, CBP waived the requirement for country of residence for departing passenger and crew manifests (but note address of permanent residence requirement for crew and non-crew members in item (26) of this listing).

(17) Content of crew and non-crew manifest updates: Based on comments received, CBP will allow crew and non-crew manifest updates to contain only those records that require amendments in lieu of submission of the entire

manifest. However, CBP will still accept resubmission of the full manifest to comply with the updating requirements, should a carrier choose to do so.

(18) PNR locator number: Based on comments received, CBP will only require the PNR locator number if PNR information is available in the carrier's reservation or departure control system. CBP will not require the submission of a unique identifier.

(19) Accuracy of travel documents: Paragraph (d) of the Customs Interim Rule's 19 CFR 122.49a—requiring the air carrier to ensure (i) the accuracy of the travel document information transmitted to CBP, (ii) that the travel document appears valid, and (iii) that the passenger or crew member is the person to whom the travel document was issued—has been included as paragraph (d) in 19 CFR 4.7b, 4.64, 122.49b, 122.75a, and 122.75b in this final rule. Travel document information (consisting primarily of personal and document data) is the information the carrier obtains from the travel document and transmits to CBP (usually using machine-reading technology).

(20) Sharing of information: Paragraph (e) of 19 CFR 122.49a—providing for sharing of information with other Federal agencies upon request—has been included as paragraph (e) in 19 CFR 4.7b, 4.64, 122.49b, 122.75a, and 122.75b. Sharing of information is further permitted as otherwise authorized by law.

(21) The chart of 19 CFR 178.2, which was amended under the Customs Interim Rule to reflect an Office of Management and Budget (OMB) information collection control number relative to passenger and crew manifest information for arriving aircraft, is further amended in this final rule to reflect a new OMB control number relative to the new CBP (of the new DHS) for such manifest information and for manifest information for vessels and aircraft. The listing can now be found (in 19 CFR 178.2) in the appropriate column under 19 CFR 4.7b rather than under 19 CFR 122.49a where it was placed per the Customs Interim Rule (see ''Paperwork Reduction Act'' section). The complete listing is for 19 CFR 4.7b, 4.64, 122.49a, 122.49b, 122.49c, 122.75a, and 122.75b.

The following provisions will assist TSA in carrying out its aviation security responsibilities. CBP notes that these additional requirements (except those pertaining to overflights) are jointly authorized under 49 U.S.C. 44909, as amended by the ATSA, and 8 U.S.C. 1221, as amended by the EBSA, in the proper exercise of authority under these statutes by the Commissioner of CBP to ensure aviation safety, enforce the immigration laws, and enhance national security and the safety of the public. Some of these additions to this final rule are found in 19 CFR 122.49b (aircraft arrivals and flights continuing within and overflying the U.S.) and 19 CFR 122.75b (aircraft departures) as follows:

(22) Air carriers are subject to the electronic manifest transmission requirement for crew members (passenger and all-cargo flights), and non-crew members (all-cargo flights only) on flights to, from, continuing within (foreign air carriers only), and overflying the United States. These manifests must be transmitted through an electronic data interchange system approved by CBP.

(23) These crew and non-crew manifests must be transmitted to CBP no later than 60 minutes prior to departure of the aircraft.

(24) The carrier is obligated to report changes to the crew and non-crew manifest after transmission of the manifest to CBP. To make an effective change within 60 minutes of departure, TSA must approve the change. Without TSA approval, the flight may be denied clearance, diverted from arrival at a U.S. port, or denied clearance to enter the territorial airspace of the United States, as appropriate.

(25) With transmission of manifest data for each crew member and non-crew member onboard the flight, the carrier certifies that each crew member and non-crew member is listed on a master crew list and a master non-crew list separately transmitted to CBP, with updates as required. Where a crew member or non-crew member onboard is not on the appropriate list, or has not been on that list for the requisite period of time, the flight may be denied clearance, diverted from arrival in the United States, or denied clearance to overfly the United States.

(26) The following data elements, in addition to those already required for arriving or departing crew members under the Customs Interim Rule and the INS NPRM, as modified in this document, must be included in a crew member manifest: place of birth; address of permanent residence; and pilot certificate number and country of issuance, if applicable. This data submission requirement applicable to crew members onboard arriving and departing aircraft also applies to crew members and, for all-cargo flights only, non-crew members, onboard flights continuing within (foreign air carriers only) and overflying the United States. As set forth below, there are two exceptions to the crew and non-crew manifest requirements for FAA inspectors and DOD personnel.

(27) The crew member and non-crew member manifest requirement does not apply to properly credentialed and authorized Air Safety Inspectors of the Federal Aviation Administration (FAA); however, these FAA inspectors are considered passengers on arriving and departing flights subject to the passenger manifest requirements for arriving and departing aircraft (19 CFR 122.49a and 122.75a).

(28) The non-crew member manifest requirement, applicable only to all-cargo flights, does not apply to flights chartered by the U.S. DOD. (However, such persons are considered passengers under 19 CFR 122.75a pertaining to departing flights and would be subject to that electronic manifest requirement.)

In 19 CFR 122.49c of this final rule, TSA requirements relative to the master crew list and the master non-crew list are found. These requirements include the following:

(29) Each carrier operating flights to, from, continuing within (foreign air carriers only), or overflying the United States is obligated to transmit a master crew list and a master non-crew list to CBP through an electronic data interchange system approved by CBP. Initial transmission of these lists must occur at least 2 days in advance of any covered flight that any person on the list will operate, serve on, or be transported on. TSA will advise the carrier if any person on the list must be removed from the list. Only those persons approved by TSA will be permitted to operate, serve on, or be transported on the carrier's flights. The carrier is obligated to keep the list updated. Any updates to the list must be made at least 24 hours in advance of any flight the person who was added to the list, or who was subject of the update, will operate, serve on, or be transported on. Failure to comply with these requirements may result in denial of flight clearance, diversion of the flight, or denial of clearance to overfly the United States.

(30) The data required on the master lists is as follows: Full name; gender; address of permanent residence (street, city, state, if applicable, country); date of birth; place of birth; passport number and country of issuance; pilot certificate number, if applicable, and country of issuance; and status onboard the aircraft.

(31) Master crew lists are not required for aircraft chartered by the U.S. DOD. Properly credentialed and authorized FAA Aviation Safety Inspectors are not subject to the master list requirement.

VII. Conclusion

After careful consideration of the comments received in response to the Customs Interim Rule and the INS NPRM, and further review of the matter subject of those rulemakings, CBP has concluded that the proposed amendments of the INS NPRM to parts 217, 231, and 251, Immigration and Naturalization Regulations (8 CFR parts 217, 231, and 251), that were published in the **Federal Register** (68 FR 292) on January 3, 2003, and the interim amendments of the Customs Interim Rule to parts 122 and 178, Customs Regulations (19 CFR parts 122 and 178) that were published in the **Federal Register** (66 FR 67482) on December 31, 2001, should be incorporated into this final rule, with the modifications discussed above in the ''Comments'' and ''Changes'' sections, as set forth in the regulatory texts below. Also, provisions have been added to this rule to assist TSA in its aviation security mission. These provisions relate to the electronic transmission of manifest information covering crew members and non-crew members traveling onboard commercial flights to, from, continuing within (foreign air carriers only), and overflying the United States.

The above amendments of this final rule are published today in the interest of national security and to protect and safeguard the international traveling public and the commercial vessel and aviation industries during a time of considerable terrorist risk to those important interests.

Signing Authority

This amendment to the regulations is being issued in accordance with § 0.2(a) of the CBP regulations (19 CFR 0.2(a)) pertaining to the authority of the Secretary of the Department of Homeland Security (or his/her delegate) to prescribe regulations not related to customs revenue functions.

Regulatory Assessment Under Executive Order 12866

The final rule, which implements the amendments of section 115 of the ATSA and section 402 of the EBSA and includes provisions authorized under 49 U.S.C 114, is considered an economically significant regulatory action under Executive Order 12866 because it requires the expenditure of over $100 million in any one year. The Office of Management and Budget (OMB) has reviewed it under that order.

As discussed previously in the preamble of this rule, the primary impetus for this rule is the increased threat facing the United States and international trade and transportation industries, particularly the commercial air and vessel carrier industries, since the terrorist attacks of September 11, 2001. The Department of Homeland Security and its agencies, including CBP, TSA, and the U.S. Coast Guard, along with the air and vessel carrier industries, are called upon to take the necessary steps to alleviate, to the greatest extent possible, the risk to these vital industries posed by the threat of terrorism, including implementing regulations under the ATSA and the EBSA.

These regulations are being finalized to meet the objectives of the new laws: To secure the United States, international travelers, and the international air and sea industries from terrorist attacks. The enforcement and administration of these requirements will provide protection without unduly affecting international trade and travel.

Summary

We estimate that the cost of this final rule will be approximately $1 billion over a 10-year period (7 percent discount rate). In the first year this rule is in effect, we estimate the cost will be $166 million (undiscounted) as companies reprogram existing systems and purchase necessary equipment. Once reprogramming is complete and equipment is in place, we estimate an average annual cost of $135 million (undiscounted) as users submit information electronically. The annual cost is driven primarily by passenger counts and crew loads in air and cruise ship travel. The average annual cost reflects an average passenger count over the 10-year period of analysis based on a 2-percent annual increase in passenger loads for air carriers and a 6.4-percent annual increase in passenger loads for cruise ships.

Population Affected

This rule will affect commercial passenger and cargo air carriers and commercial passenger and cargo vessels. These entities will be required to submit electronic passenger and crewmember manifests for inbound and outbound flights and voyages. According to CBP databases, there are an estimated 1,280 foreign and domestic air carriers that will be affected by the final rule. Of these, 92 are large air carriers (11 U.S. carriers and 81 foreign carriers) and 1,188 are small air carriers (773 U.S. carriers and 415 foreign carriers). According to U.S. Coast Guard and CBP databases, there are 16 cruise-ship companies that own approximately 150 vessels. There are also 12,835 foreign and domestic cargo vessel carriers. An estimated 585 are U.S.-flag vessels certified to operate internationally, while approximately 12,250 are foreign-flag vessels that make ports of call in the United States.

Annual costs are driven by passenger and crew loads in the air and cruise ship industries. Based on CBP data, we estimate that 2004 passenger/crew loads in the air and cruise industries will be approximately 72 million and 16 million persons, respectively. We also predict a 2-percent annual increase in passenger loads for air carriers and a 6.4-percent annual increase in passenger loads for cruise ships for the 10-year period of analysis (percentages based on trend analysis of passenger and crew data starting with data from 1999). Thus, by 2013, predicted passenger/crew loads for the air and cruise industries are approximately 86 million and 28 million, respectively. Additionally, we assume that 95 percent of the total passenger/crew loads travel on large air carriers and 47 percent of these travel on U.S. carriers. Of the 5 percent of passenger/crew on small air carriers, and estimated 65 percent travel on U.S.-owned carriers. Complete detail is presented in Table 1.

TABLE 1.—PREDICTED PASSENGER/CREW COUNTS FOR AIR CARRIERS AND CRUISE SHIPS OVER THE 10-YEAR PERIOD OF ANALYSIS

Year	Large U.S. air carriers	Large foreign air carriers	Small U.S. air carriers	Small foreign air carriers	Total for air carriers	Cruise ships
1	32,084,327	36,180,199	2,335,365	1,257,504	71,857,396	16,095,618
2	32,726,014	36,903,803	2,382,073	1,282,655	73,294,544	17,125,737
3	33,380,534	37,641,879	2,429,714	1,308,308	74,760,435	18,221,784
4	34,048,145	38,394,716	2,478,308	1,334,474	76,255,643	19,387,978
5	34,729,108	39,162,611	2,527,875	1,361,163	77,780,756	20,628,809
6	35,423,690	39,945,863	2,578,432	1,388,387	79,336,371	21,949,053

TABLE 1.—PREDICTED PASSENGER/CREW COUNTS FOR AIR CARRIERS AND CRUISE SHIPS OVER THE 10-YEAR PERIOD OF ANALYSIS—Continued

Year	Large U.S. air carriers	Large foreign air carriers	Small U.S. air carriers	Small foreign air carriers	Total for air carriers	Cruise ships
7	36,132,164	40,744,780	2,630,001	1,416,154	80,923,099	23,353,792
8	36,854,807	41,559,676	2,682,601	1,444,477	82,541,561	24,848,435
9	37,591,903	42,390,869	2,736,253	1,473,367	84,192,392	26,438,735
10	38,343,741	43,238,687	2,790,978	1,502,834	85,876,240	28,130,814

There are an estimated 585 U.S.-flag vessels that are certified to operate internationally. Based on a Coast Guard analysis for vessel security requirements (USCG–2003–14792), most of these vessels are freight ships, tank ships, and small passenger vessels. Complete detail of the vessel population and the typical number of crewmembers onboard are presented in Table 2.

TABLE 2.—U.S.-FLAG VESSELS AND AVERAGE CREW COUNTS

	Number of vessels	Average crew count	Total crew-members
Freight ships	241	15	3,615
Tank ships	114	15	1,710
Small passenger vessels	109	10	1,090
Offshore Supply Vessels	75	4	300
Industrial vessels	20	5	100
Towboats	14	4	56
Research vessels	8	5	40
Mobile Offshore Drilling Units	2	10	20
Fishing	1	5	5
Oil recovery	1	3	3
Total	585	.....	6,939

According to CBP and the Coast Guard, there are approximately 12,250 foreign-flag cargo vessels that make ports of call in the United States annually, not including cruise ships, whose passengers and crew have already been accounted for in Table 1. The vast majority of these vessels are freight ships and tank ships. We assume that these foreign-flag vessels will each have a crew of 15, for a total of 183,750 crewmembers. Also according to CBP and the Coast Guard, there are approximately 55,000 annual arrivals into U.S. ports from foreign ports of call. With approximately 12,800 vessels in the affected population, this results in an average of 4 arrivals per vessel per year.

Regulatory Baseline

Much of the information that must be submitted under this final rule is already submitted electronically to CBP by large carriers, both air and sea. Most of the large air carriers were voluntarily submitting electronic passenger and crew member manifests to CBP as early as 1989, when a voluntary program was implemented. These carriers submitted APIS in the US EDIFACT format to the former Customs Service. Carriers voluntarily submitted these manifests in electronic format in exchange for expedited processing, with a maximum processing time per flight. Also, existing immigration regulations (those effective until the effective date of this final rule) have required that air and vessel carriers submit arrival and departure manifests electronically for passengers traveling pursuant to the Visa Waiver Program (VWP). In connection with this rulemaking, carriers informed CBP that it is more efficient for them to transmit electronic manifest information for all passengers, not just VWP passengers. Overall, a substantial majority of the carriers, over 80 percent, already submit arrival and departure manifests electronically for all passengers, including much of the information this rule requires. Moreover, many carriers would likely be investing in the implementation of UN EDIFACT transmission capability in the absence of this final rule because UN EDIFACT was selected as the transmission standard by the World Customs Organization in March 2003. Also, some carriers have, in fact, already converted to UN EDIFACT. While we calculate the costs of this rule as if the industry has not acted to meet the provisions of the rule, much of the industry is already compliant. We have estimated the full costs in order not to understate costs or assume that voluntary programs were more inclusive than they actually are.

For the most part, small air carriers and vessel carriers were not participating in the voluntary program. Thus, the compliance of small air carriers began either in anticipation of a final rule following publication of the interim rule in December 2001 or as the result of TSA Emergency Amendments and Security Directives mandating manifests via APIS. Cargo vessels will begin submitting electronic manifests upon publication of this rule. However, it should be noted that all of the above were required to submit these manifests in paper form prior to finalization of this rule.

Cost Analysis

Unit Costs

The source of the estimates provided in the following tables is the U.S. Department of Homeland Security, the Bureau of Customs and Border Protection, or the Transportation Security Administration, September 2004. All costs are presented in 2004 dollars.

For this analysis, we estimate the one-time start-up costs that will be incurred in the first year the final rule is in effect as carriers modify their existing systems and purchase necessary equipment.

Following the first year, carriers will experience annual operating costs for submitting their information electronically and maintenance for their computer systems. The following is a summary of estimated unit costs for the various components of the affected population.

Large air carriers—The 92 large air carriers will incur computer programming costs associated with conversion from US EDIFACT to UN EDIFACT. According to the International Air Transport Association (IATA), the average cost for the conversion is $400,000 per carrier. Large air carriers will also have to modify their existing systems to submit master crew lists and update these lists as necessary. Since we published this estimate in the NPRM, we have received new information from seven carriers who have made the conversion to UN EDIFACT in anticipation of this rule and compliance with transmission standards of the World Customs Organization. The costs for conversion ranged from $331,000 to $500,000. Thus, we assume the cost to convert to UN EDIFACT plus the cost of system modifications to include the master crew list will be $500,000 in the first year the rule is in effect and $25,000 (5 percent of initial costs) in subsequent years as carriers make small programming changes.

Following conversion to UN EDIFACT, carriers will assume a transaction cost per passenger/crew member. These transaction costs will be incurred each year over the period of analysis. We estimate that the cost to submit the required passenger/crew information would be $1 for inbound traveler and $0.25 for outbound traveler. Using wage data from the Bureau of Labor Statistics, we estimate that, as a national average, counter and rental clerks, travel agents, and flight attendants earn $18.57 per hour without fringe benefits or about $25 per hour once the rate is ''loaded'' to include benefits. Assuming one to two minutes of added time, the additional cost would be between $0.42 and $0.84 per transaction. Because some additional training would be required to become proficient with the new system, CBP assumes that the added cost could be as high as $1 per transaction. Because only machine-readable zone data are collected on outbound trips, we assume a cost of $0.25 per transaction.

Additionally, we estimate the cost of transmitting overflight data and crew manifest data to comply with requirements from TSA Emergency Amendments and Security Directives. There are an estimated 16,800 overflights in 2004, and they are estimated to increase at a 4.9 percent rate over the 10-year period of analysis. TSA estimates the transmission cost for submitting overflight and crew information is $2.50 per submission, assuming the submission will require 10 minutes of time at a cost of $15.00 per hour. Because we cannot discern which overflights are made by large carriers versus small carriers, we include overflight costs in the ''large foreign air carrier'' component. We estimate that overflight information will cost carriers $42,000 in year 1 and $64,599 in year 10, with the increase in overflights over the period of analysis.

Finally, TSA estimates that large air carriers will submit modifications to their master crew lists an average of once per week, or 52 times per year. Again, TSA estimates this will cost $2.50 per submission, for a per-carrier cost of $130 annually.

Based on CBP data, we estimate that 95 percent of the passenger/crew loads are onboard large air carriers. Operational costs are expected to increase over the period of analysis as passenger loads increase from 68 million in year 1 to 82 million in year 10 (2 percent increase in passenger loads annually). The calculation of first-year and annual costs (undiscounted) for large air carriers, U.S. and foreign, is shown in Tables 3 and 4.

TABLE 3.—TOTAL COSTS FOR LARGE U.S. AIR CARRIERS (11 CARRIERS)

Year	UN EDIFACT conversion	Passenger/crew information*	Master crew list modifications**	Total costs
1	$5,500,000	$40,105,409	$1,430	$45,606,839
2	275,000	40,907,517	1,430	41,183,947
3	275,000	41,725,668	1,430	42,002,098
4	275,000	42,560,181	1,430	42,836,611
5	275,000	43,411,385	1,430	43,687,815
6	275,000	44,279,612	1,430	44,556,042
7	275,000	45,165,205	1,430	45,441,635
8	275,000	46,068,509	1,430	46,344,939
9	275,000	46,989,879	1,430	47,266,309
10	275,000	47,929,676	1,430	48,206,106
Total				447,132,341

* Passenger/crew loads from Table 1 × $1.25
** 11 carriers × 52 modifications per year × $2.50 transaction cost

TABLE 4.—TOTAL COSTS FOR LARGE FOREIGN AIR CARRIERS (81 CARRIERS)

Year	UN EDIFACT conversion	Passenger/crew information*	Master crew list modifications**	Overflight information***	Total costs
1	$40,500,000	$45,225,249	$10,530	$42,000	$85,777,779
2	2,025,000	46,129,754	10,530	44,058	48,209,342
3	2,025,000	47,052,349	10,530	46,217	49,134,095
4	2,025,000	47,993,396	10,530	48,481	50,077,407
5	2,025,000	48,953,264	10,530	50,857	51,039,651
6	2,025,000	49,932,329	10,530	53,349	52,021,208
7	2,025,000	50,930,975	10,530	55,963	53,022,469
8	2,025,000	51,949,595	10,530	58,705	54,043,830
9	2,025,000	52,988,587	10,530	61,582	55,085,699

TABLE 4.—TOTAL COSTS FOR LARGE FOREIGN AIR CARRIERS (81 CARRIERS)—Continued

Year	UN EDIFACT conversion	Passenger/crew information*	Master crew list modifications**	Overflight information***	Total costs
10	2,025,000	54,048,359	10,530	64,599	56,148,488
Total					554,559,967

* Passenger/crew loads from Table 1 × $1.25
** 81 carriers × 52 modifications per year × $2.50 transaction cost
*** Annual overflights × $2.50 transaction cost per overflight (16,800 overflights in 2004, 25,840 overflights in 2013 assuming a 4.9 percent annual increase)

Small air carriers—The 1,188 small air carriers, rather than converting to UN EDIFACT, will be able to use eAPIS, an internet-based submission system developed by CBP that complies with UN EDIFACT standards. These carriers may also continue to email manifests. To access eAPIS or transmit manifests via email, these carriers will need to have access to a desktop computer with compatible software and Internet access (for eAPIS only). Most, if not all, small air carriers already have desktop computers with the software necessary to access eAPIS or transmit email. In order not to underestimate the costs of this final rule to small carriers, however, we attribute a $500 cost for a computer system to each carrier. This cost will be incurred in year 1, when the final rule becomes effective, and in year 5, assuming that a computer will last for 5 years and will then need to be replaced.

We should note that large air carriers may also use eAPIS and other alternative transmission methods, though their large inbound and outbound passenger volumes make widespread use impractical. Historically, some large carriers have employed the email alternative to transmit manifests for primarily small crews. For this analysis, we assume that the 92 large carriers will undergo conversion to UN EDIFACT, as estimated above.

We estimate annual maintenance for the computer to be 10 percent of the initial cost of the computer, or $50 annually. This cost will be incurred each year of the period of analysis. As noted previously, we estimate that 5 percent of air passengers and crew are aboard small carriers and will cost $1.25 per person to submit their information through eAPIS. This cost may overstate per-person transmission costs because the eAPIS system will allow small carriers to save manifest data for reuse on subsequent flights and will allow users to select previous crew or passenger records for automatic input into the manifest. Small carrier personnel will also not require extensive training to use eAPIS.

Finally, TSA estimates that small air carriers will submit modifications to their master crew lists an average of once per month, or 12 times per year. Again, TSA estimates this will cost $2.50 per submission, for a per-carrier cost of $30 annually. The costs for submitting overflight information have already been captured above in the ''large air carrier'' component. The calculation of first-year and annual costs (undiscounted) for small air carriers, U.S. and foreign, is shown in Tables 5 and 6.

TABLE 5.—TOTAL COSTS FOR SMALL U.S. AIR CARRIERS (773 CARRIERS)

Year	Desktop computer costs	Passenger/crew information*	Master crew list modifications**	Total costs
1	$386,500	$2,919,207	$23,190	$3,328,897
2	38,650	2,977,591	23,190	3,039,431
3	38,650	3,037,143	23,190	3,098,983
4	38,650	3,097,886	23,190	3,159,726
5	38,650	3,159,843	23,190	3,221,683
6	425,150	3,223,040	23,190	3,671,380
7	38,650	3,287,501	23,190	3,349,341
8	38,650	3,353,251	23,190	3,415,091
9	38,650	3,420,316	23,190	3,482,156
10	38,650	3,488,722	23,190	3,550,562
Total				33,317,249

* Passenger/crew loads from Table 1 × $1.25
** 773 carriers × 12 modifications per year × $2.50 transaction cost

TABLE 6.—TOTAL COSTS FOR SMALL FOREIGN AIR CARRIERS (415 CARRIERS)

Year	Desktop computer costs	Passenger/crew information*	Master crew list modifications**	Total costs
1	$207,500	$1,571,881	$12,450	$1,791,831
2	20,750	1,603,318	12,450	1,636,518
3	20,750	1,635,385	12,450	1,668,585
4	20,750	1,668,092	12,450	1,701,292
5	20,750	1,701,454	12,450	1,734,654
6	228,250	1,735,483	12,450	1,976,183
7	20,750	1,770,193	12,450	1,803,393
8	20,750	1,805,597	12,450	1,838,797

TABLE 6.—TOTAL COSTS FOR SMALL FOREIGN AIR CARRIERS (415 CARRIERS)—Continued

Year	Desktop computer costs	Passenger/crew information*	Master crew list modifications**	Total costs
9	20,750	1,841,709	12,450	1,874,909
10	20,750	1,878,543	12,450	1,911,743
Total				17,937,903

* Passenger/crew loads from Table 1 × $1.25
** 415 carriers × 12 modifications per year × $2.50 transaction cost

Cruise ship companies—There are 16 cruise ship companies that will convert to an XML format to comply with the electronic submission requirements of this final rule. These 16 carriers dominate the industry. Few, if any, small cruise companies make voyages to the United States, and we do not include any in this analysis. Based on data received from the International Council of Cruise Lines (ICCL), average conversion costs will be $125,000 per company. This figure is the estimate for conversion to UN EDIFACT, and the conversion to XML should be no higher than this figure. This cost will be incurred the first year the rule is in effect. As with large air carriers, we estimate a 5 percent annual programming cost once the initial major conversion is complete in the first year.

CBP estimates a 6.4 percent annual increase in passenger loads for the cruise line industry, with an estimated 16 million passengers in year 1 and 28 million passengers in year 10; thus annual operational costs will increase with passenger loads. We assume a $1.25 transaction cost per passenger and crew member on cruise ships. The calculation of first-year and annual costs (undiscounted) for cruise ship companies is shown in Table 7.

TABLE 7.—TOTAL COSTS FOR CRUISE SHIP COMPANIES (16 COMPANIES)

Year	XML format conversion	Passenger/crew information*	Total costs
1	$2,000,000	$20,119,522	$22,119,522
2	100,000	21,407,171	21,507,171
3	100,000	22,777,230	22,877,230
4	100,000	24,234,973	24,334,973
5	100,000	25,786,011	25,886,011
6	100,000	27,436,316	27,536,316
7	100,000	29,192,240	29,292,240
8	100,000	31,060,544	31,160,544
9	100,000	33,048,419	33,148,419
10	100,000	35,163,517	35,263,517
Total			273,125,944

*Passenger/crew loads from Table 1 × $1.25

U.S.-flag cargo vessels—There are 585 U.S.-flag vessels that will use ''eNOA/D,'' a low-cost web-based system, to comply with the requirements of the final rule. While a Coast Guard system, eNOA/D will automatically transmit the necessary data to CBP, thus eliminating duplicate submissions to both agencies. As with small air carriers, the cost to these vessels will be a desktop computer with minimal software requirements and Internet access. Again, in order not to underestimate the costs to U.S.-flag cargo vessels, we assign a $500 computer cost to each vessel. This cost will be incurred in year 1, when the final rule becomes effective, and in year 5, assuming that a computer will last for 5 years and will then need to be replaced. We estimate that maintenance will be $50 annually.

Average crew size for different types of vessels was presented in Table 2, and we estimate the crew population for U.S. vessels to be 6,939. Crew information will need to be submitted via eNOA/D each time the vessel enters a U.S. port after departing a foreign port. As calculated above, we estimate that vessels will have an average of approximately 4 foreign arrivals annually (55,000 annual arrivals ÷ 12,835 total cargo vessels). While this estimate is probably low for some vessel services (such as offshore supply vessels), it is probably high for other services (container ships or vessels in tramp service). We assume that crew counts per vessel will remain constant over the period of analysis, and we do not assume a growth rate for the U.S. fleet. The calculation of first-year and annual costs (undiscounted) for U.S.-flag cargo vessels is shown in Table 8.

TABLE 8.—TOTAL COSTS FOR U.S.-FLAG CARGO VESSELS (585 VESSELS)

Year	Desktop computer costs	Crew information*	Total costs
1	$292,500	$34,695	$327,195
2	29,250	34,695	63,945
3	29,250	34,695	63,945
4	29,250	34,695	63,945
5	29,250	34,695	63,945

TABLE 8.—TOTAL COSTS FOR U.S.-FLAG CARGO VESSELS (585 VESSELS)—Continued

Year	Desktop computer costs	Crew information*	Total costs
6	321,750	34,695	356,445
7	29,250	34,695	63,945
8	29,250	34,695	63,945
9	29,250	34,695	63,945
10	29,250	34,695	63,945
Total			1,195,200

*6,939 crewmembers × $1.25 × 4 arrivals.

Foreign-flag cargo vessels—There are approximately 12,250 foreign-flag cargo vessels (not including cruise ships described previously) that will also use eNOA/D to comply with the requirements of the final rule. We again assign a $500 computer cost to each vessel. This cost will be incurred in year 1, when the final rule becomes effective, and in year 5, assuming that a computer will last for 5 years and will then need to be replaced.

We estimate annual maintenance for the computer to be 10 percent of the initial cost of the computer, or $50 annually, and the cost will be incurred each year of the period of analysis. The overwhelming majority of foreign-flag vessels arriving here from foreign ports are freighters and tankers, with an average crew size of 15 people, for a total of 183,750 crewmembers. As calculated above for U.S.-flag vessels, we estimate that vessels will have an average of 4 foreign arrivals annually. We assume that crew counts per vessel will remain constant over the period of analysis, and we do not assume a growth rate for the foreign fleet trading with the United States. The calculation of first-year and annual costs (undiscounted) for foreign-flag cargo vessels is shown in Table 9.

TABLE 9.—TOTAL COSTS FOR FOREIGN-FLAG CARGO VESSELS (12,250 VESSELS)

Year	Desktop computer costs	Crew information*	Total costs
1	$6,125,000	$918,750	$7,043,750
2	612,500	918,750	1,531,250
3	612,500	918,750	1,531,250
4	612,500	918,750	1,531,250
5	612,500	918,750	1,531,250
6	6,737,500	918,750	7,656,250
7	612,500	918,750	1,531,250
8	612,500	918,750	1,531,250
9	612,500	918,750	1,531,250
10	612,500	918,750	1,531,250
Total			$26,950,000

*$183,750 crewmembers × $1.25 × 4 arrivals.

Total Costs

Total costs for the above components are presented in the following tables. Costs to U.S. carriers are presented in Table 10 and foreign carriers in Table 11. Total final cost estimates are discounted to their present value at a 7-percent rate and shown in Table 12. As shown, the present value cost of the final rule is approximately $1 billion. Because passenger/crew loads are the primary cost drivers, large carriers comprise almost 75 percent of the costs of this rule. As stated previously, CBP estimates that 80 percent of the large air carriers already submit the information required under the final rule under the voluntary APIS program. These carriers would have converted to UN EDIFACT even in the absence of this final rule, and many carriers have started their conversion in anticipation of the new requirements. Thus, these costs likely overstate the impacts to industry but provide a good estimate of the magnitude of costs that are associated with the APIS program, TSA security directives, and other requirements that have not been accounted for in previous regulatory assessments.

TABLE 10.—TOTAL COSTS OF THE FINAL RULE TO U.S. ENTITIES, UNDISCOUNTED

Year	Large U.S. air carriers	Small U.S. air carriers	U.S.-flag cargo vessels	Total costs
1	$45,606,839	$3,328,897	$327,195	$49,262,931
2	41,183,947	3,039,431	63,945	44,287,323
3	42,002,098	3,098,983	63,945	45,165,025
4	42,836,611	3,159,726	63,945	46,060,282
5	43,687,815	3,221,683	63,945	46,973,443
6	44,556,042	3,671,380	356,445	48,583,867
7	45,441,635	3,349,341	63,945	48,854,920
8	46,344,939	3,415,091	63,945	49,823,975

TABLE 10.—TOTAL COSTS OF THE FINAL RULE TO U.S. ENTITIES, UNDISCOUNTED—Continued

Year	Large U.S. air carriers	Small U.S. air carriers	U.S.-flag cargo vessels	Total costs
9	47,266,309	3,482,156	63,945	50,812,410
10	48,206,106	3,550,562	63,945	51,820,614
Total	447,132,341	33,317,249	1,195,200	481,644,790

TABLE 11.—TOTAL COSTS OF THE FINAL RULE TO FOREIGN ENTITIES, UNDISCOUNTED

Year	Large foreign air carriers	Small foreign air carriers	Cruise ship companies	Foreign-flag cargo vessels	Total costs
1	$85,777,779	$1,791,831	$22,119,522	$7,043,750	$116,732,881
2	48,209,342	1,636,518	21,507,171	1,531,250	72,884,281
3	49,134,095	1,668,585	22,877,230	1,531,250	75,211,160
4	50,077,407	1,701,292	24,334,973	1,531,250	77,644,922
5	51,039,651	1,734,654	25,886,011	1,531,250	80,191,566
6	52,021,208	1,976,183	27,536,316	7,656,250	89,189,957
7	53,022,469	1,803,393	29,292,240	1,531,250	85,649,352
8	54,043,830	1,838,797	31,160,544	1,531,250	88,574,421
9	55,085,699	1,874,909	33,148,419	1,531,250	91,640,276
10	56,148,488	1,911,743	35,263,517	1,531,250	94,854,998
Total	554,559,967	17,937,903	273,125,944	26,950,000	872,573,814

TABLE 12.—TOTAL COSTS OF THE FINAL RULE

Year	Undiscounted			Discounted (7 percent discount rate)		
	U.S. entities	Foreign entities	Total	U.S. entities	Foreign entities	Total
1	$49,262,931	$116,732,881	$165,995,812	$49,262,931	$116,732,881	$165,995,812
2	44,287,323	72,884,281	117,171,604	41,390,022	68,116,151	109,506,172
3	45,165,025	75,211,160	120,376,186	39,448,882	65,692,340	105,141,223
4	46,060,282	77,644,922	123,705,204	37,598,910	63,381,385	100,980,295
5	46,973,443	80,191,566	127,165,009	35,835,815	61,177,762	97,013,576
6	48,583,867	89,189,957	137,773,825	34,639,626	63,591,207	98,230,833
7	48,854,920	85,649,352	134,504,272	32,554,096	57,071,779	89,625,876
8	49,823,975	88,574,421	138,398,395	31,027,867	55,159,698	86,187,565
9	50,812,410	91,640,276	142,452,686	29,573,285	53,335,475	82,908,760
10	51,820,614	94,854,998	146,675,612	28,186,980	51,594,834	79,781,814
Total	481,644,790	872,573,814	1,354,218,604	359,518,415	655,853,512	1,015,371,927

Regulatory Alternatives

The requirements of this final rule are mandated by the ATSA and the EBSA. Exploration of regulatory alternatives, therefore, was limited during the rulemaking process, as these legislative acts were explicit in the types of systems to be installed and the type of information to be submitted. CBP has, however, developed alternative submission methods for small air carriers, while the Coast Guard has developed alternative methods for vessels. These alternative methods should help small businesses comply with the final rule in the most cost-effective manner. The three alternatives considered in this assessment are presented below.

No Action Alternative

The ''no action'' alternative is not a feasible alternative because it does not meet legislative mandates.

The Final Rule

As presented above, the final rule is expected to cost $166 million in the first year, an average of $135 million annually, and $1.015 billion over the period of analysis (discounted at 7 percent).

The Final Rule Without Low-Cost Alternatives for Small Air Carriers

In response to public comment and in order to provide better service to our customers, CBP developed eAPIS to allow small air carriers to submit their information electronically without a full conversion to UN EDIFACT. These carriers may also submit their information in email and XML formats. If CBP did not allow these submission exceptions, the cost would be an estimated $7,000 to $9,000 per carrier to develop software. Additionally, the Coast Guard has developed eNOA/D similarly to accept electronic submissions simply and cheaply. If small air carriers and vessels had to spend an average of $8,000 in the first year to develop the necessary systems (and assuming large air carriers and cruise ships used the same submission methods as described in the final rule), this alternative would result in a first-year cost of $271 million, average annual costs of $150 million, and 10-year costs of $1.148 billion (discounted at 7 percent). Over 10 years, this alternative would cost small air carriers and vessels $133 million more than with low-cost alternative submission methods ($1.148 billion without the

low-cost alternative minus $1.015 billion for the final rule).

Benefit Analysis

Under the provisions of this final rule, CBP will conduct advance record checks of persons traveling on flights to and from the United States for the purpose of detecting inadmissible or removable aliens, dangerous criminals, known or potential terrorists, and others that pose risks of committing violations of our nation's laws. CBP will prescreen the names of passengers and crew against lists of these persons and a list of ''no-fly'' designees. CBP will also conduct advance record checks and prescreening of passengers and crewmembers onboard arriving and departing vessels. CBP will also be able to analyze the patterns and associations of alien smugglers.

The advance prescreening of passengers arriving in the United States prior to arrival enables CBP to process low-risk travelers expeditiously while focusing on high-risk travelers who may pose a threat to national security, international transportation, and other travelers. However, CBP continues to evaluate whether the transmission of manifest data for aircraft passengers and for passengers and crew onboard departing vessels, in accordance with the provisions of this final rule, allows CBP sufficient time to respond to identified threats.

Because CBP has been receiving similar data from the commercial air carriers on a voluntary basis for over a decade, CBP can report positive results from access to this data. For example, in the CBP ''Performance and Annual Report FY 2002 and FY 2003,'' it is reported that CBP targeting efficiency was 29.1 (FY 02) and 29.7 (FY 03) times better than random compliance exams.

The information obtained through this final rule enhances safety and security as the applicable flights may present a risk to the safety of international travelers, the international transportation industry, and to national security. Having pertinent and timely information relative to crewmembers and non-crewmembers can mitigate this threat.

Use of UN EDIFACT will improve transmission of required electronic manifest data for aircraft, since under US EDIFACT, the carriers cannot submit all the data elements required by law, and, therefore, CBP cannot conduct risk assessments with the level of detail desired. If the US EDIFACT format were retained, it would cause delays in passenger processing due to CBP inspectors having to ask passengers additional immigration-related questions that will be automatically collected under UN EDIFACT and would result in passengers missing connecting flights, at additional expense to the carrier and affected passengers.

As discussed previously, UN EDIFACT was adopted as the global technical standard for transmission of electronic passenger and crewmember manifests. Other countries, including Canada, Mexico, United Kingdom, and Costa Rica, are implementing or have indicated that they intend to implement UN EDIFACT to transmit manifests. Several other countries are awaiting legislation and conducting feasibility studies.

APIS is recognized by the international community as a facilitative tool for passenger processing. Airline industry organizations have also traditionally supported APIS as a means of mitigating processing times as passenger counts increase. Submission of APIS by air carriers results in an average of 45 minutes per flight passenger processing times. Also, according to the World Customs Organization UN EDIFACT PAXLIST guidelines, additional passenger data captured at booking or check-in could, in some instances, enhance airline security and ensure that all passengers carry valid travel documents required for admission to the destination country. Carriers complying with APIS may also achieve the additional benefit of reduced penalties for inaccurate and/or incomplete manifest submissions. According to the Cost Management Information System, the average cost of processing an improperly documented passenger is $1,507 per person.

This rule requires each carrier to provide the advance passenger manifest information in advance of the aircraft's arrival or departure. When a carrier transmits less than 100 percent of the required information, a CBP officer must manually enter the APIS information and wait for query results. Passengers awaiting CBP clearance would be subsequently delayed. This could result in costly inspections and flight delay. Each hour of delay costs $3,372 per flight. (For this cost figure, see: Massachusetts Institute of Technology, Lincoln Laboratory, Delay Causality and Reduction at the New York City Airports Using Terminal Weather Information Systems. Project Report ATC–291, by S.S. Allan, S.G. Gaddy, and J.E. Evans, February 16,2001.) Additionally, airlines could incur costs for rerouting individuals unable to make original connections.

As discussed previously, CBP developed eAPIS, a web based application, for small air carriers to submit their manifests in UN EDIFACT format. The Coast Guard developed eNOA/D for vessels. Additionally, this rule adopts the use of XML for cruise ship companies. This change eliminates duplicative reporting requirements for CBP and the Coast Guard. If CBP had required that cruise companies convert to UN EDIFACT, the carriers would have had to convert their system to accommodate two different manifest submission systems. Finally, vessels will now submit their requirements electronically, which should save time, particularly as recurrent data is stored and automatically retrieved.

Taken in their entirety, the benefits include safer and more secure air and vessel transits; reduced delay from incomplete information; more user-friendly submission methods than paper submissions; and low-cost alternatives to full conversion to UN EDIFACT.

Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circ*), in Table 13, CBP has prepared an accounting statement showing the classification of the expenditures associated with Electronic Transmission of Passenger and Crew Manifests for Vessels and Aircraft. The table provides our best estimate of the dollar amount of these costs and benefits, expressed in 2004 dollars, at three percent and seven percent discount rates. We estimate that the cost of this final rule will be approximately $135 million annualized (7 percent discount rate) and approximately $135 million annualized (3 percent discount rate). The non-quantified benefits are enhanced security.

TABLE 13.—ACCOUNTING STATEMENT: CLASSIFICATION OF EXPENDITURES, 2005 THROUGH 2014 (2004 DOLLARS)

Three Percent Annual Discount Rate	
Benefits:	
Annualized monetized benefits.	
(Un-quantified) benefits	Enhanced security.
Costs:	
Annualized monetized costs	$135 million.
Annualized quantified, but un-monetized costs..	
Qualitative (un-quantified) costs.	
Seven Percent Annual Discount Rate	
Benefits:	
Annualized monetized benefits.	
(Un-quantified) benefits	Enhanced security.
Costs:	
Annualized monetized costs	$135 million.
Annualized quantified, but un-monetized costs.	
Qualitative (un-quantified) costs.	

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget.

Regulatory Flexibility Act

We have prepared this Final Regulatory Flexibility Act Analysis (FRFA) to examine the impacts of the final rule on small entities as required by the Regulatory Flexibility Act. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

In preparing this final rule, CBP has taken into consideration the importance of minimizing its impact on small businesses. CBP has consulted with a number of the affected entities, including the National Business Aviation Association (NBAA), National Air Carrier Association (NACA), Air Transport Association (ATA), International Air Transport Association (IATA), World Shipping Council, National Association of Maritime Organizations and other appropriate associations. Also, CBP has considered the views of interested persons commenting on the amendments of the Customs Interim Rule and the INS NPRM. In addition, CBP has been working with TSA to incorporate provisions of interest to TSA relating to aviation security. These provisions are consistent with the authority of CBP and, to a large extent, the provisions of the Customs Interim Rule and the INS NPRM regarding submission of manifest information for arriving and departing aircraft. Also included in the TSA related provisions of this final rule are provisions for flights continuing within (foreign air carriers only) and overflying the United States and provisions relative to submission of master lists for crew members and non-crew members.

This FRFA addresses the following.

- The reason the agency is considering this action.
- The objectives of and legal basis for the rule.
- The number and types of small entities to which the rule will apply.
- Projected reporting, recordkeeping, and other compliance requirements of the rule, including the classes of small entities that will be subject to the requirements and the type of professional skills necessary for the preparation of the reports and records.
- Other relevant Federal rules that may duplicate, overlap, or conflict with the rule.
- Significant alternatives to the component under consideration that accomplish the stated objectives of applicable statutes and may minimize any significant economic impact of the rule on small entities.
- Significant issues that have been assessed.

Reason for Agency Action

This rule finalizes the Customs Interim Rule issued on December 31, 2001, and the NPRM issued on January 3, 2003, which, together (one rule's provisions being effective, the other's being proposed), required the electronic submission of passenger and crewmember manifests for inbound and outbound flights and voyages. This rule also incorporates crew manifesting requirements published under the TSA EAs and SDs.

Objective and Legal Basis for Rule

This final rule implements the amendments of section 115 of the Aviation and Transportation Security Act (ATSA) and section 402 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (EBSA) and includes provisions authorized under 49 U.S.C. 114. As fully discussed in the preamble and the Executive Order sections, this rule will serves to assist CBP and DHS in securing the United States, international travelers, and the international air and sea industries from terrorist attack and from violations of various customs and other applicable laws.

Number of Small Entities Affected

A ''small entity'' is defined under the RFA to be the same as a ''small business concern'' as defined under the Small Business Act (SBA; 15 U.S.C. 632). Thus, a small entity (also referred to as a small business or small carrier) for RFA purposes is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) meets any additional criteria set forth under the SBA. In accordance with provisions of the U.S. Small Business Administration (the USSBA), air carriers that employ fewer than 1,500 employees and sea carriers that employ fewer than 500 employees are small carriers.

As discussed in the Regulatory Assessment section of this preamble, a CBP database identifies, as of August 2004, 773 U.S.-based small air passenger and cargo carriers. Also, Coast Guard data for international cargo vessel entries revealed 88 additional U.S. companies owning 585 U.S.-flag vessels. For this analysis, we compared the estimated cost of the rule in the first year (when equipment is purchased) and in subsequent years to annual revenue data for the small businesses affected. To determine annual company

revenue data, we used the Reference USA database available online.

Small Air Carriers

Small air carriers will not incur substantial programming or equipment costs because, unlike the large air carriers, small carriers do not currently have reservation systems that need to be reprogrammed. Instead, these carriers may use free programs available online. As we showed in the Regulatory Assessment above, small air carriers will, in the worst case, incur the costs of a new computer with Internet access. They will also incur a per-passenger/crew cost of $1.25 and the costs associated with a master crew list. Based on CBP databases, we assume that each small carrier will carry 300 passengers and crew annually. First-year costs per small carrier, assuming that a computer must be purchased, are $905 [$500 computer cost + $30 for the master crew list and modifications + ($1.25 × 300 passengers)]. Following the first year, annual costs per small carrier are $455 [$50 computer maintenance + $30 for the master crew list and modifications + ($1.25 × 300 passengers)]. If the carrier already has a computer with internet access, both first-year and annual costs will be $405 per year.

Of the 755 small air carriers, we found revenue data for 258 of them (34 percent). Most of these carriers have average annual revenues of approximately $2.5 million. Only 30 of the 258 carriers have revenues in excess of $10 million. For all of the small air carriers, we found that the initial and annual costs of this final rule will not exceed 0.5 percent of annual revenue, and this represents the worst case where a computer will need to be purchased.

Small Sea Carriers

Like small air carriers, vessels owned by small companies will not incur substantial programming or equipment costs. Small vessel companies will, in the worst case, incur the costs of a new computer with Internet access. They will also incur a per-crew cost of $1.25. Based on Coast Guard and CBP information, we assume that each vessel will carry an average of 10 crew and make four arrivals from foreign ports of call annually. First-year costs per vessel, assuming that a computer must be purchased, are $550 [$500 computer cost + ($1.25 × 10 crew × 4 arrivals)]. Following the first year, annual costs per vessel are $100 [$50 computer maintenance + ($1.25 × 10 crew × 4 arrivals)]. Most small vessel companies own one or two vessels. If the vessel already has a computer with internet access, both first-year and annual costs will be $50 per year.

Of the 88 small vessel companies, we found revenue data for 33 of them (40 percent). These 33 companies own 74 vessels. Most of these carriers have average annual revenues of approximately $1.2 million. Only 8 of the 33 carriers have revenues in excess of $10 million. For all but three of the small vessel companies, we found that the initial costs of this final rule will not exceed 0.5 percent of annual revenue. Following the first year, no companies will incur costs exceeding 0.5 percent of annual revenue. Again, this represents the worst case where a computer will need to be purchased.

Reporting and Recordkeeping

All small carriers that transport passengers or crew members to or from any seaport or airport of the United States, as well as those small carriers that transport crew and non-crew on flights continuing within (foreign air carriers only) and overflying the United States, will be required to comply with the electronic manifest filing requirements set forth in this final rule. This final rule implements an ongoing reporting requirement for carriers.

CBP estimates that this rule will require each of the 773 small air carriers to submit a master crew list, update the list monthly, and submit individual manifests estimated at one inbound and one outbound manifest per week (104) per year. This estimate is an average of 117 APIS transmissions per year per carrier. CBP also estimates that this rule will require vessels to submit an average of four manifests a year.

Both the eAPIS and eNOA/D applications will allow for auto-population of many data elements and the auto-population of previously submitted passenger and crewmembers names. The eNOA/D application will allow the entire manifest to be saved and be resubmitted with minor modifications, such as the addition or deletion of crewmembers. This application will decrease the amount of data that must be entered in subsequent manifest submissions.

These submissions will be completed using online applications accessed via the Internet. There are no unique professional skills required other than typing and web navigation. CBP does not anticipate the need for specialized training for small entities in order to comply with the rule.

Other Federal Rules

This final rule does not duplicate, overlap, or conflict with other Federal regulations. The rule was prepared after consultation with the TSA and Coast Guard and was designed to work in coordination with their regulations. As discussed throughout this document, CBP and Coast Guard coordinated their efforts to develop an electronic arrival and departure manifest system that meets the requirements of both agencies.

Regulatory Alternatives

The requirements of this final rule are mandated by the ATSA and the EBSA. Exploration of regulatory alternatives, therefore, was limited during the rulemaking process, as these legislative acts were explicit in the types of systems to be installed and the types of information that must be submitted. The three regulatory alternatives considered were discussed in detail in the E.O. 12866 section of this preamble.

CBP has developed alternative submission methods for small air carriers (primarily eAPIS), while the Coast Guard has developed alternative methods for vessels (eNOA/D). These alternative methods should help small businesses comply with the final rule in the most cost-effective manner. Over 10 years, we estimate that without these low-cost alternatives, this rule would impose additional costs on small entities totaling $113 million.

Significant Issues That Have Been Assessed

Several issues arose during the comment period for the Customs Interim Rule published on December 31, 2001, and the INS NPRM published on January 3, 2003. A complete summary of all the comments we received and our responses can be found above. A summary of issues specific to small entities follows.

The industry expressed a desire for a separate electronic system by which small carriers could transmit passenger and crewmember manifests. A specific recommendation was made that a web-based medium be developed coupled with a telephonic or facsimile backup. As discussed in this section, CBP developed a web-based application for the air carriers and has adopted the use of Coast Guard's web application for the sea carriers. The telephonic and facsimile methods could not be implemented since they would not meet the statutory requirement for electronic submission.

The industry expressed concern over the requirement that they submit manifests in UN EDIFACT format. Since the small carriers do not have sophisticated reservation systems, this requirement would require most small carriers to purchase software from private sources and would no longer

allow them to submit manifests through email. CBP developed eAPIS to be compliant with the UN EDIFACT format. Therefore, all carriers that submit manifest via eAPIS will comply with this requirement without purchasing specific UN EDIFACT software. Also, CBP adopted the use of the eNOA/D system and therefore does not require vessel manifests to be submitted in UN EDIFACT. The vessel manifests must be submitted via eNOA/D or an XML worksheet. The industry can use the XML worksheet provided by the Coast Guard at no cost.

The industry expressed concern about the cost of creating a unique identifier in lieu of a PNR Locator. CBP has exempted this requirement. There is no requirement for carriers that do not have PNR locator numbers to create a unique identifier.

Civil Liberties Costs and Benefits

This rule contains a number of non-quantified costs and benefits related to civil liberties. The primary non-quantified costs imposed by the rule result from putting certain travelers (those law-abiding travelers who would prefer not to disclose information to the agency) to the choice of providing personal information or foregoing international travel. Many travelers who prefer not to provide personal information will do so anyway because they value the ability to travel more than the ability to resist providing information to the agency. These travelers will incur the non-quantified costs of providing the personal information. CBP expects that a smaller number of travelers may feel more strongly about providing personal information to the agency, and may therefore forego the travel in which they would otherwise engage. The costs of foregoing travel can be significant. These costs, which are the result of information being collected as mandated by statute, are non-quantified, but CBP recognizes that in particular cases they may be significant.

The rule also provides non-quantified benefits, however, and CBP considers those benefits to far outweigh the non-quantified costs. This rule will aid in both deterring and detecting terrorist threats to commercial vessels and aircraft. As our past has shown, these threats unchecked can lead to loss of life and severe restrictions on travel for scores of individuals. Considering the latter, the cost of shutting down a transportation system for a large but unknown number of individuals (and thereby restricting the ability to travel) is not quantifiable, but the benefit of preventing such an event is substantial. This rule will likely have another non-quantified benefit: Some persons wary of traveling out of fear of terrorist attacks will correctly perceive that the rule will make safer those transportation systems affected by this rule. This perception will likely have the effect of removing barriers to international travel that an unknown number of persons previously experienced, thereby expanding the opportunities for individuals to travel. This perception, therefore, is a civil liberties benefit.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), enacted as Pub. L. 104–4 on March 22, 1995, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. Section 204(a) of the UMRA, 2 U.S.C. 1534(a), requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on a ''significant intergovernmental mandate.'' A ''significant intergovernmental mandate'' under the UMRA is any provision in a Federal agency regulation that will impose an enforceable duty upon state, local, and tribal governments, in the aggregate, of $100 million (adjusted annually for inflation) in any one year. Section 203 of the UMRA, 2 U.S.C. 1533, which supplements section 204(a), provides that, before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan that, among other things, provides for notice to potentially affected small governments, if any, and for meaningful and timely opportunity to provide input in the development of regulatory proposals.

This final rule will not impose any cost on small governments or significantly or uniquely affect small governments. However, as stated in the ''E.O. 12866'' section of this document, which concluded that the final rule constitutes a significant regulatory action, the rule will result in the expenditure by the private sector of $166 million in the first year and $135 million per year over a 10-year period. Therefore, the provisions of this final rule constitute a private sector mandate under the UMRA. CBP's analysis of the cost impact on affected businesses in the ''E.O. 12866'' section of this document is incorporated here by reference as the assessment required under Title II of the UMRA.

Executive Order 13132

This final rule will 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 13132, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988 Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

National Environmental Policy Act

CBP has evaluated this final rule for purposes of the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*). CBP has determined that an environmental statement is not required, since this action is non-invasive and there is no potential impact of any kind. Record of this determination has been placed in the rulemaking docket.

Paperwork Reduction Act

This final rule requires that carriers electronically provide manifest information to CBP relative to passengers and crew members on board commercial vessels arriving in and departing from the United States and crew members and non-crew members onboard commercial aircraft operating, serving on, and traveling on flights to, from, continuing within (foreign air carriers only), and overflying the United States. This requirement is considered an information collection requirement under the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*).

The collection of information in this final rule, with respect to commercial vessels and aircraft arriving in and departing from the United States, had in part already been reviewed by the Office of Management and Budget (OMB) and assigned OMB Control Numbers 1651–0088 (Electronic manifest information required for passengers and crew on board commercial aircraft arriving in the United States) and 1651–0104 (Electronic manifest information required for passengers and crew on board commercial vessels and aircraft arriving in and departing from the

United States). In connection with this final rule, the public burden hours reported for OMB 1651–0088 have been increased to reflect appropriate addition to the estimates made under OMB 1651–0104 and to reflect a more accurate estimate of the number of respondents than were reflected in the previous estimates. These changes were submitted to OMB on March 17, 2004 (on an adjustment sheet) in connection with this rulemaking; however, a new submission for OMB has been prepared for submission to reflect further adjustments. The combined information collection will be recorded under OMB No. 1651–0088.

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. This final rule's collection of information is contained in 19 CFR 4.7b, 4.64, 122.49a, 122.49b, 122.49c, 122.75a, and 122.75b (some of which are referenced in 8 CFR 217.7, 231.1 and 231.2). This information is necessary to ensure national security and the security of commercial vessel travel to and from the United States and commercial air travel to, from, continuing within (foreign air carriers only), and overflying the United States. It will also enhance enforcement of the immigration and customs laws relative to passengers and crew members traveling to and from the United States on board commercial vessels and aircraft. The likely respondents and recordkeepers are commercial passenger and cargo sea and air carriers. Part 178, Customs Regulations (19 CFR part 178), containing the list of approved information collections, is appropriately revised.

Administrative Procedure Act

This final rule contains several provisions that, in addition to implementing authority of CBP, will assist TSA in carrying out its aviation security mission under TSA law and regulations. These provisions pertain to the electronic transmission of manifest information relative to crew and non-crew members onboard flights of commercial aircraft to, from, continuing within (after a foreign air carrier flight's arrival at a U.S. port), and overflying the United States. TSA first established these requirements in response to specific intelligence information received in December of 2003 regarding possible terrorist threats to international flights. TSA determined that the new requirements are necessary to protect air passengers and others who could be harmed by a terrorist using a commercial aircraft to perpetrate a terrorist attack. These requirements were designed to facilitate TSA's performance of security threat assessments of individuals with access to the flight deck (crew members) on these international flights. (In the case of all-cargo flights, these individuals include non-crew members.) TSA thus has issued non-public Emergency Amendments (EAs) and Security Directives (SDs) to the air carriers to implement these requirements. Over the course of the past eight months, TSA has worked with the affected air carriers to address the technological and operational issues that have arisen as the carriers have implemented the manifest reporting requirements of the SDs and EAs. In response to comments from the carriers, TSA has approved alternative procedures, as appropriate, to address operational issues.

Because the manifest reporting requirements for crew and non-crew members now being issued publicly in this final rule already are in place with respect to the carriers (under the privately issued SDs and EAs) and initially were put in place by TSA to address a possible terrorist threat to aviation safety, a threat that still exists, good cause exists for dispensing with the notice and public comment procedures of the Administrative Procedure Act (5 U.S.C. 553) as it would be unnecessary and contrary to the public interest to delay publication of these requirements in this final rule until after a public comment period. (See 5 U.S.C. 553(b)(B).)

List of Subjects

8 CFR Part 217

Air carriers, Aliens, Maritime carriers, Passports and visas.

8 CFR Part 231

Air carriers, Aliens, Maritime carriers, Reporting and recordkeeping requirements.

8 CFR Part 251

Alien crew members, Maritime carriers, Reporting and recordkeeping requirements, Vessels.

19 CFR Part 4

Aliens, Customs duties and inspection, Immigration, Maritime carriers, Passenger vessels, Reporting and recordkeeping requirements, Vessels.

19 CFR Part 122

Air carriers, Aircraft, Airports, Air transportation, Commercial aircraft, Customs duties and inspection, Entry procedure, Reporting and recordkeeping requirements, Security measures.

19 CFR Part 178

Administrative practice and procedure, Collections of information, Paperwork requirements, Reporting and recordkeeping requirements.

Department of Homeland Security

Bureau of Customs and Border Protection

8 CFR Chapter I—Amendments to the Regulations

■ For the reasons set out in the preamble, chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 217—VISA WAIVER PROGRAM

■ 1. The heading for part 217 is revised to read as set forth above.

■ 2. The authority citation for part 217 continues to read as follows:

Authority: 8 U.S.C. 1103, 1187; 8 CFR part 2.

■ 3. Section 217.7 is revised to read as follows:

§ 217.7 Electronic data transmission requirement.

(a) An alien who applies for admission under the provisions of section 217 of the Act after arriving via sea or air at a port of entry will not be admitted under the Visa Waiver Program unless an appropriate official of the carrier transporting the alien electronically transmitted to Customs and Border Protection (CBP) passenger arrival manifest data relative to that alien passenger in accordance with 19 CFR 4.7b or 19 CFR 122.49a. Upon departure from the United States by sea or air of an alien admitted under the Visa Waiver Program, an appropriate official of the transporting carrier must electronically transmit to CBP departure manifest data relative to that alien passenger in accordance with 19 CFR 4.64 and 19 CFR 122.75a.

(b) If a carrier fails to submit the required electronic arrival or departure manifests specified in paragraph (a) of this section, CBP will evaluate the carrier's compliance with immigration requirements as a whole. CBP will inform the carrier of any noncompliance and then may revoke any contract agreements between CBP and the carrier. The carrier may also be subject to fines for failure to comply with manifest requirements or other statutory provisions. CBP will also review each Visa Waiver Program applicant who applies for admission and, on a case-by-case basis, may authorize a waiver under current CBP policy and

guidelines or deny the applicant admission into the United States.

PART 231—ARRIVAL AND DEPARTURE MANIFESTS

■ 4. The heading for part 231 is revised to read as set forth above.

■ 5. The authority citation for part 231 is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1182, 1221, 1228, 1229; 8 CFR part 2.

■ 6. Section 231.1 is revised to read as follows:

§ 231.1 Electronic manifest and I–94 requirement for passengers and crew onboard arriving vessels and aircraft.

(a) *Electronic submission of manifests.* Provisions setting forth requirements applicable to commercial carriers regarding the electronic transmission of arrival manifests covering passengers and crew members under section 231 of the Act are set forth in 19 CFR 4.7b (passengers and crew members onboard vessels) and in 19 CFR 122.49a (passengers onboard aircraft) and 122.49b (crew members onboard aircraft).

(b) *Submission of Form I–94.* (1) *General requirement.* In addition to the electronic manifest transmission requirement specified in paragraph (a) of this section, and subject to the exception of paragraph (2) of this paragraph (b), the master or commanding officer, or authorized agent, owner or consignee, of each commercial vessel or aircraft arriving in the United States from any place outside the United States must present to a Customs and Border Protection (CBP) officer at the port of entry a properly completed Arrival/Departure Record, Form I–94, for each arriving passenger.

(2) *Exceptions.* The Form I–94 requirement of paragraph (1) of this paragraph (b) does not apply to United States citizens, lawful permanent residents of the United States, immigrants to the United States, or passengers in transit through the United States; nor does it apply to vessels or aircraft arriving directly from Canada on a trip originating in that country or arriving in the Virgin Islands of the United States directly from a trip originating in the British Virgin Islands.

(c) *Progressive clearance.* Inspection of arriving passengers may be deferred at the request of the carrier to an onward port of debarkation. However, verification of transmission of the electronic manifest referred to in paragraph (a) of this section must occur at the first port of arrival. Authorization for this progressive clearance may be granted by the Director, Field Operations, at the first port of arrival. When progressive clearance is requested, the carrier must present the Form I–92 referred to in paragraph (d) of this section in duplicate at the initial port of entry. The original Form I–92 will be processed at the initial port of entry, and the duplicate will be noted and returned to the carrier for presentation at the onward port of debarkation.

(d) *Aircraft/Vessel Report.* A properly completed Aircraft/Vessel Report, Form I–92, must be completed for each arriving aircraft and vessel that is transporting passengers. Submission of the Form I–92 to the CBP officer must be accomplished on the day of arrival.

■ 7. Section 231.2 is revised to read as follows.

§ 231.2 Electronic manifest and I–94 requirement for passengers and crew onboard departing vessels and aircraft.

(a) *Electronic submission of manifests.* Provisions setting forth requirements applicable to commercial carriers regarding the electronic transmission of departure manifests covering passengers and crew members under section 231 of the Act are set forth in 19 CFR 4.64 (passengers and crew members onboard vessels) and in 19 CFR 122.75a (passengers onboard aircraft) and 122.75b (crew members onboard aircraft).

(b) *Submission of Form I–94.* (1) *General requirement.* In addition to the electronic manifest transmission requirement specified in paragraph (a) of this section, and subject to the exception of paragraph (2) of this paragraph (b), the master or commanding officer, or authorized agent, owner, or consignee, of each commercial vessel or aircraft departing from the United States to any place outside the United States must present a properly completed departure portion of an Arrival/Departure Record, Form I–94, to the Customs and Border Protection (CBP) officer at the port of departure for each person on board. Whenever possible, the departure Form I–94 presented must be the same form given to the alien at the time of arrival in the United States. The carrier must endorse the I–94 with the departure information on the reverse of the form. Submission of the I–94 to the CBP officer must be accomplished within 48 hours of the departure, exclusive of Saturdays, Sundays, and legal holidays. Failure to submit the departure I–94 within this period may be regarded as a failure to comply with section 231(g) of the Act, unless prior authorization for delayed delivery is obtained from CBP. A non-immigrant alien departing on an aircraft proceeding directly to Canada on a flight terminating in that country must surrender any Form I–94 in his/her possession to the airline agent at the port of departure.

(2) *Exceptions.* The form I–94 requirement of paragraph (1) of this paragraph (b) does not apply to United States citizens, lawful permanent residents of the United States, or passengers in transit through the United States; nor does it apply to a vessel or aircraft departing on a trip directly for and terminating in Canada or departing from the United States Virgin Islands directly to the British Virgin Islands on a trip terminating there.

(c) *Aircraft/Vessel Report.* A properly completed Aircraft/Vessel Report, Form I–92, must be completed for each departing aircraft and vessel that is transporting passengers. Submission of the Form I–92 to the CBP officer must be accomplished on the day of departure.

PART 251—ARRIVAL AND DEPARTURE MANIFESTS AND LISTS: SUPPORTING DOCUMENTS

■ 8. The heading for part 251 is revised to read as set forth above.

■ 9. The authority citation for part 251 continues to read as follows:

Authority: 8 U.S.C. 1103, 1182, 1221, 1281, 1282; 8 CFR part 2.

■ 10. Section 251.5 is redesignated as § 251.6 and revised to read as follows:

§ 251.6 Exemptions for private vessels and aircraft.

The provisions of this part relating to the presentation of arrival and departure manifests do not apply to a private vessel or private aircraft not engaged directly or indirectly in the carrying of persons or cargo for hire.

■ 11. New § 251.5 is added to read as follows:

§ 251.5 Paper arrival and departure manifests for crew.

In addition to the electronic manifest transmission requirement applicable to crew members specified in §§ 231.1 and 231.2 of this chapter, the master or commanding officer, or authorized agent, owner, or consignee, of a commercial vessel or commercial aircraft arriving in or departing from the United States must submit arrival and departure manifests in a paper format in accordance with §§ 251.1, 251.3, and 251.4.

Department of Homeland Security

Bureau of Customs and Border Protection

19 CFR Chapter I—Amendments to the Regulations

■ For the reasons set out in the preamble, chapter I of title 19 of the Code of Federal Regulations is amended as follows:

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

■ 1. The general authority citation for part 4 continues to read and new specific authority citations for §§ 4.7b and 4.64 are added to read, as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624; 2071 note; 46 U.S.C. App. 3, 91.

* * * * *

Section 4.7b also issued under 8 U.S.C. 1221;

* * * * *

Section 4.64 also issued under 8 U.S.C. 1221;

* * * * *

■ 2. New § 4.7b is added to read as follows:

§ 4.7b Electronic passenger and crew arrival manifests.

(a) *Definitions.* The following definitions apply for purposes of this section:

Appropriate official. ''Appropriate official'' means the master or commanding officer, or authorized agent, owner, or consignee, of a commercial vessel; this term and the term ''carrier'' are sometimes used interchangeably.

Carrier. See ''Appropriate official.''

Commercial vessel. ''Commercial vessel'' means any civilian vessel being used to transport persons or property for compensation or hire.

Crew member. ''Crew member'' means a person serving on board a vessel in good faith in any capacity required for normal operation and service of the voyage. In addition, the definition of ''crew member'' applicable to this section should not be applied in the context of other customs laws, to the extent this definition differs from the meaning of ''crew member'' contemplated in such other customs laws.

Emergency. ''Emergency'' means, with respect to a vessel arriving at a U.S. port due to an emergency, an urgent situation due to a mechanical, medical, or security problem affecting the voyage, or to an urgent situation affecting the non-U.S. port of destination that necessitates a detour to a U.S. port.

Ferry. ''Ferry'' means any vessel which is being used to provide transportation only between places that are no more than 300 miles apart and which is being used to transport only passengers and/or vehicles, or railroad cars, which are being used, or have been used, in transporting passengers or goods.

Passenger. ''Passenger'' means any person being transported on a commercial vessel who is not a crew member.

United States. ''United States'' means the continental United States, Alaska, Hawaii, Puerto Rico, Guam, and the Virgin Islands of the United States.

(b) *Electronic arrival manifest*—(1) *General requirement.* Except as provided in paragraph (c) of this section, an appropriate official of each commercial vessel arriving in the United States from any place outside the United States must transmit to Customs and Border Protection (CBP) an electronic passenger arrival manifest and an electronic crew member arrival manifest. Each electronic arrival manifest:

(i) Must be transmitted to CPB at the place and time specified in paragraph (b)(2) of this section by means of an electronic data interchange system approved by CBP. If the transmission is in US EDIFACT format, the passenger manifest and the crew member manifest must be transmitted separately; and

(ii) Must set forth the information specified in paragraph (b)(3) of this section.

(2) *Place and time for submission*— (i) *General requirement.* The appropriate official must transmit each electronic arrival manifest required under paragraph (b)(1) of this section to the CBP Data Center, CBP Headquarters:

(A) In the case of a voyage of 96 hours or more, at least 96 hours before entering the first United States port or place of destination;

(B) In the case of a voyage of less than 96 hours but at least 24 hours, prior to departure of the vessel;

(C) In the case of a voyage of less than 24 hours, at least 24 hours before entering the first U.S. port or place of destination; and

(D) In the case of a vessel that was not destined to the United States but was diverted to a U.S. port due to an emergency, before the vessel enters the U.S. port or place to which diverted; in cases of non-compliance, CBP will take into consideration that the carrier was not equipped to make the transmission and the circumstances of the emergency situation.

(ii) *Amendment of crew member manifests.* In any instance where a crew member boards the vessel after initial submission of the manifest under paragraph (b)(2)(i) of this section, the appropriate official must transmit amended manifest information to CBP reflecting the data required under paragraph (b)(3) of this section for the additional crew member. The amended manifest information must be transmitted to the CBP data Center, CBP Headquarters:

(A) If the remaining voyage time after initial submission of the manifest is 24 hours or more, at least 24 hours before entering the first U.S. port or place of destination; or

(B) In any other case, at least 12 hours before the vessel enters the first U.S. port or place of destination.

(3) *Information required.* Each electronic arrival manifest required under paragraph (b)(1) of this section must contain the following information for all passengers and crew members, except that for commercial passenger vessels, the information specified in paragraphs (b)(3)(iv), (v), (x), (xii), (xiii), (xiv), (xvi), (xviii), and (xix) of this section must be included on the manifest only on or after October 4, 2005:

(i) Full name (last, first, and, if available, middle);

(ii) Date of birth;

(iii) Gender (F = female; M = male);

(iv) Citizenship;

(v) Country of residence;

(vi) Status on board the vessel;

(vii) Travel document type (*e.g.,* P = passport, A = alien registration);

(viii) Passport number, if a passport is required;

(ix) Passport country of issuance, if a passport is required;

(x) Passport expiration date, if a passport is required;

(xi) Alien registration number, where applicable;

(xii) Address while in the United States (number and street, city, state, and zip code), except that this information is not required for U.S. citizens, lawful permanent residents, crew members, or persons who are in transit to a location outside the United States;

(xiii) Passenger Name Record locator, if available;

(xiv) Foreign port/place where transportation to the United States began (foreign port code);

(xv) Port/place of first arrival (CBP port code);

(xvi) Final foreign port/place of destination for in-transit passenger and crew member (foreign port code);

(xvii) Vessel name;

(xviii) Vessel country of registry/flag;

(xix) International Maritime Organization number or other official number of the vessel;

(xx) Voyage number (applicable only for multiple arrivals on the same calendar day); and

(xxi) Date of vessel arrival.

(c) *Exceptions.* The electronic arrival manifest requirement specified in paragraph (b) of this section is subject to the following conditions:

(1) No passenger or crew member manifest is required if the arriving commercial vessel is operating as a ferry;

(2) If the arriving commercial vessel is not transporting passengers, only a crew member manifest is required; and

(3) No passenger manifest is required for active duty U.S. military personnel onboard an arriving Department of Defense commercial chartered vessel.

(d) *Carrier responsibility for comparing information collected with travel document.* The carrier collecting the information described in paragraph (b)(3) of this section is responsible for comparing the travel document presented by the passenger or crew member with the travel document information it is transmitting to CBP in accordance with this section in order to ensure that the information transmitted is correct, the document appears to be valid for travel to the United States, and the passenger or crew member is the person to whom the travel document was issued.

(e) *Sharing of manifest information.* Information contained in passenger and crew member manifests that is received by CBP electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security. CBP may also share such information as otherwise authorized by law.

■ 3. New § 4.64 is added to read as follows:

§ 4.64 Electronic passenger and crew member departure manifests.

(a) *Definitions.* The definitions contained in § 4.7b(a) also apply for purposes of this section.

(b) *Electronic departure manifest*—(1) *General requirement.* Except as provided in paragraph (c) of this section, an appropriate official of each commercial vessel departing from the United States to any port or place outside the United States must transmit to Customs and Border Protection (CBP) an electronic passenger departure manifest and an electronic crew member departure manifest. Each electronic departure manifest:

(i) Must be transmitted to CPB at the place and time specified in paragraph (b)(2) of this section by means of an electronic data interchange system approved by CBP. If the transmission is in US EDIFACT format, the passenger manifest and the crew member manifest must be transmitted separately; and

(ii) Must set forth the information specified in paragraph (b)(3) of this section.

(2) *Place and time for submission*—(i) *General requirement.* The appropriate official must transmit each electronic departure manifest required under paragraph (b)(1) of this section to the CBP Data Center, CBP Headquarters, no later than 15 minutes before the vessel departs from the United States.

(ii) *Amended crew member manifests.* If a crew member boards the vessel after submission of the manifest under paragraph (b)(2)(i) of this section, the appropriate official must transmit amended manifest information to CBP reflecting the data required under paragraph (b)(3) of this section for the additional crew member. The amended manifest information must be transmitted to the CBP Data Center, CBP Headquarters, no later than 12 hours after the vessel has departed from the United States.

(3) *Information required.* Each electronic departure manifest required under paragraph (b)(1) of this section must contain the following information for all passengers and crew members, except that the information specified in paragraphs (b)(3)(iv), (ix), (xi), (xv), and (xvi), of this section must be included on the manifest only on or after October 4, 2005:

(i) Full name (last, first, and, if available, middle);

(ii) Date of birth;

(iii) Gender (F = female; M = male);

(iv) Citizenship;

(v) Status on board the vessel;

(vi) Travel document type (*e.g.,* P = passport; A = alien registration card);

(vii) Passport number, if a passport is required; (viii) Passport country of issuance, if a passport is required;

(ix) Passport expiration date, if a passport is required;

(x) Alien registration number, where applicable;

(xi) Passenger Name Record locator, if available;

(xii) Departure port code (CBP port code);

(xiii) Port/place of final arrival (foreign port code);

(xiv) Vessel name;

(xv) Vessel country of registry/flag;

(xvi) International Maritime Organization number or other official number of the vessel;

(xvii) Voyage number (applicable only for multiple departures on the same calendar day); and

(xviii) Date of vessel departure.

(c) *Exceptions.* The electronic departure manifest requirement specified in paragraph (b) of this section is subject to the following conditions:

(1) No passenger or crew member departure manifest is required if the departing commercial vessel is operating as a ferry;

(2) If the departing commercial vessel is not transporting passengers, only a crew member departure manifest is required;

(3) No passenger departure manifest is required for active duty U.S. military personnel on board a departing Department of Defense commercial chartered vessel.

(d) *Carrier responsibility for comparing information collected with travel document.* The carrier collecting the information described in paragraph (b)(3) of this section is responsible for comparing the travel document presented by the passenger or crew member with the travel document information it is transmitting to CBP in accordance with this section in order to ensure that the information is correct, the document appears to be valid for travel purposes, and the passenger or crew member is the person to whom the travel document was issued.

(e) *Sharing of manifest information.* Information contained in passenger and crew member manifests that is received by CBP electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security. CBP may also share such information as otherwise authorized by law.

PART 122—AIR COMMERCE REGULATIONS

■ 4. The general authority citation for part 122 continues to read, the specific authority citations for §§ 122.49a and 122.49b are revised to read, and new specific authority citations for §§ 122.49c, 122.49d, 122.75a, and 122.75b are added to read, as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a.

Section 122.49a also issued under 8 U.S.C. 1221, 19 U.S.C. 1431, 49 U.S.C. 44909.

Section 122.49b also issued under 8 U.S.C. 1221, 19 U.S.C. 1431, 49 U.S.C. 114, 44909.

Section 122.49c also issued under 8 U.S.C. 1221, 19 U.S.C. 1431, 49 U.S.C. 114, 44909.

Section 122.49d also issued under 49 U.S.C. 44909(c)(3).

* * * * *

Section 122.75a also issued under 8 U.S.C. 1221, 19 U.S.C. 1431.

Section 122.75b also issued under 8 U.S.C. 1221, 19 U.S.C. 1431, 49 U.S.C. 114.

■ 5. The heading for Subpart E of Part 122 is revised to read as follows:

Subpart E—Aircraft Entry and Entry Documents; Electronic Manifest Requirements for Passengers, Crew Members, and Non-Crew Members Onboard Commercial Aircraft Arriving In, Continuing Within, and Overflying the United States

■ 6. Section 122.49a is revised to read as follows:

§ 122.49a Electronic manifest requirement for passengers onboard commercial aircraft arriving in the United States.

(a) *Definitions.* The following definitions apply for purposes of this section:

Appropriate official. ''Appropriate official'' means the master or commanding officer, or authorized agent, owner, or consignee, of a commercial aircraft; this term and the term ''carrier'' are sometimes used interchangeably.

Carrier. See ''Appropriate official.''

Commercial aircraft. ''Commercial aircraft'' has the meaning provided in § 122.1(d) and includes aircraft engaged in passenger flight operations, all-cargo flight operations, and dual flight operations involving the transport of both cargo and passengers.

Crew Member. ''Crew member'' means a person serving on board an aircraft in good faith in any capacity required for normal operation and service of the flight. In addition, the definition of ''crew member'' applicable to this section should not be applied in the context of other customs laws, to the extent this definition differs from the meaning of ''crew member'' contemplated in such other customs laws.

Departure. ''Departure'' means the point at which the wheels are up on the aircraft and the aircraft is en route directly to its destination.

Emergency. ''Emergency'' means, with respect to an aircraft arriving at a U.S. port due to an emergency, an urgent situation due to a mechanical, medical, or security problem affecting the flight, or to an urgent situation affecting the non-U.S. port of destination that necessitates a detour to a U.S. port.

Passenger. ''Passenger'' means any person, including a Federal Aviation Administration (FAA) Aviation Security Inspector with valid credentials and authorization, being transported on a commercial aircraft who is not a crew member.

United States. ''United States'' means the continental United States, Alaska, Hawaii, Puerto Rico, Guam, and the Virgin Islands of the United States.

(b) *Electronic arrival manifest.* (1) *General requirement.* Except as provided in paragraph (c) of this section, an appropriate official of each commercial aircraft arriving in the United States from any place outside the United States must transmit to Customs and Border Protection (CBP) an electronic passenger arrival manifest covering any passengers on board the aircraft. Each manifest must be transmitted to CPB at the place and time specified in paragraph (b)(2) of this section by means of an electronic data interchange system approved by CBP and must set forth the information specified in paragraph (b)(3) of this section. A passenger manifest must be transmitted separately from a crew member manifest required under § 122.49b if transmission is in US EDIFACT format.

(2) *Place and time for submission.* The appropriate official specified in paragraph (b)(1) of this section must transmit the electronic passenger arrival manifest required under paragraph (b)(1) of this section to the CBP Data Center, CBP Headquarters:

(i) No later than 15 minutes after departure of the aircraft;

(ii) For flights not originally destined to the United States but diverted to a U.S. port due to an emergency, no later than 30 minutes prior to arrival; in cases of non-compliance, CBP will take into consideration that the carrier was not equipped to make the transmission and the circumstances of the emergency situation; and

(iii) For an aircraft operating as an air ambulance in service of a medical emergency, no later than 30 minutes prior to arrival.

(3) *Information required.* Except as provided in paragraph (c) of this section, the electronic passenger arrival manifest required under paragraph (b)(1) of this section must contain the following information for all passengers, except that the information specified in paragraphs (b)(iv), (v), (x), (xii), (xiii), and (xiv) of this section must be included on the manifest only on or after October 4, 2005:

(i) Full name (last, first, and, if available, middle);

(ii) Date of birth;

(iii) Gender (F = female; M = male);

(iv) Citizenship;

(v) Country of residence;

(vi) Status on board the aircraft;

(vii) Travel document type (*e.g.*, P = passport; A = alien registration card);

(viii) Passport number, if a passport is required;

(ix) Passport country of issuance, if a passport is required;

(x) Passport expiration date, if a passport is required;

(xi) Alien registration number, where applicable;

(xii) Address while in the United States (number and street, city, state, and zip code), except that this information is not required for U.S. citizens, lawful permanent residents, or persons who are in transit to a location outside the United States;

(xiii) Passenger Name Record locator, if available;

(xiv) International Air Transport Association (IATA) code of foreign port/place where transportation to the United States began (foreign port code);

(xv) IATA code of port/place of first arrival (arrival port code);

(xvi) IATA code of final foreign port/place of destination for in-transit passengers (foreign port code);

(xvii) Airline carrier code;

(xviii) Flight number; and

(xix) Date of aircraft arrival.

(c) *Exception.* The electronic passenger arrival manifest specified in paragraph (b)(1) of this section is not required for active duty U.S. military personnel being transported as passengers on arriving Department of Defense commercial chartered aircraft.

(d) *Carrier responsibility for comparing information collected with travel document.* The carrier collecting the information described in paragraph (b)(3) of this section is responsible for comparing the travel document presented by the passenger with the travel document information it is transmitting to CBP in accordance with this section in order to ensure that the information is correct, the document appears to be valid for travel to the United States, and the passenger is the person to whom the travel document was issued.

(e) *Sharing of manifest information.* Information contained in the passenger manifests required by this section that is received by CBP electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security. CBP may also share such information as otherwise authorized by law.

§ 122.49b [Redesignated]

■ 7. Section 122.49b is redesignated as § 122.49d.

■ 8. New § 122.49b is added to read as follows:

§ 122.49b Electronic manifest requirement for crew members and non-crew members onboard commercial aircraft arriving in, continuing within, and overflying the United States.

(a) *Definitions.* The definitions set forth below apply for purposes of this section. The definitions set forth in § 122.49a(a), other than those for the terms set forth below, also apply for purposes of this section:

All-cargo flight. ''All-cargo flight'' means a flight in operation for the purpose of transporting cargo which has onboard only ''crew members'' and ''non-crew members'' as defined in this paragraph.

Carrier. In addition to the meaning set forth in § 122.49a(a), ''carrier'' includes each entity that is an ''aircraft operator'' or ''foreign air carrier'' with a security program under 49 CFR part 1544, 1546, or 1550 of the Transportation Security Administration regulations.

Crew member. ''Crew member'' means a pilot, copilot, flight engineer, airline management personnel authorized to travel in the cockpit, cabin crew, and relief crew (also known as ''deadheading crew''). However, for all other purposes of immigration law and documentary evidence required under the Immigration and Nationality Act (8 U.S.C. 1101, *et seq.*), ''crew member'' (or ''crewman'') means a person serving onboard an aircraft in good faith in any capacity required for the normal operation and service of the flight (8 U.S.C. 1101(a)(10) and (a)(15)(D), as applicable). In addition, the definition of ''crew member'' applicable to this section should not be applied in the context of other customs laws, to the extent this definition differs from the meaning of ''crew member'' contemplated in such other customs laws.

Flight continuing within the United States. ''Flight continuing within the United States'' refers to the domestic leg of a flight operated by a foreign air carrier that originates at a foreign port or place, arrives at a U.S. port, and then continues to a second U.S. port.

Flight overflying the United States. ''Flight overflying the United States'' refers to a flight departing from a foreign port or place that enters the territorial airspace of the U.S. en route to another foreign port or place.

Non-crew member. ''Non-crew member'' means air carrier employees and their family members and persons traveling onboard a commercial aircraft for the safety of the flight (such as an animal handler when animals are onboard). The definition of ''non-crew member'' is limited to all-cargo flights. (On a passenger or dual flight (passengers and cargo), air carrier employees, their family members, and persons onboard for the safety of the flight are considered passengers.)

Territorial airspace of the United States. ''Territorial airspace of the United States'' means the airspace over the United States, its territories, and possessions, and the airspace over the territorial waters between the United States coast and 12 nautical miles from the coast.

(b) *Electronic arrival manifest.* (1) *General requirement.* Except as provided in paragraph (c) of this section, an appropriate official of each commercial aircraft operating a flight arriving in or overflying the United States, from a foreign port or place, or continuing within the United States after arriving at a U.S. port from a foreign port or place, must transmit to Customs and Border Protection (CBP) an electronic crew member manifest and, for all-cargo flights only, an electronic non-crew member manifest covering any crew members and non-crew members onboard. Each manifest must be transmitted to CBP at the place and time specified in paragraph (b)(2) of this section by means of an electronic data interchange system approved by CBP and must set forth the information specified in paragraph (b)(3) of this section. Where both a crew member manifest and a non-crew member manifest are required with respect to an all-cargo flight, they must be combined in one manifest covering both crew members and non-crew members. Where a passenger arrival manifest under § 122.49a and a crew member arrival manifest under this section are required, they must be transmitted separately if the transmission is in US EDIFACT format.

(2) *Place and time for submission; certification; changes to manifest.* (i) *Place and time for submission.* The appropriate official specified in paragraph (b)(1) of this section must transmit the electronic manifest required under paragraph (b)(1) of this section to the CBP Data Center, CBP Headquarters:

(A) With respect to aircraft arriving in and overflying the United States, no later than 60 minutes prior to departure of the aircraft from the foreign port or place of departure, and with respect to aircraft continuing within the United States, no later than 60 minutes prior to departure from the U.S. port of arrival;

(B) For a flight not originally destined to arrive in the United States but diverted to a U.S. port due to an emergency, no later than 30 minutes prior to arrival; in cases of noncompliance, CBP will take into consideration that the carrier was not equipped to make the transmission and the circumstances of the emergency situation; and

(C) For an aircraft operating as an air ambulance in service of a medical emergency, no later than 30 minutes prior to arrival;

(ii) *Certification.* Except as provided in paragraph (c) of this section, the appropriate official, by transmitting the manifest as required under paragraph (b)(1) of this section, certifies that the flight's crew members and non-crew members are included, respectively, on the master crew member list or master non-crew member list previously submitted to CBP in accordance with § 122.49c. If a crew member or non-crew member on the manifest is not also included on the appropriate master list, the flight may be, as appropriate, denied clearance to depart, diverted from arriving in the United States, or denied clearance to enter the territorial airspace of the United States.

(iii) *Changes to manifest.* The appropriate official is obligated to make necessary changes to the crew member or non-crew member manifest after transmission of the manifest to CBP. Necessary changes include adding a name, with other required information, to the manifest or amending previously submitted information. If changes are submitted less than 60 minutes before scheduled flight departure, the air carrier must receive approval from TSA before allowing the flight to depart or the flight may be, as appropriate, denied clearance to depart, diverted from arriving in the United States, or denied clearance to enter the territorial airspace of the United States.

(3) *Information required.* The electronic crew member and non-crew member manifests required under paragraph (b)(1) of this section must contain the following information for all crew members and non-crew members, except that the information specified in paragraphs (b)(iii), (v), (vi), (vii), (xiii), (xv), and (xvi) of this section must be included on the manifest only on or after October 4, 2005:

(i) Full name (last, first, and, if available, middle);

(ii) Date of birth;

(iii) Place of birth (city, state—if applicable, country);

(iv) Gender (F = female; M = male);

(v) Citizenship;

(vi) Country of residence;

(vii) Address of permanent residence;

(viii) Status on board the aircraft;

(ix) Pilot certificate number and country of issuance (if applicable);

(x) Travel document type (*e.g.*, P = passport; A = alien registration card);

(xi) Passport number, if a passport is required;

(xii) Passport country of issuance, if a passport is required;

(xiii) Passport expiration date, if a passport is required;

(xiv) Alien registration number, where applicable;

(xv) Passenger Name Record locator, if available;

(xvi) International Air Transport Association (IATA) code of foreign port/place where transportation to the United States began or where the transportation destined to the territorial airspace of the United States began (foreign port code);

(xvii) IATA code of port/place of first arrival (arrival port code);

(xviii) IATA code of final foreign port/place of destination for (foreign port code);

(xix) Airline carrier code;

(xx) Flight number; and

(xxi) Date of aircraft arrival.

(c) *Exceptions.* The electronic crew member or non-crew member manifest requirement specified in paragraph (b)(1) of this section is subject to the following conditions:

(1) Federal Aviation Administration (FAA) Aviation Safety Inspectors with valid credentials and authorization are not subject to the requirement, but the manifest requirement of § 122.49a applies to these inspectors on flights arriving in the United States, as they are considered passengers on arriving flights;

(2) For crew members traveling onboard an aircraft chartered by the U.S. Department of Defense that is arriving in the United States, the provisions of this section apply regarding electronic transmission of the manifest, except that:

(i) The manifest certification provision of paragraph (b)(2)(ii) of this section is inapplicable; and

(ii) The TSA manifest change approval requirement of paragraph (b)(2)(iii) of this section is inapplicable;

(3) For crew members traveling onboard an aircraft chartered by the U.S. Department of Defense that is continuing a flight within the United States or overflying the United States, the manifest is not required;

(4) For non-crew members traveling onboard an all-cargo flight chartered by the U.S. Department of Defense that is arriving in the United States, the manifest is not required, but the manifest requirement of § 122.49a applies to these persons, as, in this instance, they are considered passengers on arriving flights; and

(5) For non-crew members traveling onboard an all-cargo flight chartered by the U.S. Department of Defense that is continuing a flight within the United States or overflying the United States, the manifest is not required.

(d) *Carrier responsibility for comparing information collected with travel document.* The carrier collecting the information described in paragraph (b)(3) of this section is responsible for comparing the travel document presented by the crew member or non-crew member with the travel document information it is transmitting to CBP in accordance with this section in order to ensure that the information is correct, the document appears to be valid for travel to the United States, and the crew member or non-crew member is the person to whom the travel document was issued.

(e) *Sharing of manifest information.* Information contained in the crew member and non-crew member manifests required by this section that is received by CBP electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security. CBP may also share such information as otherwise authorized by law.

(f) *Superseding amendments issued by TSA.* One or more of the requirements of this section may be superseded by specific provisions of, amendments to, or alternative procedures authorized by TSA for compliance with an aviation security program, emergency amendment, or security directive issued by the TSA to an air carrier subject to 49 CFR part 1544, 1546, or 1550. The provisions or amendments will have superseding effect only for the air carrier to which issued and only for the period of time specified in the provision or amendment.

■ 9. New § 122.49c is added to read as follows:

§ 122.49c Master crew member list and master non-crew member list requirement for commercial aircraft arriving in, departing from, continuing within, and overflying the United States.

(a) *General requirement.* Air carriers subject to the provisions of § 122.49b and § 122.75b, with respect to the flights covered in those sections, must electronically transmit to Customs and Border Protection (CBP), by means of an electronic data interchange system approved by CBP, a master crew member list and a master non-crew member list containing the information set forth in paragraph (c) of this section covering, respectively, all crew members and non-crew members operating and servicing its flights. The initial transmission of a list must be made at least two days in advance of any flight a crew member or non-crew member on the list will be operating, serving on, or traveling on and must contain the information set forth in paragraph (c) of this section. After review of the master crew list and the master non-crew list by TSA, TSA will advise the carrier of any crew members or non-crew members that must be removed from the list. Only those persons on the TSA-approved master crew and master non-crew lists will be permitted to operate, serve on, or travel on flights covered by this section. Until a carrier becomes a participant in the CBP-approved electronic interchange system, it must submit the required information in a format provided by TSA.

(b) *Changes to master lists.* After the initial transmission of the master crew member and non-crew member lists to CBP, the carrier is obligated to update the lists as necessary. To add a name to either list, along with the required information set forth in paragraph (c) of this section, or to add or change information relative to a name already submitted, the carrier must transmit the information to CBP at least 24 hours in advance of any flight the added or subject crew member or non-crew member will be operating, serving on, or traveling on. A carrier must submit deletions from the lists as expeditiously as possible.

(c) *Master list information.* The electronic master crew lists required under paragraph (a) of this section must contain the following information with respect to each crew member or non-crew member that operates, serves on, or travels on a carrier's flights that are covered by this section except that the information specified in paragraphs (c)(4), (5), (6), (7), and (10) of this section must be included on the manifest only on or after October 4, 2005:

(1) Full name (last, first, and, if available, middle);

(2) Gender;

(3) Date of birth;

(4) Place of birth (city, state—if applicable, and country);

(5) Citizenship;

(6) Country of residence;

(7) Address of permanent residence;

(8) Passport number, if passport required;

(9) Passport country of issuance, if passport required;

(10) Passport expiration date, if passport required;

(11) Pilot certificate number and country of issuance, if applicable;

(12) Status onboard the aircraft.

(d) *Exception.* The master crew member and non-crew member list requirements of this section do not apply to aircraft chartered by the U.S. Department of Defense.

(e) *Superseding amendments issued by TSA.* One or more of the requirements of this section may be superseded by specific provisions of, amendments to, or alternative procedures authorized by TSA for compliance with an aviation security

program, emergency amendment, or security directive issued by the TSA to an air carrier subject to the provisions of 49 CFR part 1544, 1546, or 1550. The amendments will have superseding effect only for the air carrier to which issued and only for the period of time specified in the amendment.

■ 10. The heading for subpart H of part 122 is revised to read as follows:

Subpart H—Documents Required for Clearance and Permission To Depart; Electronic Manifest Requirements for Passengers, Crew Members, and Non-Crew Members Onboard Commercial Aircraft Departing From the United States

■ 11. New § 122.75a is added to read as follows:

§ 122.75a Electronic manifest requirement for passengers onboard commercial aircraft departing from the United States.

(a) *Definitions.* The definitions set forth in § 122.49a(a) also apply for purposes of this section.

(b) *Electronic departure manifest.* (1) *General requirement.* Except as provided in paragraph (c) of this section, an appropriate official of each commercial aircraft departing from the United States to any port or place outside the United States must transmit to Customs and Border Protection (CBP) an electronic passenger departure manifest covering any passengers onboard. The manifest must be transmitted to CPB at the place and time specified in paragraph (b)(2) of this section by means of an electronic data interchange system approved by CBP and must set forth the information specified in paragraph (b)(3) of this section.

(2) *Place and time for submission.* The appropriate official specified in paragraph (b)(1) of this section must transmit the electronic passenger departure manifest required under paragraph (b)(1) of this section to the CBP Data Center, CBP Headquarters, no later than 15 minutes prior to departure of the aircraft from the United States, except that for an air ambulance in service of a medical emergency, the manifest must be transmitted to CBP no later than 30 minutes after departure.

(3) *Information required.* The electronic passenger departure manifest required under paragraph (b)(1) of this section must contain the following information for all passengers, except that the information specified in paragraphs (b)(3)(iv), (ix), and (xi) of this section must be included on the manifest only on or after October 4, 2005:

(i) Full name (last, first, and, if available, middle);

(ii) Date of birth;

(iii) Gender (F = female; M = male);

(iv) Citizenship;

(v) Status on board the aircraft;

(vi) Travel document type (*e.g.*, P = passport; A = alien registration card);

(vii) Passport number, if a passport is required;

(viii) Passport country of issuance, if a passport is required;

(ix) Passport expiration date, if a passport is required;

(x) Alien registration number, where applicable;

(xi) Passenger Name Record locator, if available;

(xii) International Air Transport Association (IATA) departure port code;

(xiii) IATA code of port/place of final arrival (foreign port code);

(xiv) Airline carrier code;

(xv) Flight number; and

(xvi) Date of aircraft departure.

(c) *Exception.* The electronic passenger departure manifest specified in paragraph (b)(1) of this section is not required for active duty military personnel traveling as passengers on board a departing Department of Defense commercial chartered aircraft.

(d) *Carrier responsibility for comparing information collected with travel document.* The carrier collecting the information described in paragraph (b)(3) of this section is responsible for comparing the travel document presented by the passenger with the travel document information it is transmitting to CBP in accordance with this section in order to ensure that the information is correct, the document appears to be valid for travel purposes, and the passenger is the person to whom the travel document was issued.

(e) *Sharing of manifest information.* Information contained in the passenger manifest required under this section that is received by CBP electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security. CBP may also share such information as otherwise authorized by law.

■ 12. New § 122.75b is added to read as follows:

§ 122.75b Electronic manifest requirement for crew members and non-crew members onboard commercial aircraft departing from the United States.

(a) *Definitions.* The definitions set forth in § 122.49a(a) also apply for purposes of this section, except that the definitions of ''all-cargo flight,'' ''carrier,'' ''crew member,'' and ''non-crew member'' applicable to this section are found in § 122.49b(a).

(b) *Electronic departure manifest.* (1) *General requirement.* Except as provided in paragraph (c) of this section, an appropriate official of each commercial aircraft departing from the United States to any port or place outside the United States must transmit to Customs and Border Protection (CBP) an electronic crew member departure manifest and, for all-cargo flights only, an electronic non-crew member departure manifest covering any crew members and non-crew members onboard. Each manifest must be transmitted to CBP at the place and time specified in paragraph (b)(2) of this section by means of an electronic data interchange system approved by CBP and must set forth the information specified in paragraph (b)(3) of this section. Where both a crew member departure manifest and a non-crew member departure manifest are required for an all-cargo flight, they must be combined in one departure manifest covering both crew members and non-crew members. Where a passenger departure manifest under § 122.75a and a crew member departure manifest under this section are required, they must be transmitted separately if the transmission is in US EDIFACT format.

(2) *Place and time for submission; certification; change to manifest.* (i) *Place and time for submission.* The appropriate official specified in paragraph (b)(1) of this section must transmit the electronic departure manifest required under paragraph (b)(1) of this section to the CBP Data Center, CBP Headquarters, no later than 60 minutes prior to departure of the aircraft, except that for an air ambulance in service of a medical emergency, the manifest must be transmitted to CBP no later than 30 minutes after departure.

(ii) *Certification.* Except as provided in paragraph (c) of this section, the appropriate official, by transmitting the manifest as required under paragraph (b)(1) of this section, certifies that the flight's crew members and non-crew members are included, respectively, on the master crew member list or master non-crew member list previously submitted to CBP in accordance with § 122.49c. If a crew member or non-crew member on the manifest is not also included on the appropriate master list, the flight may be denied clearance to depart.

(iii) *Changes to manifest.* The appropriate official is obligated to make necessary changes to the crew member or non-crew member departure manifest after transmission of the manifest to CBP. Necessary changes include adding a name, with other required information, to the manifest or

amending previously submitted information. If changes are submitted less than 60 minutes before scheduled flight departure, the air carrier must receive approval from TSA before allowing the flight to depart or the flight may be denied clearance to depart.

(3) *Information required.* The electronic crew member and non-crew member departure manifests required under paragraph (b)(1) of this section must contain the following information for all crew members and non-crew members, except that the information specified in paragraphs (b)(iii), (v), (vi), (xii), and (xiv) of this section must be included on the manifest only on or after October 4, 2005:

(i) Full name (last, first, and, if available, middle);

(ii) Date of birth;

(iii) Place of birth (city, state—if applicable, country);

(iv) Gender (F = female; M = male);

(v) Citizenship;

(vi) Address of permanent residence;

(vii) Status on board the aircraft;

(viii) Pilot certificate number and country of issuance (if applicable);

(ix) Travel document type (*e.g.*, P = passport; A = alien registration card);

(x) Passport number, if a passport is required;

(xi) Passport country of issuance, if a passport is required;

(xii) Passport expiration date, if a passport is required;

(xiii) Alien registration number, where applicable;

(xiv) Passenger Name Record locator, if available;

(xv) International Air Transport Association (IATA) departure port code;

(xvi) IATA code of port/place of final arrival (foreign port code);

(xvii) Airline carrier code;

(xviii) Flight number; and

(xix) Date of aircraft departure.

(c) *Exceptions.* The electronic departure manifest requirement specified in paragraph (b)(1) of this section is subject to the following conditions:

(1) Federal Aviation Administration (FAA) Aviation Safety Inspectors with valid credentials and authorization are not subject to the requirement, but the manifest requirement of § 122.75a applies to these inspectors, as they are considered passengers on departing flights;

(2) For crew members traveling onboard departing aircraft chartered by the U.S. Department of Defense, the provisions of this section apply regarding electronic transmission of the manifest, except that:

(i) The manifest certification provision of paragraph (b)(2)(ii) of this section is inapplicable; and

(ii) The TSA manifest change approval requirement of paragraph (b)(2)(iii) of this section is inapplicable; and

(3) For non-crew members traveling onboard a departing all-cargo flight chartered by the U.S. Department of Defense, the manifest is not required, but the manifest requirement of § 122.75a applies to these persons, as, in this instance, they are considered passengers on departing flights.

(d) *Carrier responsibility for comparing information collected with travel document.* The carrier collecting the information described in paragraph (b)(3) of this section is responsible for comparing the travel document presented by the crew member or non-crew member with the travel document information it is transmitting to CBP in accordance with this section in order to ensure that the information is correct, the document appears to be valid for travel, and the crew member or non-crew member is the person to whom the travel document was issued.

(e) *Sharing of manifest information.* Information contained in the crew member and non-crew member manifests required under this section that is received by CBP electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security. CBP may also share such information as otherwise authorized by law.

(f) *Master crew member and non-crew member lists.* Air carriers subject to the requirements of this section must also comply with the requirements of § 122.49c pertaining to the electronic transmission of a master crew member list and a master non-crew member list as applied to flights departing from the United States.

(g) *Superseding amendments issued by TSA.* One or more of the requirements of this section may be superseded by provisions of, amendments to, or alternative procedures authorized by TSA for compliance with an aviation security program, emergency amendment, or security directive issued by the TSA to an air carrier subject to the provisions of 49 CFR part 1544, 1546, or 1550. The amendments will have superseding effect only for the airline to which issued and only for the period of time they remain in effect.

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

■ 13. The authority citation for part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624, 44 U.S.C. 3501 *et seq.*

■ 14. Section 178.2 is amended by removing from the chart the entry for § 122.49a and adding to the chart the following in appropriate numerical sequence according to the section number under the columns indicated:

§ 178.2 Listing of OMB control numbers.

19 CFR section	Description	OMB control No.
§§ 4.7b, 4.64, 122.49a, 122.49b, 122.49c, 122.75a, 122.75b.	Electronic manifest requirements for carriers transporting passengers and crew on-board vessels and aircraft.	1651–0088

* * * * *

Robert C. Bonner,

Commissioner, Customs and Border Protection.

Approved: March 25, 2005.

Michael Chertoff,

Secretary.

[FR Doc. 05–6523 Filed 4–6–05; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS–2005–0005]

Privacy Impact Assessment and Privacy Policy

AGENCY: Department of Homeland Security.

ACTION: Notice.

SUMMARY: Pursuant to the E–Government Act of 2002, the Department of Homeland Security, Bureau of Customs and Border Protection, is publishing a privacy impact assessment and privacy policy concerning the Advanced Passenger Information System.

DATES: Written comments must be received on or before May 9, 2005.

ADDRESSES: You may submit comments, identified by Docket Number DHS–2005–0005, by one of the following methods:

- EPA Federal Partner EDOCKET Web site: *http://www.epa.gov/feddocket*. Follow the instructions for submitting comments on the Web site.
- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Comments by mail are to be addressed to the Bureau of Customs and Border Protection, Office of Regulations and Rulings, 1300 Pennsylvania Avenue, NW. (Mint Annex), Washington, DC 20229. Comments submitted by mail may be inspected at the Bureau of Customs and Border Protection at 799 9th Street, Washington, DC. To inspect comments, please call (202) 572–8768 to arrange for an appointment.

Instructions: All submissions received must include the agency name and docket number for this privacy impact assessment. All comments received, including any personal information, will be posted without change to *http://www.epa.gov/feddocket*.

Docket: For access to the docket to read background documents or comments received, go to *http://www.epa.gov/feddocket*. You may also access the Federal eRulemaking Portal at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Charles Perez, Program Manager, Office of Field Operations, Bureau of Customs and Border Protection at (202) 344–2605 or Nuala O'Connor Kelly, Chief Privacy Officer, Department of Homeland Security at (202) 772–9848.

SUPPLEMENTARY INFORMATION: Elsewhere in the **Federal Register** today, the Department of Homeland Security, Bureau of Customs and Border Protection (CBP), is publishing a final rule concerning the Advanced Passenger Information System (APIS). The rule requires that all commercial inbound and outbound air and sea carriers submit certain data on all passengers and crew members prior to entry to or departure from the United States. The data that must be provided includes the following: the country that issued the passport or alien registration number; the passenger or crew member's full name, date of birth, passport or alien registration number, country of residence, and U.S. destination address (foreign nationals only); and the locator number for the passenger's airline reservation data. For crew members and non-crew members,[1] the address of permanent residence and the pilot certificate number are also required.

Pursuant to the CBP Final Rule, the APIS data must be submitted to CBP by the carrier: (i) For passenger flights into the United States, 15 minutes after departure from a foreign port or place; (ii) for passenger flights departing the United States, 15 minutes prior to departure from the United States; (iii) for crew members (on passenger and all-cargo flights) and non-crew members (limited to all-cargo flights), 60 minutes prior to the departure of any covered flight[2] from a foreign port, the U.S. port of departure, or the U.S. port of arrival en route to a second U.S. port, as applicable; (iv) for vessel arrivals, no later than 24 hours and up to 96 hours prior to the vessel's entry at a U.S. port, depending on the length of the voyage; and (v) for vessel departures, no later than 15 minutes prior to the vessel's departure from a U.S. port. The CBP Final Rule also requires the carrier industry to submit APIS data in an electronic interchange approved by CBP.

In connection with this final rule, and in accordance with Section 208 of the E-Government Act of 2002, which requires federal agencies to conduct a privacy impact assessment when they use information technology to collect new information or make significant changes in existing information technology collections, the Department of Homeland Security conducted a Privacy Impact Assessment of APIS, and developed a privacy policy for this program. The privacy impact assessment and privacy policy are attached as appendix 1 to this notice, in keeping with the statutory requirement that such documents be published.

Dated: March 21, 2005.

Nuala O'Connor Kelly,

Chief Privacy Officer, Department of Homeland Security.

Appendix 1—Privacy Impact Assessment and Privacy Policy; Advance Passenger Information System (APIS) Program

The Aviation and Transportation Security Act of 2001 and the Enhanced Border Security and Visa Reform Act of 2002 together mandated the collection of certain information on all passenger and crew members who arrive in or depart from the United States on a commercial air or sea carrier. The information required to be collected and submitted to the Advance Passenger Information System (APIS) can be found on routine entry documents that passenger and crew members must provide when processed into or out of the United States. The APIS information includes full name, date of birth, citizenship, passport/alien registration card number, passport/alien registration card country of issuance, passport expiration date country of residence and U.S. destination address (where applicable). The APIS information is collected in advance of a passenger's arrival or departure from the United States in order to perform law enforcement queries to identify security risks to the aircraft or vessel, to its occupants, or to the United States and in order to expedite CBP processing.

Advance Passenger Information System (APIS)—Privacy Impact Assessment

I. Introduction

The Advance Passenger Information System (APIS) was developed as a voluntary program by the former United States Customs Service (Customs Service) in 1989 in cooperation with the former United States Immigration and Naturalization Service (INS) and the airline industry. Air carriers and sea vessels collected passengers' biographical data and transmitted the data to the Customs Service while the flight or the vessel was en route. The Customs Service Data Center used APIS data to perform a check against the combined Federal law enforcement database known as the Interagency Border Inspection System (IBIS). Through the voluntary APIS program, these checks were performed in advance of arrival and quickly referenced once the passengers arrived. This resulted in a significant time savings for the passengers and carriers.

In the Aviation and Transportation Security Act of 2001 (ATSA) and the Enhanced Border Security and Visa Reform Act of 2002 (EBSA), Congress made mandatory the collection of certain information on all passenger and crew

[1] "Non-crew member" means air carrier employees and their family members and persons traveling onboard a commercial aircraft for the safety of the flight (such as an animal handler when animals are onboard). The definition of "non-crew member" is limited to all-cargo flights. (On a passenger or dual flight (passengers and cargo), air carrier employees, their family members, and persons onboard for the safety of the flight are considered passengers).

[2] A "covered flight" is one to, from, continuing within, or overflying the United States.

members who arrive in, depart from, or transit through the United States on a commercial air or sea carrier, and, in the case of foreign crew members, those who continue domestically on a foreign carrier. The purpose of this collection is to identify high risk passengers and crew members who may pose a risk or threat to vessel or aircraft safety or to national security, while simultaneously facilitating the travel of legitimate passengers and crew members. As mentioned above, this information collection also assists in immigration processing at ports of entry, resulting in a significant time savings.

To implement the mandatory collection of APIS information under ATSA and EBSA, the Customs Service issued an interim regulation (see 19 CFR 122.49a), 66 FR 67484 (December 31, 2001), as amended 67 FR 42712 (June 25, 2002) (Interim Regulation), mandating the transmission of APIS data for all inbound commercial air carriers. The INS issued a Notice of Proposed Rulemaking (NPRM) on January 3, 2003, expanding these requirements to outbound commercial air carriers and inbound and outbound commercial sea carriers. (*See* 68 FR 292.) With the creation of the Department of Homeland Security (DHS), the inspection and patrol functions of the former INS were incorporated in the U.S. Customs Service which was renamed United States Customs and Border Protection (CBP) under DHS. CBP is now responsible for border enforcement activities, including the collection of APIS information.

To carry out its statutory responsibilities, CBP is now issuing a final rule to require the submission of certain biographical data to CBP through APIS prior to a passenger's or crew member's entry into and exit from the United States. CBP's final rule also provides small air and sea carriers, which do not have the means to transmit data through APIS, a web site to collect this information in the required timeframe. In keeping with the requirements of Section 208 of the E-Government Act of 2002 and Section 222 of the Homeland Security Act, the mandatory collection of information required by APIS is the subject of this Privacy Impact Assessment.

II. System Overview

What Information Is To Be Collected

The information to be collected from passengers and crew members by the air and sea carrier industry consists of: Complete name, date of birth, gender, country of citizenship, passport/alien registration number and country of issuance, passport expiration date, country of residence, travel document type, U.S. destination address for foreign nationals (other than those in transit), and the passenger name record locator number.[1] Most of the information collected is contained in the machine-readable zone (MRZ) of an official travel document such as a passport or alien registration card. When a traveler checks in for an international flight, the airline representative will swipe the traveler's travel document through a document reader designed to electronically capture specific information and populate the carrier's computer screen. The carrier will also collect and transmit to CBP the U.S. destination address (foreign nationals only, other than those in transit) and country of residence, which is not contained in the MRZ.

In addition to collecting information directly from the traveler, the carrier also must transmit to CBP the following supplementary information: Foreign airport/port where the passengers and crew members began their air transportation to the United States; for passengers and crew member destined for the U.S. the location where the passenger will be processed through customs and immigration formalities; and for passengers and crew members that are transiting through the U.S. and not clearing customs and immigration formalities, the foreign airport of ultimate destination, and status on board (whether an individual is crew or non-crew). Finally, information also is collected about the particular flight or voyage, such as date of arrival/departure, carrier name, flight number, departure location, arrival location, country of registry.

Why the Information Is Being Collected and Intended Use of the Information

The information is being collected pursuant to the ATSA and the EBSA. The purpose of the collection is to screen passengers arriving from foreign travel points and departing the United States to identify those passengers who (1) may pose a risk to the transportation industry, to other travelers and to the United States, (2) are identified as or suspected of being a terrorist or having affiliations to terrorist organizations, (3) have active wants and warrants for criminal activity, (4) are currently inadmissible, or have been previously deported from the United States, or (5) are subject to other intelligence that may identify them as a security risk.

At the same time, the system allows CBP to facilitate effectively and efficiently the entry of legitimate travelers into the United States. As travelers arrive into the United States, through APIS, CBP officers can quickly reference the results of the advanced research that has been conducted through CBP's law enforcement databases, confirm the accuracy of that information by comparison of it with information obtained from the traveler and from the carriers, and make immediate determinations as to a traveler's security risk and admissibility.

How Will Information Be Checked for Accuracy?

Upon a traveler's arrival into the United States, a CBP officer verifies that the data transmitted by the carrier is the same as that on the traveler's travel documents. If discrepancies are found, a CBP officer can correct the data at the point of entry and update the information. Additionally, CBP audits and tracks the sufficiency and error rates of individual carrier transmissions to APIS and may assess penalties against carriers that fail to transmit APIS data within system parameters on a recurring basis or incur large error rates in the review of their transmissions. CBP also performs periodic audits and routine maintenance on its Information Technology Systems to ensure that system protocols and programming remain intact and operational.

Will the System Derive New Data or Create Previously Unavailable Data About an Individual Through Aggregation From the Information Collected?

Certain APIS data is maintained and examined in order to view an individual's travel history. In addition to maintaining an individual's travel record, this data is aggregated with information from law enforcement databases to assist CBP employees in making determinations as to a traveler's security risk and admissibility into the United States.

What Notice Is Given and What Opportunities Does an Individual Have To Consent?

CBP has provided notice through publication of its Interim Regulation (*see* 66 FR 67484; as amended 67 FR 42712), the NPRM (*see* 68 FR 292), as well as this privacy impact assessment and its privacy policy, which is being published simultaneously.

Clearance for the arrival or departure of a commercial vessel or aircraft may be contingent upon the submission of passenger and crew manifest information to CBP through APIS.

A foreign traveler who declines to provide APIS information to a carrier is inadmissible to the United States. Such an individual may withdraw his or her application for admission, or be subject to removal proceedings.

United States citizens who refuse to provide the information to the air or sea carrier may be subject to action by that particular carrier. A carrier may prohibit the person from traveling. However, if the carrier allows the passenger to board without providing the required information, the person will be subject to security checks upon arrival.

III. APIS System Architecture

APIS is a system that resides within the Treasury Enforcement Communications System (TECS), a law enforcement database. (The most recent System of Records Notice for TECS can be found at 66 FR 52984 (October 18, 2001).) APIS comprises a subset of the data collected and maintained within TECS. The data particular to APIS is accessed through functionality that is separate from data within TECS. Certain APIS data (complete name, date of birth, date of arrival, date of departure, time arrived, means of arrival (air/sea), immigration lane, ID inspector, travel document, departure location, airline code and flight number, and result of the CBP processing) is moved to the general TECS database once an individual traveler has cleared immigration.

The APIS data is cross-referenced or compared against other law enforcement data maintained in TECS. These cross-references and comparisons occur through IBIS. IBIS resides in TECS and provides access to the National Crime Information Center (NCIC), which allows users to interface with all 50 states via the National Law Enforcement Telecommunications System (NLETS). IBIS

[1] The Passenger Name Record locator number allows CBP to access PNR if necessary, consistent with its regulatory authority under 19 CFR 122.49b.

also contains the names of individuals on terrorist watch lists.

IV. Maintenance and Administrative Controls on Access to the Data

With Whom the Information Will Be Shared

The personal information collected and maintained by APIS will be accessed by employees of DHS components. Strict security and access controls are in place to ensure that only those personnel with a need for the information in the performance of their official duties will be able to access information in the system.

Additionally, the information may be shared with other federal, state, local or foreign agencies responsible for investigating or prosecuting violations of, or for enforcing or implementing a statute, rule, regulation, order, or license, where DHS becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation. The system of records notice for TECS, where APIS data reside, provides notice as to the conditions of disclosure and routine uses for the information collected by APIS, and provides that any dissemination of information maintained within APIS be compatible with the purpose for which the information originally was collected.

As discussed previously, certain APIS data are transferred to the general TECS database after a traveler has cleared immigration. The information transferred to and stored in the general TECS database includes: Complete name, date of birth, date of arrival, date of departure, time arrived, means of arrival (air/sea), immigration lane, ID inspector, travel document, departure location, airline code and flight number, and result of the CBP processing. APIS is the source data for this travel information stored in the general TECS database.

For individuals subject to US–VISIT requirements, certain APIS data also is transferred to the Arrival and Departure Information System (ADIS) for effective and efficient tracking of foreign nationals. This information includes: Complete name, date of birth, gender, nationality, U.S. destination address, passport number, country of issuance,[2] alien registration number, port of entry, entry date, port of departure, and departure date.

Retention and Destruction

APIS information, which is used at the port of entry for verification purposes, is retained temporarily in the APIS component of the TECS system for no more than 12 months from the date of collection at which time the data is erased from the APIS component of the TECS system. Information that is transferred to the general TECS database (as described above) will be maintained for as long as operationally necessary, subject to retention reviews that occur both periodically and each time information is accessed, but in no case will information be retained longer than fifty years past the date of collection. Information that is transferred to ADIS (as described above) is maintained for 100 years in accordance with the retention period of the ADIS system of records notice.

[2] For non-immigrants authorized to work.

How the Information Will Be Secured

APIS, as a component of TECS, is approved through the TECS Certification and Accreditation (C&A) under the National Institute of Standards and Technology. The last certification was on February 23, 2003. Although APIS is currently under the TECS C&A, it will have its own certification and accreditation in calendar year 2005, to provide specific assurances regarding the safety and security of APIS data.

APIS information is secured in full compliance with the requirements of the DHS IT Security Program Handbook. This handbook establishes a comprehensive program, consistent with federal law and policy, to provide complete information security, including directives on roles and responsibilities, management policies, operational policies, and application rules, which will be applied to component systems, communications between component systems, and at interfaces between component systems and external systems.

One aspect of the DHS comprehensive program to provide information security involves the establishment of rules of behavior for each major application, including APIS. These rules of behavior require users to be adequately trained regarding the security of their systems. These rules also require a periodic assessment of technical, administrative and managerial controls to enhance data integrity and accountability. System users must sign statements acknowledging that they have been trained and understand the security aspects of their systems. System users must also complete annual privacy awareness training to maintain current access.

APIS transactions are tracked and can be monitored. This allows for oversight and audit capabilities to ensure that the data are being handled consistent with all applicable federal laws and regulations regarding privacy and data integrity.

Data exchange, which will take place over an encrypted network between the carrier industry and CBP and between CBP and other DHS components that have access to the APIS data, is limited and confined only to those entities that have a need for the data in the performance of official duties. These encrypted networks comply with standards set forth in the Interconnection Security Agreements required to be executed prior to external access to a CBP computer system.

The eAPIS Web based system, which permits submission of manifest information over the Internet by carriers who do not have the capability to transmit electronic PNR data, is subject to the same security precautions, standards, laws, and regulations with respect to the collection, retention, and safeguarding of APIS data. Exchanges of data submitted via eAPIS will be no different than exchanges of APIS data collected by other means. eAPIS submissions will be made over an encrypted Internet portal accessed via an approved username and password.

V. Redress

CBP has created a Customer Satisfaction Unit in its Office of Field Operations to provide redress with respect to incorrect or inaccurate information collected or maintained by its electronic systems (including TECS, IBIS, and APIS). If the traveler believes that CBP actions are the result of incorrect or inaccurate information, then inquiries should be directed to the Customer Satisfaction Unit at the following address: Customer Satisfaction Unit, Office of Field Operations, U.S. Customs and Border Protection, Room 5.5C, 1300 Pennsylvania Avenue, NW., Washington, D.C. 20229, fax (202) 344–2791. Individuals making inquiries should provide as much identifying information as possible regarding themselves, to identify the record at issue. Individuals may provide additional information to CBP to ensure that the information maintained by CBP is accurate and complete. The Customer Satisfaction Unit will respond in writing to each inquiry.

The DHS Chief Privacy Officer will exercise comprehensive oversight of all phases of the program to ensure that privacy concerns are respected throughout the process. The DHS Chief Privacy Officer will also serve as the final review authority for all individual complaints and concerns about the program.

VI. System of Records

APIS data is a subset of the system data within the Treasury Enforcement Communications System (TECS) and is covered by the System of Records Notice for TECS. The most recent TECS publication can be found at 66 FR 52984 (October 18, 2001). APIS data is also contained in the system data for the Arrival and Departure Information System (ADIS) and is also covered by the System of Records Notice for ADIS. The most recent ADIS publication can be found at 68 FR 69412 (December 12, 2003).

Privacy Controls

APIS collects personal information necessary for its purposes. While APIS does not constitute a new system of records, the final rule requiring submission of data expands the types of data collected, the number of travelers from which the data is collected, and makes the system mandatory rather than voluntary. These changes create a potential privacy risk. This risk is mitigated, however, by establishment of the privacy policy supported and enforced by the comprehensive privacy program. This program includes mandatory privacy training for system operators and appropriate safeguards for data handling.

The APIS system collects data to be compared against an existing law enforcement database—TECS—to promote the safety and security of sea and air carriers, their passengers and the United States. Some data collected via APIS manifests is transferred to TECS and may become available for later research of the entry and exit of travelers. This presents a potential privacy risk. This risk is mitigated in several ways. First, APIS data is controlled by separate functionality within the TECS system from other data maintained in that system. While the APIS data may be compared against other data maintained in TECS, this action requires an affirmative act by the user that is subject to regular agency review and audit. Second, the TECS system,

and APIS within TECS, has its own published System of Records Notice (SORN), which explains the uses to which the data that is collected will be put. This SORN includes the purposes underlying APIS as part of its terms. This SORN assists in putting the travelling public on notice of the uses of APIS data. Third, Memoranda of Understanding and of Agreement with other agencies carefully regulate the uses for TECS data. This PIA and APIS Privacy Policy make this use of APIS data transparent.

APIS intends to ensure that the program is as transparent as possible. To that end, in addition to publishing this privacy impact assessment and the final rule, CBP has developed a comprehensive privacy policy, a copy of which is appended to this report and which is posted on the DHS Web site.

VII. Summary and Conclusions

The APIS program is based on Congressional concerns with improving the safety and security not only of sea and air carriers and their passengers, but also the national security of the United States. Requirements for the program, including the implementation of an integrated and interoperable passenger manifest screening system, are established by various provisions of the Aviation and Transportation Security Act of 2001 and the Enhanced Border Security and Visa Reform Act of 2002. These requirements include, in particular, the integration of arrival, departure, and transit data on all passengers and crew members traveling and listed on commercial sea or air carrier manifests; and integration of this information with other law enforcement and security systems.

CBP structured the APIS program, as promulgated in the final rule, to foster the goals of these statutes, mindful of the need to protect the privacy of the individuals whose data is being collected. This PIA examines the potential privacy risks and describes those actions CBP has taken to mitigate these risks.

Contact Point and Reviewing Official

Contact Point: Charles Perez, Program Manager, Office of Field Operations, U.S. Customs and Border Protection, (202) 344–2605.

Reviewing Official: Nuala O'Connor Kelly, Chief Privacy Officer, DHS, (202) 772–9848.

Advance Passenger Information System (APIS)—Privacy Policy

What Is the Purpose of the APIS Program?

The Aviation and Transportation Security Act of 2001 and the Enhanced Border Security and Visa Reform Act of 2002 together mandated the collection of certain information on all passenger and crew members who arrive into or depart from the United States on a commercial air or sea carrier. The Advance Passenger Information System (APIS) information is collected in advance of a passenger's arrival into the United States in order to perform law enforcement queries to identify security risks to the aircraft/vessel, its occupants, and the United States. The information is also used to verify departure when the traveler leaves the United States at the conclusion of a visit.

Who Is Affected by the Program?

All travelers and crew members who arrive and depart the United States, all crew members on aircraft who fly over the United States, and crew members on foreign aircraft who arrive from an international departure location and continue domestically within the United States are covered by the APIS Program.

What Information Is Collected?

The information to be collected from passengers and crew members by the air and sea carrier industry consists of: complete name, date of birth, gender, country of citizenship, passport/alien registration number and country of issuance, passport expiration date, country of residence, travel document type, U.S. destination address for foreign nationals (other than those in transit), and the passenger name record locator number.[3] Most of the information collected is contained in the machine-readable zone (MRZ) of an official travel document such as a passport or alien registration card. When a traveler checks in for an international flight, the airline representative will swipe the traveler's travel document through a document reader designed to electronically capture specific information and populate the carrier's computer screen. The carrier will also collect and transmit to CBP the U.S. destination address (foreign nationals only, other than those in transit) and country of residence, which is not contained in the MRZ.

In addition to collecting information directly from the traveler, the carrier also must transmit to CBP the following supplementary information: Foreign airport/port where the passengers and crew members began their air transportation to the United States; for passengers and crew member destined for the U.S. the location where the passenger will be processed through customs and immigration formalities; and for passengers and crew members that are transiting through the U.S. and not clearing customs and immigration formalities, the foreign airport of ultimate destination, and status on board (whether an individual is crew or non-crew). Finally, information also is collected about the particular flight or voyage, such as date of arrival/departure, carrier name, flight number, departure location, arrival location, country of registry.

How Is the Information Used?

The purpose of the information collection is to screen passengers arriving from foreign travel points and departing the United States to identify those passengers who (1) may pose a risk to the transportation industry, to other travelers and to the United States, (2) are identified as or suspected of being a terrorist or having affiliations to terrorist organizations, (3) have active warrants for criminal activity, (4) are currently inadmissible, or have been previously deported from the United States, or (5) are subject to other intelligence that may identify them as a security risk.

At the same time, the system allows CBP to facilitate effectively and efficiently the entry of legitimate travelers into and through the United States. As travelers arrive into the United States, CBP officers can quickly reference the results of the advanced research conducted through the law enforcement databases and make immediate determinations as to a traveler's security risk and admissibility.

Is the Collection of APIS Data Duplicative of Data Collected by the US–VISIT?

No. US–VISIT does not, in itself, collect traveler manifest data. US–VISIT coordinates the exchange of data collected by existing systems that are utilized by the Department of Homeland Security (DHS), such as the APIS system operated by CBP.

Will the Collection of APIS Data Be Duplicative of the Data Required by the Secure Flight Program as Proposed by the Transportation and Security Administration?

No. The Secure Flight Program is proposed only for domestic carriers transporting travelers within the United States. APIS is restricted to passengers entering and exiting the United States and crew members entering, exiting, overflying, and continuing domestically on a foreign carrier.

Who Will Have Access to the Information?

The personal information collected and maintained by APIS will be accessed by employees of DHS components. Strict security and access controls are in place to ensure that only those personnel with a need for the information in the performance of their official duties will be able to access information in the system.

Additionally, the information may be shared with other federal, state, local, or tribal or foreign agencies responsible for investigating or prosecuting violations of, or for enforcing or implementing a statute, rule, regulation, order, or license, where DHS becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

How Will the Information Be Protected?

Personal information will be kept secure and confidential and will not be discussed with, nor disclosed to, any person within or outside the APIS program other than as authorized by law and as required for the performance of official duties. Careful safeguards, including appropriate security controls, will ensure that the data is not used or accessed improperly. The APIS functionality is a part of the Treasury Enforcement Communications System (TECS), a law enforcement database. Its accreditation is in accordance with the CBP Information Systems Security Policy and Procedures Handbook (CIS HB 1400–05A, dated June 22, 2001) and with National Information Standards and Technology (NIST) guidance. The TECS system was certified and accredited on February 23, 2003. APIS also will have individual certification utilizing the NIST guidance in calendar year 2005.

Roles and responsibilities of DHS employees, system owners and managers,

[3] The Passenger Name Record locator number allows CBP to access PNR if necessary, consistent with its regulatory authority under 19 CFR 122.49b.

and third parties who manage or access information in the APIS program include:

1. DHS Employees and Contractors

As users of APIS systems and records, DHS employees shall:

• Access records containing personal information only when the information is needed to carry out their official duties.

• Disclose personal information only for legitimate government purposes and in accordance with applicable laws, regulations, and applicable policies and procedures.

2. Owners/Managers of the DHS Systems Storing APIS Data

System Owners/Managers shall:

• Follow applicable laws, regulations, APIS program guidance and DHS policies and procedures in the development, implementation, and operation of information systems under their control.

• Conduct a risk assessment to identify privacy risks and determine whether it is necessary and appropriate to implement additional security controls to protect against the risk.

• Ensure that only personal information that is necessary and relevant for legally mandated or authorized purposes is collected.

• Ensure that all business processes that contain personal information have an approved Privacy Impact Assessment, which meets appropriate DHS and OMB guidance and which is updated as the system progresses through its development stages.

• Ensure that all personal information is protected and disposed of in accordance with applicable laws, regulations, APIS program guidance and DHS policies and procedures.

• Use personal information collected only for the purposes for which it was collected, unless other purposes are explicitly mandated or authorized by law.

• Establish and maintain appropriate administrative, technical, and physical security safeguards to protect personal information.

How Long Is Information Retained?

APIS data is subject to temporary and permanent retention requirements. The information initially collected by APIS is used for entry screening purposes and is retained for twelve months. Certain data obtained through the APIS transmission (complete name, date of birth, date of arrival, date of departure, time arrived, means of arrival (air/sea), primary inspection, ID inspector, travel document, departure location, airline code and flight number, and result of the CBP processing), however, is moved to the general TECS database once an individual traveler has cleared primary inspection. Other information is transferred to the Arrival and Departure Information System (ADIS) for US–VISIT purposes. The transferred data is retained in accordance with the retention schedules approved for TECS and ADIS, as applicable. In general, information stored in the TECS database will be retained for as long as operationally necessary, subject to retention reviews that occur both periodically and each time information is accessed, but in no case will information be retained longer than fifty years past the date of collection. Information stored in ADIS will be retained consistent with the retention schedule for that records system (100 years).

Is a Form of Redress Available?

CBP has created a Customer Satisfaction Unit in its Office of Field Operations to provide redress with respect to incorrect or inaccurate information collected or maintained by its electronic systems. Inquiries should be addressed to: Customer Satisfaction Unit, Office of Field Operations, U.S. Customs and Border Protection, Room 5.5C, 1300 Pennsylvania Avenue, NW., Washington, DC 20229, fax (202) 344–2791. Individuals making inquiries should provide as much identifying information as possible, to identify the record at issue.

The DHS Chief Privacy Officer will exercise comprehensive oversight of all phases of the program to ensure that privacy concerns are respected throughout the process and will also serve as the final review authority for all individual complaints and concerns about the program.

For Further Information Contact:

Charles Perez, Program Manager, APIS, Office of Field Operations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Washington, DC 20229, Tel: (202) 344–2605.

Nuala O'Connor Kelly, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528, Tel: (202) 772–9848.

[FR Doc. 05–6522 Filed 4–6–05; 8:45 am]

BILLING CODE 4410–10–P

Federal Register

Thursday,
April 7, 2005

Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Establishment of an Additional Manatee Protection Area in Lee County, Florida; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AT65

Endangered and Threatened Wildlife and Plants; Establishment of an Additional Manatee Protection Area in Lee County, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the Fish and Wildlife Service (Service), establish an additional manatee protection area in Lee County, Florida (Pine Island-Estero Bay Manatee Refuge). This action is authorized under the Endangered Species Act of 1973, as amended (ESA) and the Marine Mammal Protection Act of 1972, as amended (MMPA), to further recovery of the Florida manatee (*Trichechus manatus latirostris*) by preventing the taking of one or more manatees. We are designating an area in Lee County as a manatee refuge in which certain waterborne activities will be regulated. Specifically, watercraft will be required to proceed at either ''slow speed'' or at not more than 25 miles per hour, on an annual or seasonal basis, as described in the rule. We also announce the availability of a final environmental assessment for this action.

DATES: *Effective date:* April 4, 2005

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business hours from 8 a.m. to 4:30 p.m. at the South Florida Field Office, U.S. Fish and Wildlife Service, 1339 20th Street, Vero Beach, Florida 32960.

FOR FURTHER INFORMATION CONTACT: Jay Slack or Kalani Cairns (see **ADDRESSES** section), telephone 772/562–3909; or visit our Web site at *http://verobeach.fws.gov.*

SUPPLEMENTARY INFORMATION:

Background

The West Indian manatee (*Trichecus manatus*) is federally listed as an endangered species under the ESA (16 U.S.C. 1531 *et seq.*) (32 FR 4001) and the population is further protected as a depleted stock under the MMPA (16 U.S.C. 1361–1407). Manatees reside in freshwater, brackish, and marine habitats in coastal and inland waterways of the southeastern United States. The majority of the population can be found in waters of the State of Florida throughout the year, and nearly all manatees live around peninsular Florida during the winter months. The manatee is a cold-intolerant species and requires warm water temperatures generally above 20° Celsius (68° Fahrenheit) to survive during periods of cold weather. During the winter months, most manatees rely on warm water from natural springs and industrial discharges for warmth. In warmer months, they expand their range and are seen rarely as far north as Rhode Island on the Atlantic Coast and as far west as Texas on the Gulf Coast.

Recent information indicates that the overall manatee population has grown since the species was listed (Service 2001). However, in order for us to determine that an endangered species has recovered to a point that it warrants removal from the List of Endangered and Threatened Wildlife and Plants, the species must have improved in status to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the ESA.

Human activities, particularly waterborne activities, can result in the take of manatees. Take, as defined by the ESA, means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, collect, or to attempt to engage in any such conduct. Harm means an act which kills or injures wildlife (50 CFR 17.3). Such an act may include significant habitat modification or degradation that kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering. Harass includes intentional or negligent acts or omissions that create the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3).

The MMPA establishes a moratorium, with certain exceptions, on the taking and importation of marine mammals and marine mammal products and makes it unlawful for any person to take, possess, transport, purchase, sell, export, or offer to purchase, sell, or export, any marine mammal or marine mammal product unless authorized. Take, as defined by section 3(13) of the MMPA, means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. Harassment is defined by section 3(18) of the MMPA as any act of pursuit, torment, or annoyance which—(i) has the potential to injure a marine mammal or marine mammal stock in the wild; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering.

Human use of the waters of the southeastern United States has increased as a function of residential growth and increased visitation. This increase is particularly evident in the State of Florida. The population of Florida has grown by 135 percent from 1970 to 2000 (6.8 million to 15.9 million, U.S. Census Bureau) and is expected to exceed 18 million by 2010 and 20 million by the year 2020. According to a report by the Florida Office of Economic and Demographic Research (2005), it is expected that, by the year 2010, 14.7 million people will reside in the 35 coastal counties of Florida. In a parallel fashion to residential growth, visitation to Florida has also increased. It is expected that Florida will have 83 million visitors annually by the year 2020, up from 48.7 million visitors in 1998. In concert with this increase of human population growth and visitation is the increase in the number of watercraft that travel Florida waters. In 2003, 743,243 vessels were registered in the State of Florida. This represents an increase of more than 26 percent since 1993. The apparent decline in the number of vessels that were registered between 2001 and 2003 is due to a change in the way registrations are counted. The earlier (2001) numbers included all registrations occurring during the year and therefore double-counted vessels that were sold and re-registered during the same year.

The increase in and projected growth of human use of manatee habitat has had direct and indirect impacts on this endangered species. Direct impacts include injuries and deaths from watercraft collisions, deaths and injuries from water control structure operations, lethal and sublethal entanglements with commercial and recreational fishing gear, and alterations of behavior due to harassment. Indirect impacts include habitat destruction and alteration, including decreases in water quality throughout some aquatic habitats, decreases in the quantity of warm water in natural spring areas, the spread of marine debris, and general disturbance from human activities.

Federal authority to establish protection areas for the Florida manatee is provided by the ESA and the MMPA and is codified in 50 CFR, part 17, subpart J. In accordance with 50 CFR 17.106, manatee protection areas may be established on an emergency basis when such takings are imminent. Such was the case for the emergency designation of these areas within Lee County as a manatee refuge. The first of three

emergency rules for the establishment of the Pine Island-Estero Bay Manatee Refuge was published in the **Federal Register** on April 7, 2004 (69 FR 18279). The emergency designation was temporary, lasting only 120 days, and expired on August 5, 2004. On August 6, 2004, we published a proposed rule in the **Federal Register** (69 FR 48102) to establish the Pine Island-Estero Bay Manatee Refuge by standard rulemaking procedures. In order to provide for continued protection of this area during the rulemaking process and to allow adequate time for a public hearing and comments on the proposed designation, we used our emergency authority to re-establish the temporary Pine Island-Estero Bay Manatee Refuge, effective on August 6, 2004 (69 FR 48115). This second emergency designation lasted another 120 days and expired on December 6, 2004. Due to delays in scheduling the public hearing caused by the hurricanes affecting peninsular Florida (*e.g.*, Charley, Frances, and Jeanne) and to provide for continued protection of this area during the rulemaking process while allowing adequate time for public hearings and comments on the proposed designation, we used our emergency authority, a third time, to re-establish the temporary Pine Island-Estero Bay Manatee Refuge, effective on December 6, 2004 (69 FR 70382). This designation lasted 120 days and expired on April 5, 2005.

Pursuant to 50 CFR 17.103, we may establish two types of manatee protection areas: manatee refuges and manatee sanctuaries. A manatee refuge is an area in which we have determined that certain waterborne activities would result in the taking of one or more manatees, or that certain waterborne activities must be restricted to prevent the taking of one or more manatees, including but not limited to, a taking by harassment. A manatee sanctuary is an area in which we have determined that any waterborne activity would result in the taking of one or more manatees, including but not limited to, a taking by harassment. A waterborne activity is defined as including, but not limited to, swimming, diving (including skin and scuba diving), snorkeling, water skiing, surfing, fishing, the use of water vehicles, and dredge and fill activities (50 CFR 17.102).

Reasons for Designating a Manatee Refuge

In deciding to implement this rule, we assessed the effects of a recent County Court ruling overturning State-designated manatee speed zones in Lee County (*State of Florida Fish and Wildlife Conservation Commission* vs. *William D. Wilkinson, Robert W. Watson, David K. Taylor, James L. Frock* [2 cases], *Jason L. Fluharty, Kenneth L. Kretsh, Harold Stevens, Richard L. Eyler,* and *John D. Mills,* County Court of the 20th Judicial Circuit) as well as the best available information to evaluate manatee and human interactions in the former State speed zones affected by the ruling.

In the *State of Florida Fish and Wildlife Conservation Commission (FWC)* v. *Wilkinson* et al., boaters, who were issued citations which alleged different violations of Rule 68C–22.005 (Rule), challenged the Rule adopted by the FWC regulating the operation and speed of motorboat traffic in Lee County waters to protect manatees. In its ruling, the court determined that, under Florida law, the FWC can regulate the operation and speed of motorboats in order to protect manatees from harmful collisions with motorboats, however: (1) In the area to be regulated, manatee sightings must be frequent and, based upon available scientific information, manatees inhabit these areas on a regular, periodic, or continuous basis; and, (2) when the FWC adopts rules, it must consider the rights of boaters, fishermen and water-skiers and the restrictions adopted by the FWC must not unduly interfere with those rights. In this instance, the court found that the Rule for four of the regulated areas did not meet the State standard for the frequency of sightings and the rule unduly interfered with the rights of boaters. Thus, the designated manatee protection zones were invalidated, and the citations were dismissed. The absence of zones and enforcement in these areas increases the potential for manatees to suffer injury and death from watercraft collisions. The court's ruling does not affect Federal speed zones in Lee County. The Service established Shell Island as a manatee refuge in November 2002 (67 FR 68450) and the Caloosahatchee River-San Carlos Bay as a manatee refuge in August 2003 (68 FR 46870).

The legal basis for the action to be taken by the Service differs markedly from that in the *FWC* v. *Wilkinson* et al. case. The Service's action is not based on State law, but rather is based upon a Federal regulation, 50 CFR 17.103, which provides the standard for designation of a manatee protection area.

Manatees are especially vulnerable to fast-moving power boats. The slower a boat is traveling, the more time a manatee has to avoid the vessel and the more time the boat operator has to detect and avoid the manatee. Nowacek *et al.* (2000) documented manatee avoidance of approaching boats. Wells *et al.* (1999) confirmed that, at a response distance of 20 meters, a manatee's time to respond to an oncoming vessel increased by at least 5 seconds if the vessel was required to travel at slow speed. Therefore, the potential for take of manatees can be greatly reduced if boats are required to travel at slow speed in areas where manatees can be expected to occur.

The waterbodies encompassed in this proposed designation receive extensive manatee use either on a seasonal or year-round basis as documented in radio telemetry and aerial survey data (FWC 2003). The areas contain feeding habitats and serve as travel corridors for manatees (FWC 2003). Although residents are likely accustomed to the presence of speed zones in the area, which existed as State regulations since 1999, some of these regulations are no longer in effect. Therefore, without this Federal designation, watercraft can be expected to travel at high speeds in areas frequented by manatees, which would result in the take of one or more manatees. Also, while the County Court invalidated State-designated speed limits in the areas adjacent to navigation channels, it did not invalidate the 25-miles per hour speed limit in the navigation channels that traverse the affected area. Therefore, the speed limit in the navigation channel is now lower than that of the surrounding, shallower areas. As a result, shallow-draft high-speed boats capable of traveling outside the navigation channels can be expected to operate at high speeds (greater than 25 miles per hour) in the areas more likely to be frequented by manatees. In the areas encompassed by this designation that receive more seasonal use by manatees, the slow speed requirements would begin on April 1.

There is a history of watercraft-related manatee mortality in the area. At least 18 manatees killed in collisions with watercraft have been recovered in or immediately adjacent to the designated areas since 1999 (*http://www.floridamarine.org*), with four carcasses recovered in 2004 from the sites that were former State speed zones eliminated by the court's ruling. Necropsies revealed that these animals died of wounds from boat collisions.

Manatees make extensive use of these areas, there is a history of take at these sites, future take will occur without protection measures, protection measures will be insufficient upon expiration of the current emergency designation, and we do not anticipate any alternative protection measures being enacted by State or local government in sufficient time to reduce

the likelihood of take occurring. For these reasons, we believe that establishment of a manatee refuge is necessary to prevent the take of one or more manatees in these areas.

Definitions

The following terms are defined in 50 CFR 17.102. We present them here to aid in understanding this rule.

''Planing'' means riding on or near the water's surface as a result of the hydrodynamic forces on a watercraft's hull, sponsons (projections from the side of a ship), foils, or other surfaces. A water vehicle is considered on plane when it is being operated at or above the speed necessary to keep the vessel planing.

''Slow speed'' means the speed at which a water vehicle proceeds when it is fully off plane and completely settled in the water. Due to the different speeds at which watercraft of different sizes and configurations may travel while in compliance with this definition, no specific speed is assigned to slow speed. A watercraft is *not* proceeding at slow speed if it is: on a plane, in the process of coming up on or coming off of plane, or creating an excessive wake. A water vehicle is proceeding at slow speed if it is fully off plane and completely settled in the water, not creating an excessive wake.

''Wake'' means all changes in the vertical height of the water's surface caused by the passage of a watercraft, including a vessel's bow wave, stern wave, and propeller wash, or a combination thereof.

Summary of Comments and Recommendations

In the August 6, 2004, proposed rule (69 FR 48102), we requested all interested parties to submit factual reports or information that might contribute to the development of a final rule. We published legal notices announcing the proposal, inviting public comment, and announcing the schedule for the public hearing in the *Fort Myers News-Press* and *Cape Coral Daily Breeze*. We held the public hearing at the Harborside Event Center in Fort Myers, Florida, on January 12, 2005, between 6:30 and 9:30 p.m. Approximately 250 people attended the public hearing. We received oral comments from 30 individuals. The comment period closed on February 2, 2005. Their comments and our responses are summarized below.

During the comment period, we received approximately 4,100 written and oral comments concerning the proposal. The majority of written comments were form letters expressing support for the proposed designation. Most of the substantive comments recommended additional protection measures to the proposed action. Conversely, many of the oral comments expressed opposition to the proposed manatee refuge. The following is a summary of all comments received and our responses. Comments of a similar nature have been grouped together.

Comment 1: Several commentors recommended that the seasonal zones be replaced with year-round zones in the final rule.

Response 1: The waterbodies encompassed in this designation receive extensive manatee use either on a seasonal or year-round basis as documented in radio telemetry and aerial survey data (FWC 2003). These areas contain feeding habitat or serve as travel corridors for manatees. During the colder months (late November through March), manatees were found less frequently in Estero Bay and the York Island area; whereas, they use these same waterbodies to forage during the remainder of the year. Based on these data, seasonal speed zones were established for these areas in 1999 (slow speed during the warmer months, 25 miles per hour or unregulated during the colder months). We considered this information in establishing the Pine Island-Estero Bay Manatee Refuge. As such, we believe these seasonal zones are an appropriate protective measure and, provided the regulations are appropriately enforced, future take in these zones is unlikely.

Comment 2: Several commentors recommended that we establish year-round slow speed zones for the east-west and north-south channels that run through San Carlos Bay, waterways that are outside the boundaries of the proposed Pine Island-Estero Bay Manatee Refuge.

Response 2: Designation of manatee protection areas involves both scientific and practical considerations. The boundaries for the east-west channel, known as Miserable Mile, and the north-south channel were excluded during the configuration of the final rule for the Caloosahatchee River-San Carlos Bay Manatee Refuge to avoid creating a boating safety issue in the bay while protecting the shallow water seagrass beds where the manatees occur. This final rule reflects the results of indepth analysis of the areas, including careful evaluation of manatee and watercraft use information, site visits, coordination with State and local regulatory experts, and review of public comments. We believe that the current designation boundary is sufficient to prevent the take of one or more manatees.

Comment 3: Several commentors recommended that we establish the Pine Island-Estero Bay Manatee Refuge even if the FWC re-establishes the previous State speed zones.

Response 3: Manatee protection area designations serve different purposes in different areas. The purpose of this manatee refuge, which is to establish slow speed zones where none currently exist, is to minimize the risk of high-speed collisions between watercraft and manatees in areas where collisions are likely to occur. It should be noted that if the State and Lee County are able to enact protective measures comparable to FWC's assessment of the recommendations cited within the Local Rule Review Committee's Report, we would consider withdrawing our Federal designation. We are committed to continuing the protection of the manatee through a cooperative effort with our management partners at the State and county level, as well as efforts involving private entities and members of the public. We encourage State and local measures to improve and maintain manatee protection.

Comment 4: One commentor recommended reducing the current 25-miles per hour speed limit in the marked channels to a speed slower than 25 miles per hour.

Response 4: We believe that the 25-miles per hour speed zone is sufficient to prevent the taking of one or more manatees, based on the establishment of speed zones in other areas. Twenty-five miles per hour in the channel seems to be a reasonably effective management alternative in areas where manatee use is well documented and there is a well defined, marked channel. We have also made our 25-miles per hour designations consistent with the former State speed zone regulations in order to minimize the boating public's confusion and to facilitate signage, enforcement, and compliance, while ensuring appropriate protection for manatees.

Comment 5: Some commentors stated that the economic effects of the proposed manatee refuge would be the same as the previously designated State manatee protection zones since the proposed speed zones are identical to the former State speed zones.

Response 5: We believe that economic effects would be the same.

Comment 6: Several commentors suggested that we accept the recommendations in the Local Rule Review Committee's Report and allow the State and local authorities to provide for manatee protection.

Response 6: We are the Federal agency responsible for manatee management and protection activities

under both the ESA and the MMPA. As such, we must take an active role in regulatory activities involving the manatee. This in no way diminishes the important role that the State and Lee County play or the role of the private sector. Recognition is given to both State and local efforts to establish manatee protection, and we are committed to supporting these efforts. We have stated that the State should have leadership in establishing additional manatee protection areas. With this final rule, we have focused on the sites where there is evidence at this time showing that these measures are necessary to prevent take of one or more manatees, and where we determined that Federal action can effectively address the needs in the particular area. If the State is successful in implementing their pending rules for Lee County, we will consider withdrawing the Federal designation of these sites.

Comment 7: A few commentors suggested establishing a 25-miles per hour speed limit zone around the Shell Island Manatee Refuge.

Response 7: We carefully considered this comment in light of the increased travel time that would result from our proposed designation. However, this area represents the confluence between the Caloosahatchee River and San Carlos Bay. Manatees use this area as a travel corridor that connects important habitat features in San Carlos Bay and Matlacha Pass. This area also has a high density of boat traffic and high diversity of boating activities. In light of the available information, we have concluded that a year-round slow speed designation should be applied to this waterway in order to effectively improve manatee protection in this area.

Comment 8: One commentor stated that the Service does not have the resources to enforce the additional speed zones associated with the proposed manatee refuge.

Response 8: We are fully committed to implementing these protection areas, including enforcement of these areas upon posting. However, we are very aware of the fact that compliance is critical to the effectiveness of manatee protection area regulations and that compliance is facilitated, in large part, by enforcement. We are also aware that enforcement resources are limited at all levels of government, and that cooperation among law enforcement agencies is needed to maximize effectiveness of limited resources. We know that State and local law enforcement agencies have many enforcement mandates in addition to manatee protection and that it may be difficult for these agencies to make enforcement of Federal manatee protection areas a high priority. We believe that local and State law enforcement improves compliance with Federal designations and leads to more effective Federal rules. The final rule has been designed to reflect the best available information regarding manatee and boating use of these waters and is also intended to address (to the extent possible) State and local concerns regarding the rule. Again, we have made our designations consistent with the former regulations in order to minimize the boating public's confusion and to facilitate signage, enforcement, and compliance, while ensuring appropriate protection for manatees.

Comment 9: Some commentors stated that the final rule establishing a Federal manatee refuge infringes on State and local rights and self-government.

Response 9: As it was presented in the ''Background'' section, the Service's action is not based on State law, but on a Federal regulation (50 CFR 17.103) which provides the standard for designation of a manatee protection area. The Service made the decision to establish this manatee refuge after carefully assessing the impacts the recent court rulings had on manatee protection as well as the best available information to evaluate manatee and human interactions at these former State speed zone sites in Lee County. If the State is successful in implementing its pending rules for Lee County, we will consider withdrawing the Federal designation of these sites.

Comment 10: One commentor stated that the proposed manatee refuge poses a burden to boaters and to the county's economy.

Response 10: We acknowledge that the speed limits would restrict boater's ability to travel at higher speeds and could result in some negative effect on recreational boaters and commercial fishermen. We have not been able to quantify the negative economic effects resulting from this rule, although we believe they would be small. The regulations associated with the manatee refuge are identical to the regulations associated with the former State speed zones which were established in 1999.

Comment 11: One commentor stated that there are no data that speed zones protect manatees.

Response 11: While no empirical studies specifically address this issue, we did consider the effects of speed zones on watercraft-related manatee mortality in the Caloosahatchee River, where similar restrictions (State and Federal) have been in place since 2003, to draw some conclusions regarding their potential effectiveness in the absence of data. The speed zones coupled with enforcement have so far been effective in protecting manatees. Our assessment indicates that the existing zones and the associated enforcement do in fact provide appropriate protection over most of the areas on the river where manatees and watercraft are likely to interact. For example, watercraft-related manatee mortality decreased in the Caloosahatchee River from 7 manatees in 2002, to 1 manatee in 2003 and 2004, respectively. Similarly, other areas have experienced the same trend; for instance, there have been no manatee deaths in the Barge Canal Federal Manatee Protection Area in Brevard County, Florida, since this area was posted.

Comment 12: One commentor stated that slower boat speeds increase the risk of watercraft collisions with manatees.

Response 12: As noted in our response to question 11, there have been no formal studies to date addressing this issue, however, similar restrictions on the Caloosahatchee River appear to have significantly reduced watercraft-related manatee mortalities.

Comment 13: One commentor stated that carcass recovery does not equate to where manatees are killed or injured by watercraft.

Response 13: Carcass recovery location does not necessarily correspond with the exact location of death and almost certainly does not correspond exactly with the point of contact for watercraft related injuries that result in mortality. However, there is a history of manatee mortalities in the manatee protection area as a result of collisions with watercraft. At least 18 manatees killed in collisions with watercraft have been recovered in the designated areas since 1999, with four carcasses recovered in 2004 from the sites that were former State speed zones eliminated by the court's ruling.

Comment 14: One commentor stated that there is no evidence that protecting manatees will increase tourism.

Response 14: To the extent that some portion of Florida's tourism is due to the existence of the manatee in Florida waters, the protection provided by this rule may result in an economic benefit to the tourism industry. However, we are not able to make an estimate of this benefit based on the available information.

Comment 15: Two commentors stated that there is no evidence that slower boat speeds will result in economic benefits to waterfront property homeowners by reducing the costs to maintain and/or repair their seawalls.

Response 15: Due to reduction in boat wake associated with speed zones, property owners may experience some economic benefits related to decreased expenditures for maintenance and repair of shoreline stabilization structures (*i.e.*, seawalls along the water's edge). Bell and McLean's study (1997) of shoreline property values in Broward County indicate that, with all other factors being equal, shoreline property values went up by as much as 15 percent when there was a manatee slow speed zone adjacent to the property. However, we are not able to make an estimate of this benefit based on available information.

Comment 16: One commentor stated that speed zones force boaters to other non-restricted areas that may not be as enjoyable or as suitable as the original destinations.

Response 16: Some boaters may have to travel farther to participate in certain activities or they may choose to forgo some activities. However, the speed zone restrictions imposed by the rule do not prohibit any boating activities.

Comment 17: One commentor stated that adding slow speed zones crowds more boats into areas where boating safety becomes an issue.

Response 17: We were very cognizant of human safety issues when we designated these former State speed zones as emergency manatee protection areas and the manatee refuge. Human safety while boating has always been and will continue to be the responsibility of the vessel operator. The manatee refuge measures described in this final rule require vessels to proceed at slow speed and, as such, should enhance boater safety in these areas. At no site does the designation of these manatee protection areas place mariners in a position of encountering high-speed vessel traffic with no alternative safe route (what about crowding in the navigational channels?). We believe that our final designation should result in little or no adverse impacts on the boating public.

Comment 18: One commentor stated that adding slow speed zones deters boaters from using their boats and encourages them towards other non-boating activities resulting in decreased spending by recreational boaters.

Response 18: Please refer to the response to Comment 10.

Comment 19: One commentor stated that speed zone posts and signs are a navigational hazard.

Response 19: When we propose to designate a Federal manatee protection area, we must do so in accordance with the provisions of the United States Aids to Navigation System, part 62 of title 33 of the Code of Federal Regulations. The primary objective of the aids to navigation system is to mark navigable channels and waterways, obstructions adjacent to these waterways, and obstructions in areas of general navigation which may not be anticipated. Other waters, even if navigable, are generally not marked. Furthermore, we consider and assess all options for making the requisite postings safe for the boating public. Chapter 68D–23 Florida Administrative Code prescribe the procedures by which the State of Florida permits and regulates the placement of markers in, on, and over the waters of the state. These provisions also provide for the design, construction, characteristics and coloring of all such markers. These regulatory markers noticing boating restricted areas (speed zones) are authorized only for the purposes of protecting human life and limb, vessel traffic safety and maritime property, and manatees. Despite these requirements and precautions, there may be some waterbodies (*e.g.*, physical configuration, intensity of boating activities) where the placement of posts and signs could pose a navigational hazard. Under such circumstances, the use of buoys instead of posts is a satisfactory alternative and meets the necessary marking requirements to define a manatee protection area.

Comment 20: One commentor stated that speed zones force boats to travel outside of channels increasing the likelihood of groundings and motor/propeller damage.

Response 20: Boaters in these waterways should be familiar with the proposed speed zones since they are identical to the former State speed zones which were in effect from 1999 to 2004. It should be noted that, while the County Court invalidated State-designated speed limits in the areas adjacent to navigation channels, it did not invalidate the 25-miles per hour speed limit in the navigation channels that traverse the affected area. Thus, the speed limit in the navigation channel was lower than that of the surrounding, shallower areas. As a result, shallow-draft high-speed boats capable of traveling outside the navigation channels could operate at speeds greater than 25 miles per hour in the areas more likely to be frequented by manatees. This was one of several factors in our decision to emergency designate a manatee protection area.

Comment 21: One commentor stated that slow speed zones increase the likelihood of carbon monoxide poisoning among boaters.

Response 21: To date, we know of no reports citing the occurrence of carbon monoxide poisoning among Lee County boaters traveling in these former slow speed zones which were established in 1999 nor do we have any data or reports of this potential hazard occurring among boaters statewide.

Comment 22: Two commentors stated that the Service has ignored a local court's decision which ruled that the former State speed zones were invalid and failed to adequately consider boaters' rights.

Response 22: The court's decision in *FWC* vs. *Wilkinson* et al. was based on its review of a State statute and administrative code, as stated in our response to Comment 9. Our action is based on Federal law.

Comment 23: Two commentors stated that the proposed rule threatens marine contractors with future moratoriums if Federal interests are not satisfied.

Response 23: There is no language in the proposed or final rule that threatens to impose a moratorium on marine-related activities. This rule does not intend to suspend any activities, simply to modify speeds at which vessels travel in the areas outline in this rule.

Comment 24: Many commentors recommended that sound science should be used in establishing manatee speed zones.

Response 24: Designation of manatee protection areas involves both scientific and practical considerations. This final rule reflects the results of in-depth analysis of the best available scientific and commercial data, including careful evaluation of manatee and watercraft use information. In addition, we have conducted site visits, coordinated with State and local regulatory experts, and reviewed public comments.

Comment 25: Some commentors recommended educating the boating public as a better alternative to implementing more boating rules and regulations.

Response 25: Education and public awareness are important elements in the ongoing efforts to protect manatees; however, our analysis of the best available information indicates that speed zones and their requisite enforcement are equally important components in the comprehensive approach toward manatee protection.

Comment 26: Some commentors suggest that the data do not warrant or support establishing additional manatee speed zones.

Response 26: The Service has conducted an in-depth analysis of the best available data and evidence at this time has shown that establishing speed

zones is necessary to prevent the taking of one or more manatees.

Comment 27: Some commentors believe that Save the Manatee Club will seek court action if the Service does not establish the Pine Island-Estero Bay Manatee Refuge.

Response 27: The judicial process is available to all persons or entities seeking to enforce a legal right or obtain a legal remedy. The Service cannot dictate the actions of these persons or entities. In designating the Pine Island-Estero Bay Refuge, the Service was guided by the provisions of 50 CFR 17.103.

Comment 28: Some commentors suggest eliminating the warm water discharge from Florida Power and Light's power plant will do more to protect manatees than establishing additional speed zones.

Response 28: A task force has been established to address issues related to warm-water discharge. However, this rule deals directly with mortality resulting from waterborne activities. The areas within the Pine Island-Estero Bay Manatee Protection Area have significant potential for ''take'' based on both manatee use and boating use. Additionally, without Federal protection these areas lack protective regulations at this time. Therefore, we are establishing this manatee protection area to prevent further take of manatees resulting from waterborne activities.

Comment 29: Some commentors stated that, with the manatee population increasing, there is no need for establishing a Federal manatee refuge in Lee County.

Response 29: The MMPA sets a general moratorium for the taking of marine mammals, including manatees. While there are provisions for incidental take of listed species under the ESA and the MMPA, authorization for incidental take of manatees under the MMPA has not been requested, nor have regulations to provide this authorization been developed. Incidental take of manatees without authorization is unlawful. Preventing the take of manatees as a result of watercraft collisions is a top priority in manatee recovery and management programs. The areas addressed in this rule have a significant potential for ''take'' based on the amount of manatee use as well as boating use and are characterized by the lack of current protective regulations. After evaluating the best available data, we have determined that designation is warranted pursuant to 50 CFR 17.103.

Comment 30: One commentor expressed concerns with the effects of the proposed regulations on seaplane operations and recommended that seaplanes, in general, be excluded from the regulations associated with the proposed Pine Island-Estero Bay Manatee Refuge.

Response 30: According to our regulations, the terms ''Water vehicle, watercraft, and vessel'' are defined to include, but are not limited to, ''boats (whether powered by engine, wind, or other means), ships (whether powered by engine, wind, or other means), barges, surfboards, personal watercraft, water skis, or any other device or mechanism the primary or an incidental purpose of which is locomotion on, or across, or underneath the surface of the water.'' This definition is sufficiently broad to include seaplanes, and the slow speed zones associated with this manatee refuge would effectively preclude the use of seaplanes on these waterways. We reviewed a similar comment for the Caloosahatchee River-San Carlos Bay Manatee Refuge and concluded that the seaplane business operating on the Caloosahatchee River, at that time, posed an insignificant and discountable threat to manatees (August 6, 2003; 68 FR 46870; see response to Comment 54). As far as we knew, there were no other seaplane operations in other parts of the county that would be affected by the regulations established in the Caloosahatchee, so we did not adopt a broader exclusion for seaplanes at the time. However, the aerial survey and telemetry data indicate the areas encompassing the Pine Island-Estero Bay manatee refuge receive significant manatee use although the use in Estero Bay is more seasonal. Given what we know about the distribution of manatees throughout the refuge, we conclude it is possible that a seaplane could encounter manatees in the refuge. In addition, during takeoff and landing, seaplanes operate at speeds in excess of 25 miles per hour over a distance of approximately 1,500 feet. Therefore, the final rule effectively prohibits seaplanes from landing or taking off throughout the Pine Island-Estero Bay Manatee Refuge year-round, although they may transit Estero Bay at speeds up to 25 miles per hour during the winter months.

Area Designated as a Manatee Refuge

Pine Island-Estero Bay Manatee Refuge

The Pine Island-Estero Bay Manatee Refuge encompasses waterbodies in Lee County including portions of Matlacha Pass and San Carlos Bay south of Green Channel Marker 77 and north of the Intracoastal Waterway, portions of Pine Island Sound in the vicinity of York and Chino Islands, portions of Punta Rassa Cove and Shell Creek in San Carlos Bay and the mouth of the Caloosahatchee River, and portions of Estero Bay and connecting waterways. These waterbodies are designated, as posted, as either slow speed or with a speed limit of 25 miles per hour, on either a seasonal or annual basis. Legal descriptions and maps are provided in the ''Regulation Promulgation'' section of this notice.

Effective Date

Under the Administrative Procedure Act, our normal practice is to publish rules with a 30-day delay in effective date. However, for this rule, we are using the ''good cause'' exemption under 5 U.S.C. 553(d)(3) to make this rule effective immediately upon publication because the data indicate manatees utilize these areas year-round, there is a history of take at these sites, and we do not anticipate any alternative protection measures being enacted by State or local governments in sufficient time to reduce the likelihood of take from occurring. The evidence leading to the imminent danger of taking one or more manatees is such that the Service established these areas as a Federal manatee refuge using the emergency rule process on April 7, 2004; August 6, 2004; and December 6, 2004. Future take is imminent if the effective date of the rule is delayed.

Required Determinations

Regulatory Planning and Review

In accordance with the criteria in Executive Order 12866, the Office of Management and Budget has determined that this rule is a significant regulatory action, as it may raise novel legal or policy issues The Office of Management and Budget has reviewed this rule.

a. This rule will not have an annual economic impact of over $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. It is not expected that any significant economic impacts would result from the establishment of a manatee refuge (approximately 30 miles of waterways) in Lee County in the State of Florida.

The purpose of this rule is to establish a manatee refuge in Lee County, Florida. We are preventing the take of manatees by controlling certain human activity in this county. For the manatee refuge, the areas are year-round slow speed, seasonal slow speed or seasonal speed limits of 25 miles per hour. Affected waterborne activities include, but are not limited to, transiting, cruising, water skiing, fishing, marine construction, and the use of all water vehicles. This rule

will impact recreational boaters, commercial charter boats, and commercial fishermen, primarily in the form of restrictions on boat speeds in specific areas. We will experience increased administrative costs due to this rule. Conversely, the rule may also produce economic benefits for some parties as a result of increased manatee protection and decreased boat speeds in the manatee refuge areas.

Regulatory impact analysis requires the comparison of expected costs and benefits of the rule against a ''baseline,'' which typically reflects the regulatory requirements in existence prior to the rulemaking. For purposes of this analysis, the baseline assumes that the Pine Island-Estero Bay area has no regulating speed limits other than the 25 miles per hour in the navigation channels. The State-designated speed zones, other than in the navigation channels, have been lifted by a County Court decision. However, residents and other waterway users have lived with speed restrictions in these areas since 1999 and have established business and recreational patterns on the water to accommodate their needs and desires for water-based recreation. The actual economic effects may very well be insignificant because almost all users have been previously subject to these restrictions. Thus, the rule is expected to have only an incremental effect. As discussed below, the net economic impact is not expected to be significant, but cannot be monetized given available information.

The actual economic impacts of this rule are expected to be insignificant and would be due to the changes in speed zone restrictions in the manatee refuge area. These speed zone changes are summarized in the proposed and final rules.

In addition to speed zone changes, the rule no longer allows for the speed zone exemption process in place under State regulations. Currently, Florida's Manatee Sanctuary Act allows the State to provide exemptions from speed zone requirements for certain commercial activities, including fishing and events such as high-speed boat races. Under State law, commercial fishermen and professional fishing guides can apply for permits granting exemption from speed zone requirements in certain counties. Speed zone exemptions were issued to 27 permit holders in the former State zones that comprise the proposed manatee refuge area.

In order to gauge the economic effect of this rule, both benefits and costs must be considered. Potential economic benefits related to this rule include increased manatee protection and tourism related to manatee viewing, increased number of marine construction permits issued, increased fisheries health, and decreased seawall maintenance costs. Potential economic costs are related to increased administrative activities related to implementing the rule and affected waterborne activities. Economic costs are measured primarily by the number of recreationists who use alternative sites for their activity or have a reduced quality of the waterborne activity experience at the designated sites. In addition, the rule may have some impact on commercial fishing because of the need to maintain slower speeds in some areas. The extension of slower speed zones in this rule is not expected to affect enough waterborne activity to create a significant economic impact (*i.e.*, an annual impact of over $100 million).

Economic Benefits

We believe that the designation of the Pine Island-Estero Bay Manatee Refuge in this rule will increase the level of manatee protection in the area. A potential economic benefit is increased tourism resulting from an increase in manatee protection. To the extent that some portion of Florida's tourism is due to the existence of the manatee in Florida waters, the protection provided by this rule may result in an economic benefit to the tourism industry. We are not able to make an estimate of this benefit given available information.

In addition, due to reductions in boat wake associated with speed zones, property owners may experience some economic benefits related to decreased expenditures for maintenance and repair of shoreline stabilization structures (*i.e.*, seawalls along the water's edge). Speed reductions may also result in increased boater safety. Another potential benefit of slower speeds is that fisheries in these areas may be more productive because of less disturbance. These types of benefits cannot be quantified with available information.

Based on previous studies, we believe that this rule produces some economic benefits. However, given the lack of information available for estimating these benefits, the magnitude of these benefits is unknown.

Economic Costs

The economic impact of the designation of a manatee refuge results from the fact that, in certain areas, boats are required to go slower than they would under certain conditions. Some impacts may be felt by recreationists who have to use alternative sites for their activity or who have a reduced quality of the waterborne activity experience throughout the designated site because of the rule. For example, the extra time required for anglers to reach fishing grounds could reduce onsite fishing time and could result in lower consumer surplus for the trip. Consumer surplus, in this case, could be defined as the difference between what consumers are willing to pay for the trip and the amount consumers actually pay for the trip. Other impacts of the rule may be felt by commercial charter boat outfits, commercial fishermen, and agencies that perform administrative activities related to implementing the rule.

Affected Recreational Activities

For some boating recreationists, the inconvenience and extra time required to cross additional slow speed areas may reduce the quality of the waterborne activity or cause them to forgo the activity. This will manifest in a loss of consumer surplus to these recreationists. In addition, to the extent that recreationists forgo recreational activities, this could result in some regional economic impact. In this section, we examine the waterborne activities taking place in each area and the extent to which they may be affected by designation of the proposed manatee refuge. The resulting potential economic impacts are discussed below. These impacts cannot be quantified because the number of recreationists and anglers using the designated sites is not known.

Recreationists engaging in cruising, fishing, and waterskiing may experience some inconvenience by having to go slower or use undesignated areas; however, the extension of slow speed zones is not likely to result in a significant economic impact.

Currently, not enough data are available to estimate the loss in consumer surplus that water skiers will experience. While some may use substitute sites, others may forgo the activity. The economic impact associated with these changes on demand for goods and services is not known. However, given the number of recreationists potentially affected, and the fact that alternative sites are available, it is not expected to amount to a significant economic impact. Until recently, speed zones were in place in this area and recreationists have adjusted their activities to accommodate them.

Affected Commercial Charter Boat Activities

Various types of charter boats use the waterways in the affected counties,

primarily for fishing and nature tours. The number of charter boats using the Pine Island-Estero Bay area is currently unknown. For nature tours, the extension of slow speed zones is unlikely to cause a significant impact, because these boats are likely traveling at slow speeds. The extra time required for commercial charter boats to reach fishing grounds could reduce onsite fishing time and could result in fewer trips. The fishing activity is likely occurring at a slow speed and will not be affected. Added travel time may affect the length of a trip, which could result in fewer trips overall, creating an economic impact. According to one professional guide with a State permit, the exemption is important to him financially. The exemption allows him to take clients to areas where they spend more time fishing instead of traveling to fish, an important requirement for paying customers. Without the exemption, he doesn't take clients on a half-day charter to fish an area with an idle or slow speed zone at the risk of losing the charter. As his primary source of income, the loss of a charter has a significant affect on his ability to make a living. Instead, he travels to areas where there are no speed zones in order for his clients to fish.

Affected Commercial Fishing Activities

Several commercial fisheries will experience some impact due to the regulation. To the extent that the regulation establishes additional speed zones in commercial fishing areas, this will increase the time spent on the fishing activity, affecting the efficiency of commercial fishing. While limited data are available to address the size of the commercial fishing industry in the manatee refuge, county-level data generally provide an upper bound estimate of the size of the industry and potential economic impact.

Given available data, the impact on the commercial fishing industry of extending slow speed zones in the Pine Island-Estero Bay area cannot be quantified. The designation will likely affect commercial fishermen by way of added travel time, which can result in an economic impact. Some of the 27 active permit holders with speed limit exemptions are commercial fishermen. According to one commercial mullet fisherman with a State permit, the exemption is worthless to him. The State's permit exempts him from the speed zones restrictions in Matlacha Pass; however, the schools of mullet which he targets are primarily in the Caloosahatchee River, an area where he cannot get an exemption because of the Caloosahatchee River-San Carlos Bay Manatee Refuge established in 2003. Nevertheless, because the manatee refuge designation will not prohibit any commercial fishing activity and because there is a channel available for boats to travel up to 25 miles per hour in the affected areas, the Service believes that it is unlikely that the rule will result in a significant economic impact on the commercial fishing industry. It is important to note that, in 2001, the total annual value of potentially affected fisheries was approximately $8.3 million (2001$); this figure represents the economic impact on commercial fisheries in these counties in the unlikely event that the fisheries would be entirely shut down, which is not the situation associated with this rule.

Agency Administrative Costs

The cost of implementing the rule has been estimated based on historical expenditures by the Service for manatee refuges and sanctuaries established previously. The Service expects to spend approximately $600,000 (2002$) for posting and signing 15 previously designated manatee protection areas (an average of $40,000 per area). This represents the amount that the Service will pay contractors for creation and installation of manatee refuge signs. While the number and location of signs needed to post the manatee refuge is not known, the cost of manufacturing and posting signs to delineate the manatee refuge in this rule is not expected to exceed the amount being spent to post previously designated manatee protection areas (Service 2003a). Furthermore, there are unknown additional costs associated with the semi-annual requirement for seasonal conversion (flipping) of regulatory signs as well as routine maintenance of these posts and signs. In addition, the Service anticipates that it will spend additional funds for enforcement of a newly designated manatee refuge once the final rule is passed. These costs, including the cost of fuel, cannot be accurately estimated at this time. The costs of enforcement may also include hiring and training new manatee enforcement officers and special agents as well as the associated training, equipment, upkeep, and clerical support (Service 2003b). Finally, there are some costs for education and outreach to inform the public about this new manatee refuge area.

While the State of Florida has 12,000 miles of rivers and 3 million acres of lakes, this rule will affect approximately 30 waterway miles. The speed restrictions in this rule will cause inconvenience due to added travel time for recreationists and commercial charter boats and fishermen. As a result, the rule will impact the quality of waterborne activity experiences for some recreationists and may lead some recreationists to forgo the activity. This rule does not prohibit recreationists from participating in any activities. Alternative sites are available for all waterborne activities that may be affected by this rule. The distance that recreationists may have to travel to reach an undesignated area varies. The regulation will likely impact some portion of the charter boat and commercial fishing industries in these areas as well. The inconvenience of having to go somewhat slower in some areas may result in changes to commercial and recreational behavior, resulting in some regional economic impacts. Given available information, the net economic impact of designating the manatee refuge is not expected to be significant (*i.e.*, an annual economic impact of over $100 million). While the level of economic benefits that may be attributable to the manatee refuge is unknown, these benefits would cause a reduction in the economic impact of the rule.

b. This rule will not create inconsistencies with other agency actions. The precedent to establish manatee protection areas has been established primarily by State and local governments in Florida. We recognize the important role of State and local partners and continue to support and encourage State and local measures to improve manatee protection. We are designating the Pine Island-Estero Bay area, where previously existing State designations have been eliminated, to protect the manatee population in that area.

c. This rule will not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. Minimal restriction to existing human uses of the sites would result from this rule. No entitlements, grants, user fees, loan programs or effects on the rights and obligations of their recipients are expected to occur.

d. OMB has determined that this rule may raise legal and policy issues. Therefore, OMB has reviewed the rule pursuant to E.O. 12866.

Regulatory Flexibility Act

We certify that this rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). An initial/final Regulatory Flexibility Analysis is not required. Accordingly, a Small

Entity Compliance Guide is not required.

In order to determine whether the rule will have a significant economic effect on a substantial number of small entities, we utilize available information on the industries most likely to be affected by the designation of the manatee refuge. Currently, no information is available on the specific number of small entities that are potentially affected. However, 27 permit holders were exempt from the speed limits in the former State-designated speed zones. Since these speed zones have been in place since 1999 and boaters have adjusted to their presence and there were no other permit holders, it is reasonable to expect that the proposed rule will impact only the 27 permit holders. They are primarily commercial fishing boats and fishing guides. Both would be considered small businesses. The 27 permit holders had State exemptions from the speed restrictions based on an application that stated they would suffer at least a 25 percent income loss without the permit. The usual income level for these businesses is not known; however, a 25 percent loss of business income is significant regardless of the level of business income. We acknowledge that there could be a significant loss of income to those permit holders that rely on speed to carry out their business activities; however, the Service believes that the 27 permit holders do not constitute a substantial number.

Except for the former 27 permit holders, this rule will not really affect the travel time for recreational boating and commercial activities. Because the only restrictions on recreational activity result from added travel time and alternative sites are available for all waterborne activities, we believe that the economic effect on small entities resulting from changes in recreational use patterns will not be significant. The economic effects on most small businesses resulting from this rule are likely to be indirect effects related to reduced demand for goods and services if recreationists choose to reduce their level of participation in waterborne activities. Similarly, because the only restrictions on commercial activity result from the inconvenience of added travel time, and boats can continue to travel up to 25 miles per hour in the navigation channels, we believe that any economic effect on small commercial fishing or charter boat entities (other than the 27 permit holders) will not be significant. Also, the indirect economic impact on small businesses that may result from reduced demand for goods and services from commercial entities is likely to be insignificant.

The employment characteristics of Lee County are shown in Table 1 for the year 1997. We included the following SIC (Standard Industrial Classification) categories, because they include businesses most likely to be directly affected by the designation of a manatee refuge:

Fishing, hunting, trapping (SIC 09)

Water transportation (SIC 44)

Miscellaneous retail (SIC 59)

Amusement and recreation services (SIC 79)

Non-classifiable establishments (NCE)

TABLE 1.—EMPLOYMENT CHARACTERISTICS OF LEE COUNTY IN FLORIDA—1997

[Includes SIC Codes 09, 44, 59, 79, and NCE[a]]

County	Total Mid-March employment[b] (All industries)	Mid-March employment[b] (select SIC codes)	Total establishments (all industries)	Total establishments	Select SIC codes (includes SIC codes 09, 44, 59, 79, and NCE[a])			
					Number of establishments (1–4 employees)	Number of establishments (5–9 employees)	Number of establishments (10–19 employees)	Number of establishments (20+ employees)
Lee	135,300	7,734	11,386	974	602	193	92	87

Source: U.S. Census County Business Patterns (*http://www.census.gov/epcd/cbp/view/cbpview.html*).

[a] Descriptions of the SIC codes included in this table as follows:

SIC 09—Fishing, hunting, and trapping.

SIC 44—Water transportation.

SIC 59—Miscellaneous retail service division.

SIC 79—Amusement and recreation services.

NCE—non-classifiable establishments division.

[b] Table provides the high-end estimate whenever the Census provides a range of mid-March employment figures for select counties and SIC codes.

As shown in Table 1, the vast majority (over 80 percent) of these business establishments in Lee County have fewer than 10 employees, with the largest number of establishments employing fewer than 4 employees. Any economic impacts associated with this rule will affect some proportion of these small entities.

Since the designation is for a manatee refuge, which only requires a reduction in speed, we do not believe the designation would cause significant economic effect on a substantial number of small businesses. Currently, available information does not allow us to quantify the number of small business entities such as charter boats or commercial fishing entities that may incur direct economic impacts due to the inconvenience of added travel times resulting from the rule, but it is safe to assume that the former 27 permit holders may constitute the parties affected by the final rule. The Service does not believe the 27 permit holders constitute a substantial number. In addition, the inconvenience of slow speed zones may cause some recreationists to change their behavior, which may cause some loss of income to some small businesses. The number of recreationists that will change their behavior, and how their behavior will change, is unknown; therefore, the impact on potentially affected small business entities cannot be quantified. However, because boaters will experience only minimal added travel time in most affected areas and the fact that speed zones were in place until recently, we believe that this designation will not cause a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804 (2). This rule:

a. Does not have an annual effect on the economy of $100 million or more. As shown above, this rule may cause some inconvenience in the form of

added travel time for recreationists and commercial fishing and charter boat businesses because of speed restrictions in manatee refuge areas, but this should not translate into any significant business reductions for the many small businesses in the affected county. An unknown portion of the establishments shown in Table 1 could be affected by this rule. Because the only restrictions on recreational activity result from added travel time, and alternative sites are available for all waterborne activities, we believe that the economic impact on small entities resulting from changes in recreational use patterns will not be significant. The economic impacts on small business resulting from this rule are likely to be indirect effects related to a decreased demand for goods and services if recreationists choose to reduce their level of participation in waterborne activities. Similarly, because the only restrictions on commercial activity result from the inconvenience of added travel time, and boats can continue to travel up to 25 miles per hour in the navigational channels, we believe that any economic impact on most small commercial fishing or charter boat entities will not be significant. Also, the indirect economic impact on small businesses that may result from reduced demand for goods and services from commercial entities is likely to be insignificant.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. It is unlikely that there are unforeseen changes in costs or prices for consumers stemming from this rule. The recreational charter boat and commercial fishing industries may be affected by lower speed limits for some areas when traveling to and from fishing grounds. However, because of the availability of 25 miles per hour navigational channels, this impact is likely to be limited. Further, only 27 active permit holders were exempt from the former State speed zones. The impact will most likely stem from only these permit holders.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. As stated above, this rule may generate some level of inconvenience to recreationists and commercial users due to added travel time, but the resulting economic impacts are believed to be minor and will not interfere with the normal operation of businesses in the affected counties. Added travel time to traverse some areas is not expected to be a major factor that will impact business activity.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

a. This rule will not ''significantly or uniquely'' affect small governments. A Small Government Agency Plan is not required. The designation of manatee refuges and sanctuaries, while imposing regulations for at least a limited period, will not impose obligations on State or local governments that have not previously existed.

b. This rule will not produce a Federal mandate of $100 million or greater in any year. As such, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Takings

In accordance with Executive Order 12630, this rule does not have significant takings implications. A takings implication assessment is not required. The manatee protection areas are located over State-owned submerged lands.

Federalism

In accordance with Executive Order 13132, this rule does not have significant Federalism effects. A Federalism assessment is not required. This rule will not have substantial direct effects on the State, in the relationship between the Federal Government and the State, or on the distribution of power and responsibilities among the various levels of government. We coordinated with the State of Florida to the extent possible on the development of this rule.

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This regulation does not contain any collections of information that require approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The regulation will not impose new record keeping or reporting requirements on State or local governments, individuals, businesses or organizations. A Federal 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.

National Environmental Policy Act

We have analyzed this rule in accordance with criteria of the National Environmental Policy Act. This rule does not constitute a major Federal action significantly affecting the quality of the human environment. An Environmental Assessment has been prepared and is available for review by written request to the Field Supervisor (*see* **ADDRESSES** section).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes on a Government-to-Government basis. We have evaluated possible effects on federally recognized Indian tribes and have determined that there are no effects.

Energy Supply, Distribution or Use

On May 18, 2001, the President issued Executive Order 13211 on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Because this rule is not a significant regulatory action under Executive Order 12866 and it only requires vessels to continue their operation as they have in the past, it is not expected to significantly affect energy supplies, distribution, and use. Therefore, this action is a not a significant energy action and no Statement of Energy Effects is required.

References Cited

A complete list of all references cited in this rule is available upon request from the South Florida Field Office (*see* **ADDRESSES** section).

Author

The primary author of this document is Kalani Cairns (*see* **ADDRESSES** section).

Authority

The authority to establish manatee protection areas is provided by the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of

1972 (16 U.S.C. 1361–1407), as amended.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

■ Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. Amend § 17.108 by revisng paragraph (c)(13) as follows:

§ 17.108 List of designated manatee protection areas.

* * * * *

(c) * * *

(13) *The Pine Island-Estero Bay Manatee Refuge.* (i) Watercraft are required to proceed at slow speed all year in all waters of Matlacha Pass, south of a line that bears 90° and 270° from Matlacha Pass Green Channel Marker 77 (approximate latitude 26°40′00″ North, approximate longitude 82°06′00″ West), and north of Pine Island Road (State Road 78), excluding:

(A) The portion of the marked channel otherwise designated in paragraph (c)(13)(iii) of this section;

(B) All waters of Buzzard Bay east and northeast of a line beginning at a point (approximate latitude 26°40′00″ North, approximate longitude 82°05′20″ West) on the southwest shoreline of an unnamed mangrove island east of Matlacha Pass Green Channel Marker 77 and bearing 219° to the northeasternmost point (approximate latitude 26°39′58″ North, approximate longitude 82°05′23″ West) of another unnamed mangrove island, then running along the eastern shoreline of said island to its southeasternmost point (approximate latitude 26°39′36″ North, approximate longitude 81°05′09″ West), then bearing 115° to the westernmost point (approximate latitude 26°39′34″ North, approximate longitude 82°05′05″ West) of the unnamed mangrove island to the southeast, then running along the western shoreline of said island to its southwesternmost point (approximate latitude 26°39′22″ North, approximate longitude 82°04′53″ West), then bearing 123° to the northwesternmost point (approximate latitude 26°39′21″ North, approximate longitude 82°04′52″ West) of an unnamed mangrove island, then running along the western shoreline of said island to its southeasternmost point (approximate latitude 26°39′09″ North, approximate longitude 82°04′44″ West), then bearing 103° to the northwesternmost point (approximate latitude 26°39′08″ North, approximate longitude 82°04′41″ West) of a peninsula on the unnamed mangrove island to the southeast, then running along the southwestern shoreline of said island to its southeasternmost point (approximate latitude 26°38′51″ North, approximate longitude 82°04′18″ West), then bearing 99° to the southernmost point (approximate latitude 26°38′50″ North, approximate longitude 82°04′03″ West) of the unnamed mangrove island to the east, then bearing 90° to the line's terminus at a point (approximate latitude 26°38′50″ North, approximate longitude 82°03′55″ West) on the eastern shoreline of Matlacha Pass; and

(C) All waters of Pine Island Creek and Matlacha Pass north of Pine Island Road (State Road 78) and west and southwest of a line beginning at a point (approximate latitude 26°39′29″ North, approximate longitude 82°06′29″ West) on the western shoreline of Matlacha Pass and bearing 160° to the westernmost point (approximate latitude 26°39′25″ North, approximate longitude 82°06′28″ West) of an unnamed island, then running along the western shoreline of said island to its southernmost point (approximate latitude 26°39′18″ North, approximate longitude 82°06′24″ West), then bearing 128° to the northernmost point (approximate latitude 26°39′12″ North, approximate longitude 82°06′17″ West) of an unnamed mangrove island to the south, then running along the eastern shoreline of said island to its southeasternmost point (approximate latitude 26°39′00″ North, approximate longitude 82°06′09″ West), then bearing 138° to a point (approximate latitude 26°38′45″ North, approximate longitude 82°05′53″ West) on the northern shoreline of Bear Key, then running along the northern shoreline of Bear Key to its easternmost point (approximate latitude 26°38′44″ North, approximate longitude 82°05′46″ West), then bearing 85° to the westernmost point (approximate latitude 26°38′45″ North, approximate longitude 82°05′32″ West) of Deer Key, then running along the northern shoreline of Deer Key to its easternmost point (approximate latitude 26°38′46″ North, approximate longitude 82°05′22″ West), then bearing 103° to the northwesternmost point (approximate latitude 26°38′45″ North, approximate longitude 82°05′17″ West) of the unnamed mangrove island to the east, then running along the western shoreline of said island to its southernmost point (approximate latitude 26°38′30″ North, approximate longitude 82°05′04″ West), then bearing 106° to the westernmost point (approximate latitude 26°38′30″ North, approximate longitude 82°04′57″ West) of the unnamed island to the southeast, then running along the northern and eastern shorelines of said island to a point (approximate latitude 26°38′23″ North, approximate longitude 82°04′51″ West) on its eastern shoreline, then bearing 113° to the northernmost point of West Island (approximate latitude 26°38′21″ North, approximate longitude 82°04′37″ West), then running along the western shoreline of West Island to the point where the line intersects Pine Island Road (State Road 78).

(ii) Watercraft are required to proceed at slow speed all year in all waters of Matlacha Pass, St. James Creek, and San Carlos Bay, south of Pine Island Road (State Road 78), north of a line 500 feet northwest of and parallel to the main marked channel of the Intracoastal Waterway, west of a line that bears 302° from Intracoastal Waterway Green Channel Marker 99 (approximate latitude 26°31′00″ North, approximate longitude 82°00′52″ West), and east of a line that bears 360° from Intracoastal Waterway Red Channel Marker 10 (approximate latitude 26°29′16″ North, approximate longitude 82°03′35″ West), excluding:

(A) The portions of the marked channels otherwise designated in paragraphs (c)(15)(iv) and (v) of this section;

(B) All waters of Matlacha Pass south of Pine Island Road (State Road 78) and west of the western shoreline of West Island and a line beginning at the southernmost point (approximate latitude 26°37′25″ North, approximate longitude 82°04′17″ West) of West Island and bearing 149° to the northernmost point (approximate latitude 26°37′18″ North, approximate longitude 82°04′12″ West) of the unnamed mangrove island to the south, then running along the eastern shoreline of said island to its southernmost point (approximate latitude 26°36′55″ North, approximate longitude 82°04′02″ West), then bearing 163° to the line's terminus at a point (approximate latitude 26°36′44″ North, approximate longitude 82°03′58″ West) on the eastern shoreline of Little Pine Island;

(C) All waters of Matlacha Pass, Pontoon Bay, and associated embayments south of Pine Island Road (State Road 78) and east of a line beginning at a point (approximate

latitude 26°38′12″ North, approximate longitude 82°03′46″ West) on the northwestern shoreline of the embayment on the east side of Matlacha Pass, immediately south of Pine Island Road and then running along the eastern shoreline of the unnamed island to the south to its southeasternmost point (approximate latitude 26°37′30″ North, approximate longitude 82°03′22″ West), then bearing 163° to the northwesternmost point of the unnamed island to the south, then running along the western shoreline of said island to its southernmost point (approximate latitude 26°37′15″ North, approximate longitude 82°03′15″ West), then bearing 186° to the line's terminus at a point (approximate latitude 26°37′10″ North, approximate longitude 82°03′16″ West) on the eastern shoreline of Matlacha Pass;

(D) All waters of Pine Island Creek south of Pine Island Road (State Road 78); and all waters of Matlacha Pass, Rock Creek, and the Mud Hole, west of a line beginning at a point (approximate latitude 26°33′52″ North, approximate longitude 82°04′53″ West) on the western shoreline of Matlacha Pass and bearing 22° to a point (approximate latitude 26°34′09″ North, approximate longitude 82°04′45″ West) on the southern shoreline of the unnamed island to the northeast, then running along the southern and eastern shorelines of said island to a point (approximate latitude 26°34′15″ North, approximate longitude 82°04′39″ West) on its northeastern shoreline, then bearing 24° to a point (approximate latitude 26°34′21″ North, approximate longitude 82°04′36″ West) on the southern shoreline of the large unnamed island to the north, then running along the southern and eastern shorelines of said island to a point (approximate latitude 26°34′31″ North, approximate longitude 82°04′29″ West) on its eastern shoreline, then bearing 41° to the southernmost point (approximate latitude 26°34′39″ North, approximate longitude 82°04′22″ West) of another unnamed island to the northeast, then running along the eastern shoreline of said island to its northwesternmost point (approximate latitude 26°35′22″ North, approximate longitude 82°04′07″ West), then bearing 2° to the southernmost point (approximate latitude 26°35′32″ North, approximate longitude 82°04′07″ West) of the unnamed island to the north, then running along the eastern shoreline of said island to its northernmost point (approximate latitude 26°35′51″ North, approximate longitude 82°03′59″ West), then bearing 353° to the line's terminus at a point (approximate latitude 26°36′08″ North, approximate longitude 82°04′01″ West) on the eastern shoreline of Little Pine Island; and

(E) All waters of Punta Blanca Bay and Punta Blanca Creek, east of the eastern shoreline of Matlacha Pass and east and north of the eastern and northern shorelines of San Carlos Bay.

(iii) Watercraft may not exceed 25 miles per hour, all year, in all waters within the main marked channel in Matlacha Pass south of Green Channel Marker 77 (approximate latitude 26°40′00″ North, approximate longitude 82°06′00″ West) and north of a line perpendicular to the channel at a point in the channel ¼ mile northwest of the Pine Island Road Bridge (State Road 78).

(iv) Watercraft may not exceed 25 miles per hour, all year, in all waters within the main marked channel in Matlacha Pass south of a line perpendicular to the channel at a point in the channel ¼ mile southeast of the Pine Island Road Bridge (State Road 78), and north of a line 500 feet northwest of and parallel to the main marked channel of the Intracoastal Waterway (just north of Green Channel Marker 1).

(v) Watercraft may not exceed 25 miles per hour, all year, in all waters within the marked channel in Matlacha Pass that intersects the main Matlacha Pass channel near Green Channel Marker 15 (approximate latitude 26°31′57″ North, approximate longitude 82°03′38″ West) and intersects the main marked channel of the Intracoastal Waterway near Green Channel Marker 101 (approximate latitude 26°30′39″ North, approximate longitude 82°01′00″ West).

(vi) Watercraft are required to proceed at slow speed from April 1 through November 15 in all canals and boat basins of St. James City and the waters known as Long Cut and Short Cut; and all waters of Pine Island Sound and San Carlos Bay south of a line beginning at the southernmost tip (approximate latitude 26°31′28″ North, approximate longitude 82°06′19″ West) of a mangrove peninsula on the western shore of Pine Island approximately 2200 feet north of Galt Island and bearing 309° to the southeasternmost point (approximate latitude 26°31′32″ North, approximate longitude 82°06′25″ West) of another mangrove peninsula, then running along the southern shoreline of said peninsula to its southwesternmost point (approximate latitude 26°31′40″ North, approximate longitude 82°06′38″ West), then bearing 248° to a point (approximate latitude 26°31′40″ North, approximate longitude 82°06′39″ West) on the eastern shoreline of an unnamed mangrove island, then running along the southern shoreline of said island to its southwesternmost point (approximate latitude 26°31′39″ North, approximate longitude 82°06′44″ West), then bearing 206° to the line's terminus at the northernmost point of the Mac Keever Keys (approximate latitude 26°31′09″ North, approximate longitude 82°07′09″ West), east of a line beginning at said northernmost point of the Mac Keever Keys and running along and between the general contour of the western shorelines of said keys to a point (approximate latitude 26°30′27″ North, approximate longitude 82°07′08″ West) on the southernmost of the Mac Keever Keys, then bearing 201° to a point (approximate latitude 26°30′01″ North, approximate longitude 82°07′19″ West) approximately 150 feet due east of the southeasternmost point of Chino Island, then bearing approximately 162° to Red Intracoastal Waterway Channel Marker 22 (approximate latitude 26°28′57″ North, approximate longitude 82°06′55″ West), then bearing approximately 117° to the line's terminus at Red Intracoastal Waterway Channel Marker 20 (approximate latitude 26°28′45″ North, approximate longitude 82°06′38″ West), north of a line beginning at said Red Intracoastal Waterway Channel Marker 20 and bearing 86° to a point (approximate latitude 26°28′50″ North, approximate longitude 82°05′48″ West) ¼ mile south of York Island, then running parallel to and ¼ mile south of the general contour of the southern shorelines of York Island and Pine Island to the line's terminus at a point on a line bearing 360° from Red Intracoastal Waterway Channel Marker 10 (approximate latitude 26°29′16″ North, approximate longitude 82°03′35″ West), and west and southwest of the general contour of the western and southern shorelines of Pine Island and a line that bears 360° from said Red Intracoastal Waterway Channel Marker 10, excluding the portion of the marked channel otherwise designated in paragraph (c)(13)(vii) of this section.

(vii) Watercraft may not exceed 25 miles per hour from April 1 through November 15 in all waters of the marked channel that runs north of the power lines from the Cherry Estates area of St. James City into Pine Island Sound, east of the western boundary of the zone designated in 17.108(c)(13)(vi), and west of a line perpendicular to the power lines that begins at the easternmost point (approximate latitude 26°30′25″ North, approximate longitude 82°06′15″ West) of the mangrove island on the north side of the power lines approximately 1,800 feet southwest of the Galt Island Causeway.

(viii) Watercraft are required to proceed at slow speed all year in all waters of San Carlos Bay and Punta Rassa Cove east of a line that bears 352° from the northernmost tip of the northern peninsula on Punta Rassa (approximate latitude 26°29′44″ North, approximate longitude 82°00′33″ West), and south of a line that bears 122° from Intracoastal Waterway Green Channel Marker 99 (approximate latitude 26°31′00″ North, approximate longitude 82°00′52″ West), including all waters of Shell Creek and associated waterways.

(ix) Watercraft are required to proceed at slow speed all year in all waters of San Carlos Bay and the Caloosahatchee River, including the residential canals of Cape Coral, northeast of a line that bears 302° and 122° from Intracoastal Waterway Green Channel Marker 99 (approximate latitude 26°31′00″ North, approximate longitude 82°00′52″ West), west of a line that bears 346° from Intracoastal Waterway Green Channel Marker 93 (approximate latitude 26°31′37″ North, approximate longitude 81°59′46″ West), and north and northwest of the general contour of the northwestern shoreline of Shell Point and a line that bears approximately 74° from the northernmost tip (approximate latitude 26°31′31″ North, approximate longitude 81°59′57″ West) of Shell Point to said Intracoastal Waterway Green Channel Marker 93, excluding the Intracoastal Waterway between markers 93 and 99 (which is already designated as a Federal manatee protection area, requiring watercraft to proceed at slow speed, and is not impacted by this rule).

(x) Watercraft are required to proceed at slow speed from April 1 through November 15 and at not more than 25 miles per hour the remainder of the year in all waters of Hell Peckney Bay southeast of Hurricane Bay, northeast of the northern shorelines of Julies Island and the unnamed island immediately northwest of Julies Island and a line that bears 312° from the northwesternmost point of Julies Island (approximate latitude 26°26′37″ North, approximate longitude 81°54′57″ West), northwest of Estero Bay, and southwest of a line beginning at the southernmost point (approximate latitude 26°27′23″ North, approximate longitude 81°55′11″ West) of an unnamed mangrove peninsula in northwest Hell Peckney Bay and bearing 191° to the northernmost point (approximate latitude 26°27′19″ North, approximate longitude 81°55′11″ West) of an unnamed mangrove island, then running along the northern shoreline of said island to its southeasternmost point (approximate latitude 26°27′11″ North, approximate longitude 81°55′05″ West), then bearing 115° to a point (approximate latitude 26°27′03″ North, approximate longitude 81°54′47″ West) on the northwest shoreline of an unnamed mangrove island, then running along the northern shoreline of said island to its northeasternmost point (approximate latitude 26°27′02″ North, approximate longitude 81°54′33″ West), and then bearing 37° to the line's terminus at the westernmost point of an unnamed mangrove peninsula in eastern Hell Peckney Bay.

(xi) Watercraft are required to proceed at slow speed from April 1 through November 15 and at not more than 25 miles per hour the remainder of the year in all waters of Hendry Creek south of a line that bears 270° from a point (approximate latitude 26°28′40″ North, approximate longitude 81°52′56″ West) on the eastern shoreline of Hendry Creek; and all waters of Estero Bay southeast and east of Hell Peckney Bay, a line that bears 340° from a point (approximate latitude 26°25′56″ North, approximate longitude 81°54′25″ West) on the northern tip of an unnamed mangrove peninsula on the northeastern shoreline of Estero Island, and the northern shoreline of Estero Island, south of Hendry Creek and a line that bears 135° and 315° from Red Channel Marker 18 (approximate latitude 26°27′46″ North, approximate longitude 81°52′00″ West) in Mullock Creek, and north of a line that bears 72° from the northernmost point (approximate latitude 26°24′22″ North, approximate longitude 81°52′34″ West) of Black Island, including the waters of Buccaneer Lagoon at the southern end of Estero Island, but excluding:

(A) The portions of the marked channels otherwise designated in paragraph (c)(13)(xiii) of this section;

(B) The Estero River; and

(C) To waters of Big Carlos Pass east of a line beginning at a point (approximate latitude 26°24′34″ North, approximate longitude 81°53′05″ West) on the eastern shoreline of Estero Island and bearing 36° to a point (approximate latitude 26°24′40″ North, approximate longitude 81°53′00″ West) on the southern shoreline of Coon Key, south of a line beginning at a point (approximate latitude 26°24′36″ North, approximate longitude 81°52′30″ West) on the eastern shoreline of Coon Key and bearing 106° to a point (approximate latitude 26°24′39″ North, approximate longitude 81°52′34″ West) on the southwestern shoreline of the unnamed mangrove island north of Black Island, and west of a line beginning at a point (approximate latitude 26°24′36″ North, approximate longitude 81°52′30″ West) on the southern shoreline of said unnamed mangrove island north of Black Island and bearing 192° to the northernmost point (approximate latitude 26°24′22″ North, approximate longitude 81°52′34″ West) of Black Island.

(xii) Watercraft are required to proceed at slow speed from April 1 through November 15 and at not more than 25 miles per hour the remainder of the year in all waters of Estero Bay and Big Hickory Bay south of a line that bears 72° from the northernmost point (approximate latitude 26°24′22″ North, approximate longitude 81°52′34″ West) of Black Island, east of the centerline of State Road 865 (but including the waters of the embayment on the eastern side of Black Island and the waters inshore of the mouth of Big Hickory Pass that are west of State Road 865), and north of a line that bears 90° from a point (approximate latitude 26°20′51″ North, approximate longitude 81°50′33″ West) on the eastern shoreline of Little Hickory Island, excluding Spring Creek and the portions of the marked channels otherwise designated under 17.108(c)(13)(xiii) and the portion of Hickory Bay designated in paragraph (c)(13)(xiii) of this section.

(xiii) Watercraft may not exceed 25 miles per hour all year in:

(A) All waters of Big Hickory Bay north of a line that bears 90° from a point (approximate latitude 26°20′51'' North, approximate longitude 81°50′33″ West) on the eastern shoreline of Little Hickory Island, west of a line beginning at a point (approximate latitude 26°20′48″ North, approximate longitude 81°50′24″ West) on the southern shoreline of Big Hickory Bay and bearing 338° to a point (approximate latitude 26°21′39″ North, approximate longitude 81°50′48″ West) on the water in the northwestern end of Big Hickory Bay near the eastern end of Broadway Channel, south of a line beginning at said point on the water in the northwestern end of Big Hickory Bay and bearing 242° to the northernmost point (approximate latitude 26°21′39″ North, approximate longitude 81°50′50″ West) of the unnamed mangrove island south of Broadway Channel, and east of the eastern shoreline of said mangrove island and a line beginning at the southernmost point of said island (approximate latitude 26°21′07″ North, approximate longitude 81°50′58″ West) and bearing 167° to a point on Little Hickory Island (approximate latitude 26°21′03″ North, approximate longitude 81°50′57″ West);

(B) All waters of the main marked North–South channel in northern Estero Bay from Green Channel Marker 37 (approximate latitude 26°26′02 North, approximate longitude 81°54′29″ West)

to Green Channel Marker 57 (approximate latitude 26°25′08″ North, approximate longitude 81°53′29″ West);

(C) All waters of the main marked North-South channel in southern Estero Bay south of a line beginning at a point (approximate latitude 26°24′36″ North, approximate longitude 81°52′30″ West) on the southern shoreline of the unnamed mangrove island north of Black Island and bearing 192° to the northernmost point (approximate latitude 26°24′22″ North, approximate longitude 81°52′34″ West) of Black Island, and north and east of Red Channel Marker 62 (approximate latitude 26°21′31″ North, approximate longitude 81°51′20″ West) in Broadway Channel;

(D) All waters within the portion of the marked channel leading to the Gulf of Mexico through New Pass, west of the North-South channel and east of State Road 865; all waters of the marked channel leading to Mullock Creek north of a line beginning at a point (approximate latitude 26°24′36″ North, approximate longitude 81°52′30″ West) on the eastern shoreline of Coon Key and bearing 106° to a point (approximate latitude 26°24′39″ North, approximate longitude 81°52′34″ West) on the southwestern shoreline of the unnamed mangrove island north of Black Island, and south of Red Channel Marker 18 (approximate latitude 26°27′46″ North, approximate longitude 81°52′00″ West);

(E) All waters of the marked channel leading from the Mullock Creek Channel to the Estero River, west of the mouth of the Estero River. (This designation only applies if a channel is marked in accordance with permits issued by all applicable State and federal authorities. In the absence of a properly permitted channel, this area is as designated under paragraph (c)(13)(xi) of this section);

(F) All waters of the marked channel commonly known as Alternate Route Channel, with said channel generally running between Channel Marker 1 (approximate latitude 26°24′29″ North, approximate longitude 81°51′53″ West) and Channel Marker 10 (approximate latitude 26°24′00″ North, approximate longitude 81°51′09″ West);

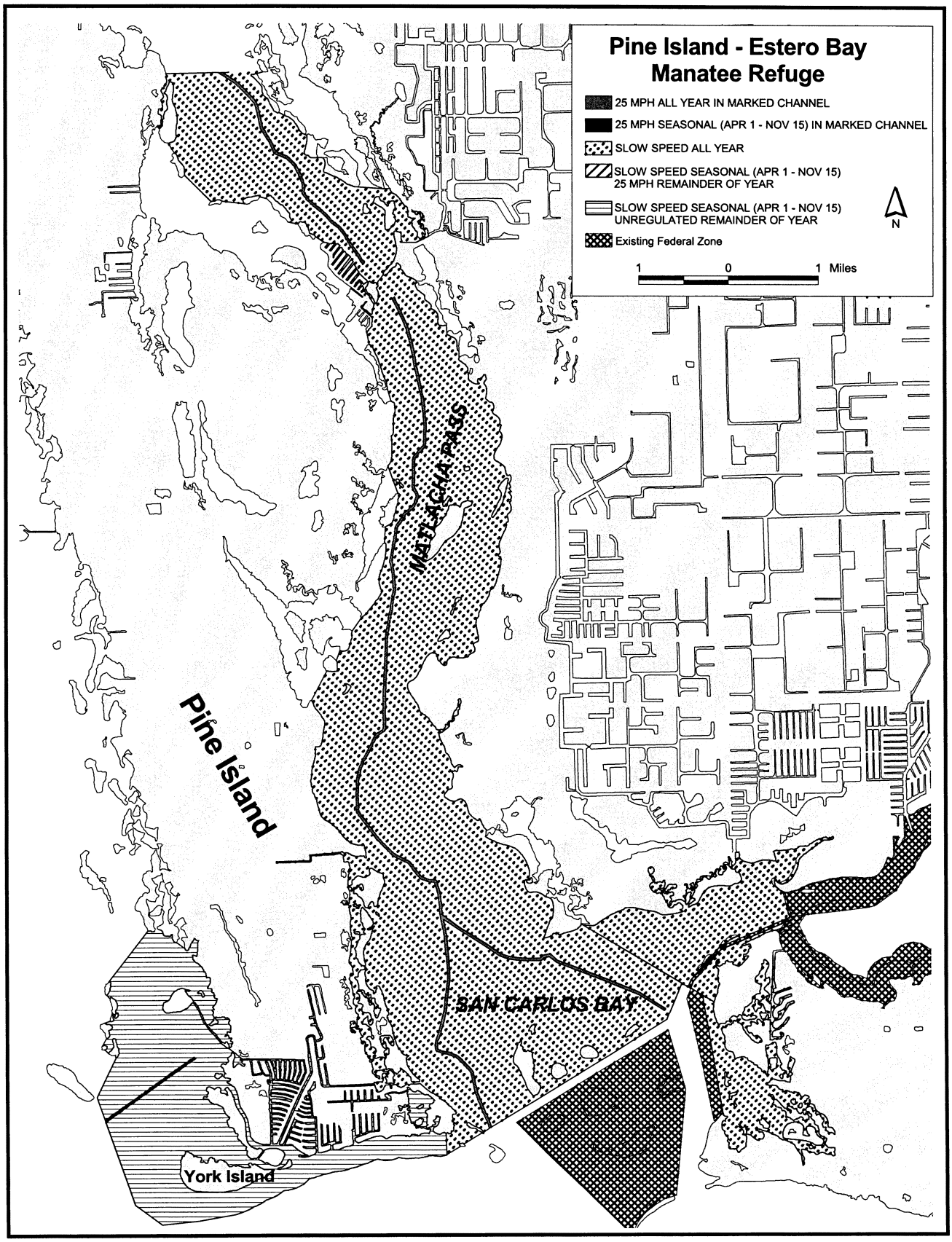
(G) All waters of the marked channel commonly known as Coconut Channel, with said channel generally running between Channel Marker 1 (approximate latitude 26°23′44″ North, approximate longitude 81°50′55″ West) and Channel Marker 23 (approximate latitude 26°24′00″ North, approximate longitude 81°50′30″ West);

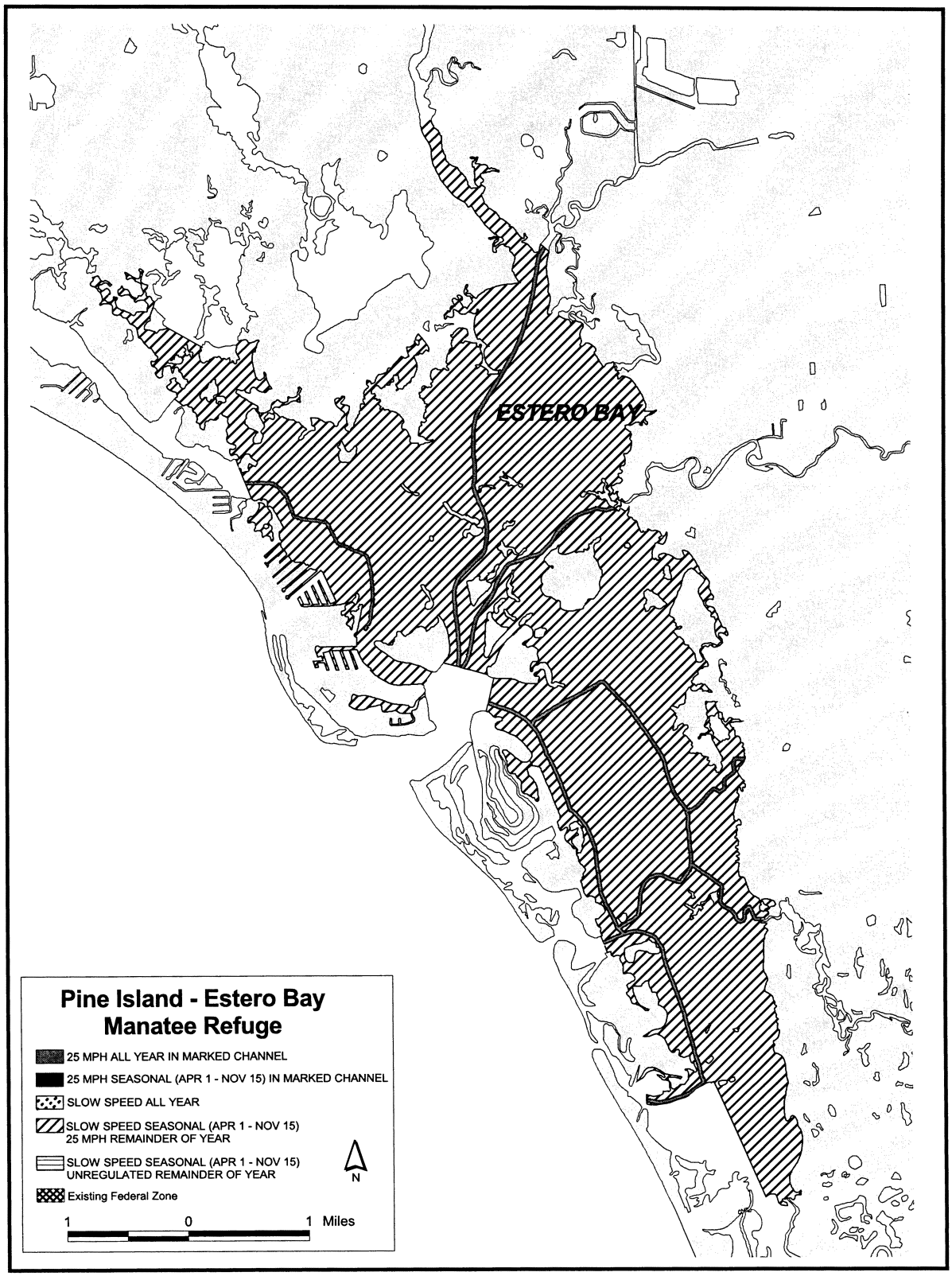
(H) All waters of the marked channel commonly known as Southern Passage Channel, with said channel generally running between Channel Marker 1 (approximate latitude 26°22′58″ North, approximate longitude 81°51′57″ West) and Channel Marker 22 (approximate latitude 26°23′27″ North, approximate longitude 81°50′46″ West); and

(I) All waters of the marked channel leading from the Southern Passage Channel to Spring Creek, west of the mouth of Spring Creek.

(xiv) Maps of the Pine Island-Estero Bay Manatee Refuge follow:

BILLING CODE 4310–55–P


Pine Island - Estero Bay
Manatee Refuge
25 MPH ALL YEAR IN MARKED CHANNEL
25 MPH SEASONAL (APR 1 - NOV 15) IN MARKED CHANNEL
SLOW SPEED ALL YEAR
SLOW SPEED SEASONAL (APR 1 - NOV 15)
25 MPH REMAINDER OF YEAR
SLOW SPEED SEASONAL (APR 1 - NOV 15)
UNREGULATED REMAINDER OF YEAR
Existing Federal Zone
N
1 0 1 Miles
MATLACHA PASS
Pine Island
SAN CARLOS BAY
York Island



Dated: April 1, 2005.

Craig Manson,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 05–6919 Filed 4–4–05; 2:49 pm]

BILLING CODE 4310–55–C

Federal Register

Thursday,
April 7, 2005

Part V

The President

Proclamation 7882—Pan American Day and Pan American Week, 2005

Proclamation 7883—National D.A.R.E. Day, 2005

Federal Register
Vol. 70, No. 66
Thursday, April 7, 2005

Presidential Documents

Title 3—

The President

Proclamation 7882 of April 5, 2005

Pan American Day and Pan American Week, 2005

By the President of the United States of America

A Proclamation

Leaders across the Americas understand that the hope for peace in our world depends on the unity of free nations. Each year, the people of the United States observe Pan American Day and Pan American Week to honor our shared commitment to freedom, prosperity, and security. We are working with our partners in the Western Hemisphere to advance our common interests and values so that we can build a brighter future for our citizens.

The idea of regional solidarity and inter-American cooperation, first envisioned in 1826 by Simon Bolivar, became a reality in 1890 when the First International Conference of American States concluded its meetings in Washington, D.C. There, President Benjamin Harrison praised the efforts of the countries in attendance for their desire to work together as American States. Through the years, these efforts, shared values, and mutual respect have strengthened this partnership.

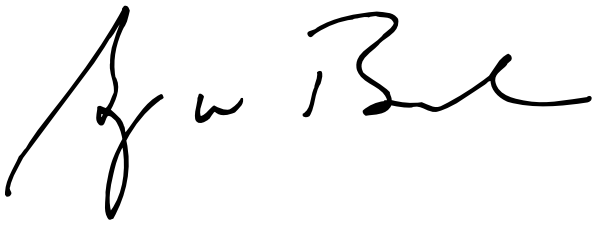
Across our hemisphere, social, economic, military, and political cooperation are widespread. Last year, trade officials of five Central American nations and the Dominican Republic signed the Central American-Dominican Republic Free Trade Agreement with the United States. I urge the Congress to ratify this agreement, which will eliminate tariffs and trade barriers and expand regional opportunities.

My Administration remains committed to the Inter-American Democratic Charter to advance democracy and defend freedom across our region. Our Nation's continued support of democratic institutions, constitutional processes, and basic liberties gives hope and strength to those struggling in our hemisphere and around the world to preserve the rule of law and their God-given rights.

The democratic nations of the Western Hemisphere believe in the rights and dignity of every person, and we believe that liberty is worth defending. In the spirit of Pan American cooperation, we will continue to work to strengthen ties among our nations and further democracy, peace, and prosperity.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 14, 2005, as Pan American Day and April 10 through April 16, 2005, as Pan American Week. I urge the Governors of the 50 States, the Governor of the Commonwealth of Puerto Rico, and the officials of other areas under the flag of the United States of America to honor these observances with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of April, in the year of our Lord two thousand five, and of the Independence of the United States of America the two hundred and twenty-ninth.



[FR Doc. 05–7139
Filed 4–6–05; 8:54 am]
Billing code 3195–01–P

Presidential Documents

Proclamation 7883 of April 5, 2005

National D.A.R.E. Day, 2005

By the President of the United States of America

A Proclamation

Across America, law enforcement officers, volunteers, parents, and teachers are helping to send the right message to our Nation's youth about illegal drugs and violence through the Drug Abuse Resistance Education (D.A.R.E.) Program. On National D.A.R.E. Day, we express our gratitude for the important work of these individuals and reaffirm our commitment to ensuring that every child has an opportunity for a bright and hopeful future.

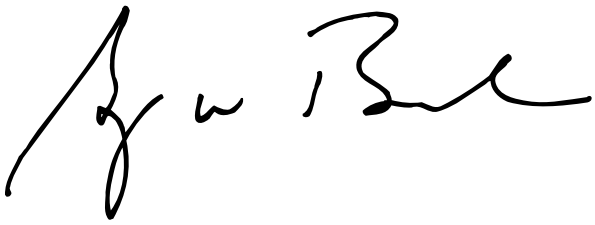
For over two decades, D.A.R.E. programs have taught our Nation's young people about the dangers of drug use and encouraged them to lead productive, drug-free, and violence-free lives. Police officers and all those involved in D.A.R.E. help save lives by opening the lines of communication between law enforcement and our young people to better enable them to make the right choices. In a culture in which bad influences and temptations are all too present, these soldiers in the armies of compassion are fostering a culture of responsibility among young people.

My Administration will continue to stand with families and communities to combat the dangers of drugs and violence. In my State of the Union Address, I announced a new initiative called Helping America's Youth to help ensure a successful future for young Americans. Led by First Lady Laura Bush, this initiative is educating parents and communities on the importance of positive youth development and is supporting organizations, including faith-based and community groups, who are helping young people to overcome the risks they face. We also support random student drug testing as a prevention tool, and we are helping educate young people about the dangers of illicit drug use through the National Youth Anti-Drug Media Campaign and Drug-Free Communities Program.

The decisions our children make today will affect their health and character for the rest of their lives. By giving them the tools they need to make the right choices, D.A.R.E. programs help prepare our Nation's young people for the promising future our Nation holds for each of them.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 14, 2005, as National D.A.R.E. Day. I call upon Americans, particularly our youth, to help fight drug use in our communities, and I urge our citizens to show their appreciation for the law enforcement officials, volunteers, teachers, health care professionals, and all those who dedicate themselves to helping our children avoid drugs and violence.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of April, in the year of our Lord two thousand five, and of the Independence of the United States of America the two hundred and twenty-ninth.



[FR Doc. 05–7140
Filed 4–6–05; 8:54 am]
Billing code 3195–01–P

Reader Aids

Federal Register

Vol. 70, No. 66

Thursday, April 7, 2005

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **http://www.gpoaccess.gov/nara/index.html**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **http://www.archives.gov/federal_register/**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, APRIL

16691–16920 1
16921–17196 4
17197–17300 5
17301–17582 6
17583–17886 7

CFR PARTS AFFECTED DURING APRIL

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:
7877 17197
7878 17293
7879 17295
7880 17297
7881 17301
7882 17883
7883 17885

Administrative Orders:
Memorandums:
Memorandums of March 31, 2005 17195

Executive Orders:
13295 (Amended by EO 13375) 17299
13375 17299

4 CFR

Ch. I 17583

5 CFR

Proposed Rules:
337 17610

7 CFR

54 17611
62 17611
354 16691
624 16921
723 17150
1463 17150
1464 17150
1700 17199
1709 17199
1738 16930
4279 17616

Proposed Rules:
946 16759
1738 16967

8 CFR

217 17820
231 17820
251 17820

9 CFR

97 16691

11 CFR

Proposed Rules:
100 16967
110 16967
114 16967

12 CFR

303 17550
325 17550
327 17550
347 17550
1710 17303

13 CFR

134 17583
140 17583

14 CFR

39 ..... 17199, 17312, 17315, 17590, 17591, 17594, 17596, 17598, 17600, 17603, 17604, 17606
71 ..... 16931, 16932
97 17318

Proposed Rules:
39 ..... 16761, 16764, 16767, 16769, 16771, 16979, 16981, 16984, 16986, 17212, 17216, 17340, 17342, 17345, 17347, 17349, 17351, 17353, 17354, 17357, 17359, 17361, 17366, 17368, 17370, 17373, 17375, 17377, 17618, 17620, 17621
256 16990

16 CFR

Proposed Rules:
410 17623

17 CFR

211 16693

18 CFR

Proposed Rules:
45 17219

19 CFR

4 17820
122 17820
178 17820

20 CFR

Proposed Rules:
655 16774

21 CFR

2 17168
510 17319
520 ..... 16933, 17319
522 16933
558 16933
1305 16902
1308 16935
1311 16902

Proposed Rules:
101 ..... 16995, 17008, 17010

22 CFR

10 16937

23 CFR

772 16707

26 CFR

301 16711

27 CFR

Proposed Rules:
479 17624

30 CFR

936 16941
950 16945
Proposed Rules:
701 17626
774 17626
913 17014

31 CFR

351 17288
542 17201

33 CFR

165 17608
Proposed Rules:
100 16781
165 17627

34 CFR

Proposed Rules:
Ch. I 16784

36 CFR

7 16712
1270 16717

37 CFR

258 17320
Proposed Rules:
1 17629
2 17636
3 17629
7 17636
10 17629

40 CFR

52 ....16717, 16955, 16958, 17321
174 17323
271 17286
Proposed Rules:
51 17018
52 ....16784, 17027, 17028, 17029, 17640
152 16785
158 16785

42 CFR

403 16720
405 16720
410 16720
411 16720
412 16724
413 16724
414 16720
418 16720
424 16720
484 16720
486 16720

44 CFR

64 16964
65 ....16730, 16733
67 ....16736, 16738
Proposed Rules:
67 ....16786, 16789, 17037

47 CFR

2 17327
15 17328
22 17327
24 17327
64 ....17330, 17334
73 17334
74 17327
78 17327
90 17327
Proposed Rules:
73 ....17042, 17043, 17044, 17045, 17046, 17047, 17048, 17049, 17381, 17382, 17383, 17384

49 CFR

219 16966
573 16742
1002 17335
Proposed Rules:
172 17385

50 CFR

17 17864
20 17574
223 ....17211, 17386
300 16742
622 ....16754, 17401
648 16758
679 16742
Proposed Rules:
223 17223
224 17223

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 APRIL 7, 2005

AGRICULTURE DEPARTMENT

Rural Housing Service

Program regulations:

Rural Development Single Family Housing Program; surety requirements; published 1-7-05

GOVERNMENT ACCOUNTABILITY OFFICE

Nomenclature changes; published 4-7-05

HOMELAND SECURITY DEPARTMENT

Coast Guard

Drawbridge operations:

New York; published 3-29-05

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Cotton classing, testing and standards:

Classification services to growers; 2004 user fees; Open for comments until further notice; published 5-28-04 [FR 04-12138]

AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

Plant-related quarantine, domestic:

Bay leaves; comments due by 4-11-05; published 2-8-05 [FR 05-02322]

Plant-related quarantine, foreign:

Nursery stock; comments due by 4-11-05; published 3-10-05 [FR 05-04705]

AGRICULTURE DEPARTMENT

Food Safety and Inspection Service

Meat and poultry inspection:

North Dakota; State inspection of poultry and poultry products; comments due by 4-13-05; published 3-14-05 [FR 05-04993]

AGRICULTURE DEPARTMENT

Rural Housing Service

Direct single family housing loans and grants; comments due by 4-11-05; published 2-8-05 [FR 05-02429]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Ocean and coastal resource management:

Florida Keys National Marine Sanctuary, FL; revised management plan; comments due by 4-15-05; published 2-16-05 [FR 05-02949]

COMMODITY FUTURES TRADING COMMISSION

Commodity Exchange Act:

Federal speculative position limits; comments due by 4-14-05; published 3-15-05 [FR 05-05088]

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

Semi-annual agenda; Open for comments until further notice; published 12-22-03 [FR 03-25121]

DEFENSE DEPARTMENT

Acquisition regulations:

Pilot Mentor-Protege Program; Open for comments until further notice; published 12-15-04 [FR 04-27351]

EDUCATION DEPARTMENT

Grants and cooperative agreements; availability, etc.:

Vocational and adult education—

Smaller Learning Communities Program; Open for comments until further notice; published 2-25-05 [FR E5-00767]

ENERGY DEPARTMENT

Meetings:

Environmental Management Site-Specific Advisory Board—

Oak Ridge Reservation, TN; Open for comments until further notice; published 11-19-04 [FR 04-25693]

ENERGY DEPARTMENT

Energy Efficiency and Renewable Energy Office

Commercial and industrial equipment; energy efficiency program:

Test procedures and efficiency standards—

Commercial packaged boilers; Open for comments until further notice; published 10-21-04 [FR 04-17730]

ENERGY DEPARTMENT

Federal Energy Regulatory Commission

Electric rate and corporate regulation filings:

Virginia Electric & Power Co. et al.; Open for comments until further notice; published 10-1-03 [FR 03-24818]

ENVIRONMENTAL PROTECTION AGENCY

Air quality implementation plans; approval and promulgation; various States:

Maine; comments due by 4-11-05; published 3-10-05 [FR 05-04708]

Oregon; comments due by 4-14-05; published 3-15-05 [FR 05-05045]

Environmental statements; availability, etc.:

Coastal nonpoint pollution control program—

Minnesota and Texas; Open for comments until further notice; published 10-16-03 [FR 03-26087]

Hazardous waste program authorizations:

Alabama; comments due by 4-14-05; published 3-15-05 [FR 05-05047]

Tennessee; comments due by 4-13-05; published 3-14-05 [FR 05-04952]

Pesticides; emergency exemptions, etc.

Removal of expired time-limited tolerances for emergency exemptions; comments due by 4-11-05; published 2-10-05 [FR 05-02614]

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Thiamethoxam; comments due by 4-12-05; published 2-11-05 [FR 05-02715]

Radiation protection programs:

Transuranic radioactive waste for disposal at Waste Isolation Pilot Plant; waste characterization program documents availability—

Idaho National Engineering and Environmental Laboratory, ID; comments due by 4-11-05; published 3-10-05 [FR 05-04713]

Water pollution control:

National Pollutant Discharge Elimination System—

Concentrated animal feeding operations in New Mexico and Oklahoma; general permit for discharges; Open for comments until further notice; published 12-7-04 [FR 04-26817]

Ocean dumping; site designations—

Port Royal, SC; comments due by 4-11-05; published 2-24-05 [FR 05-03525]

Water pollution; effluent guidelines for point source categories:

Meat and poultry products processing facilities; Open for comments until further notice; published 9-8-04 [FR 04-12017]

FEDERAL COMMUNICATIONS COMMISSION

Committees; establishment, renewal, termination, etc.:

Technological Advisory Council; Open for comments until further notice; published 3-18-05 [FR 05-05403]

Common carrier services:

Interconnection—

Incumbent local exchange carriers unbounding obligations; local competition provisions; wireline services offering advanced telecommunications capability; Open for comments until further notice; published 12-29-04 [FR 04-28531]

Prepaid calling card services; comments due by 4-15-05; published 3-16-05 [FR 05-05167]

Wireless telecommunications services—

800 MHz cellular handsets, telephones, and other wireless devices use aboard airborne aircraft; facilitation; comments due by 4-11-05; published 3-10-05 [FR 05-04725]

Radio stations; table of assignments:

Florida; comments due by 4-11-05; published 3-3-05 [FR 05-04114]

HARRY S. TRUMAN SCHOLARSHIP FOUNDATION

Scholar accountability policy; comments due by 4-13-05;

published 3-14-05 [FR 05-04951]

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Human drugs:
Antiperspirant products (OTC); final monograph; partial stay; comments due by 4-13-05; published 10-15-04 [FR 04-23106]
Reports and guidance documents; availability, etc.:
Evaluating safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern; Open for comments until further notice; published 10-27-03 [FR 03-27113]
Medical devices—
Dental noble metal alloys and base metal alloys; Class II special controls; Open for comments until further notice; published 8-23-04 [FR 04-19179]

HOMELAND SECURITY DEPARTMENT
Coast Guard
Anchorage regulations:
Maryland; Open for comments until further notice; published 1-14-04 [FR 04-00749]
Port access routes:
Portland, ME and Casco Bay; comments due by 4-11-05; published 2-10-05 [FR 05-02559]

HOMELAND SECURITY DEPARTMENT
Federal Emergency Management Agency
Disaster assistance:
National Urban Search and Rescue Response System; financing, administration, and operation standardization; comments due by 4-11-05; published 2-24-05 [FR 05-03192]

HOMELAND SECURITY DEPARTMENT
Transportation Security Administration
Civil aviation security:
Enhanced security procedures for certain airports' operations in the Washington, DC metropolitan area flight restricted zone; comments due by 4-11-05; published 2-10-05 [FR 05-02630]

INTERIOR DEPARTMENT
Fish and Wildlife Service
Endangered and threatened species permit applications
Recovery plans—
Paiute cutthroat trout; Open for comments until further notice; published 9-10-04 [FR 04-20517]
Endangered and threatened species:
Northern aplomado falcons; nonessential experimental population establishment in New Mexico and Arizona; comments due by 4-11-05; published 2-9-05 [FR 05-02415]

INTERIOR DEPARTMENT
Minerals Management Service
Outer Continental Shelf; oil, gas, and sulphur operations:
Service fees; comments due by 4-14-05; published 3-15-05 [FR 05-04999]

INTERIOR DEPARTMENT
Surface Mining Reclamation and Enforcement Office
Surface coal mining and reclamation operations:
Transfer, assignment, or sale of permit rights; comments due by 4-15-05; published 4-7-05 [FR 05-06858]

LIBRARY OF CONGRESS
Copyright Office, Library of Congress
Copyright Arbitration Royalty Panel rules and procedures:
Sound recordings under statutory license; usage reports; comments due by 4-14-05; published 3-15-05 [FR 05-05064]

NUCLEAR REGULATORY COMMISSION
Environmental statements; availability, etc.:
Fort Wayne State Developmental Center; Open for comments until further notice; published 5-10-04 [FR 04-10516]

SMALL BUSINESS ADMINISTRATION
Disaster loan areas:
Maine; Open for comments until further notice; published 2-17-04 [FR 04-03374]

OFFICE OF UNITED STATES TRADE REPRESENTATIVE
Trade Representative, Office of United States
Generalized System of Preferences:
2003 Annual Product Review, 2002 Annual Country Practices Review, and previously deferred product decisions; petitions disposition; Open for comments until further notice; published 7-6-04 [FR 04-15361]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
AeroSpace Technologies of Australia Pty Ltd.; comments due by 4-15-05; published 3-16-05 [FR 05-05153]
Agusta S.p.A.; comments due by 4-11-05; published 2-10-05 [FR 05-02588]
Airbus; comments due by 4-15-05; published 3-16-05 [FR 05-05138]
Boeing; Open for comments until further notice; published 8-16-04 [FR 04-18641]
Bombardier; comments due by 4-14-05; published 3-15-05 [FR 05-05012]
Eurocopter France; comments due by 4-11-05; published 2-10-05 [FR 05-02586]
Fokker; comments due by 4-14-05; published 3-15-05 [FR 05-05011]
MD Helicopters, Inc.; comments due by 4-11-05; published 2-10-05 [FR 05-02608]
New Piper Aircraft, Inc.; comments due by 4-11-05; published 2-9-05 [FR 05-02374]
Saab; comments due by 4-14-05; published 3-15-05 [FR 05-05013]
Airworthiness standards:
Special conditions—
Cessna 172R and 172S airplanes; comments due by 4-11-05; published 3-10-05 [FR 05-04745]
Class D airspace; comments due by 4-11-05; published 3-11-05 [FR 05-04134]
Class E airspace; comments due by 4-13-05; published 3-14-05 [FR 05-04980]

TRANSPORTATION DEPARTMENT
Federal Motor Carrier Safety Administration
Civil rights; Title VI procedures for financial assistance recipients; comments due by 4-15-05; published 2-14-05 [FR 05-02768]

TRANSPORTATION DEPARTMENT
National Highway Traffic Safety Administration
Anthropomorphic test devices:
Occupant crash protection—
SID-IIsFRG side impact crash test dummy, 5th percentile adult female; specifications and qualification requirements; comments due by 4-12-05; published 3-8-05 [FR 05-04432]
Motor vehicle safety standards:
Side impact protection—
Phase-in reporting requirements; comments due by 4-12-05; published 1-12-05 [FR 05-00548]

TREASURY DEPARTMENT
Internal Revenue Service
Procedure and administration:
Written contracts or agreements for acquisition of property and services for tax administration purposes; returns and return information disclosure; comments due by 4-12-05; published 1-12-05 [FR 05-00636]

TREASURY DEPARTMENT
Alcohol and Tobacco Tax and Trade Bureau
Alcohol; viticultural area designations:
Niagara Escarpment, Niagara County, NY; comments due by 4-11-05; published 2-9-05 [FR 05-02489]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal_register/public_laws/public_laws.html.*

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html.* Some laws may not yet be available.

H.R. 1270/P.L. 109–6
To amend the Internal Revenue Code of 1986 to

extend the Leaking Underground Storage Tank Trust Fund financing rate. (Mar. 31, 2005; 119 Stat. 20)
Last List April 1, 2005

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.